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Title 3—

The President

Proclamation 10128 of December 22, 2020

To Take Certain Actions Under the African Growth and Opportunity Act and for Other Purposes

By the President of the United States of America

A Proclamation

1. In Proclamation 8618 of December 21, 2010, the President determined that the Democratic Republic of the Congo (DRC) was not making continual progress in meeting the requirements described in section 506A(a)(1) of the Trade Act of 1974, as amended (the ''Trade Act''), as added by section 111(a) of the African Growth and Opportunity Act (the ''AGOA'') (title I of Public Law 106–200, 114 Stat. 251, 257–58 (19 U.S.C. 2466a(a)(1))). Thus, pursuant to section 506A(a)(3) of the Trade Act (19 U.S.C. 2466a(a)(3)), the President terminated the designation of the DRC as a beneficiary sub-Saharan African country for purposes of section 506A(a)(1) of the Trade Act.

2. Section 506A(a)(1) of the Trade Act authorizes the President to designate a country listed in section 107 of the AGOA (19 U.S.C. 3706) as a ''beneficiary sub-Saharan African country'' if the President determines that the country meets the eligibility requirements set forth in section 104 of the AGOA (19 U.S.C. 3703), as well as the eligibility criteria set forth in section 502 of the Trade Act (19 U.S.C. 2462).

3. Pursuant to section 506A(a)(1) of the Trade Act, based on actions that the Government of the DRC has taken, I have determined that the DRC meets the eligibility requirements set forth in section 104 of the AGOA and the eligibility criteria set forth in section 502 of the Trade Act, and I have determined to designate the DRC as a beneficiary sub-Saharan African country.

4. Section 112(c) of the AGOA, as amended in section 6002 of the Africa Investment Incentive Act of 2006 (division D of title VI of Public Law 109–432, 120 Stat. 2922, 3190–93 (19 U.S.C. 3721(c))), provides special rules for certain apparel articles imported from ''lesser developed beneficiary sub-Saharan African countries.''

5. I have also determined that the DRC satisfies the criterion for treatment as a ''lesser developed beneficiary sub-Saharan African country'' under section 112(c) of the AGOA.

6. On April 22, 1985, the United States and Israel entered into the Agreement on the Establishment of a Free Trade Area between the Government of the United States of America and the Government of Israel (the ''USIFTA''), which the Congress approved in section 3 of the United States-Israel Free Trade Area Implementation Act of 1985 (the ''USIFTA Act'') (Public Law 99–47, 99 Stat. 82 (19 U.S.C. 2112 note)).

7. Section 4(b) of the USIFTA Act provides that, whenever the President determines that it is necessary to maintain the general level of reciprocal and mutually advantageous concessions with respect to Israel provided for by the USIFTA, the President may proclaim such withdrawal, suspension, modification, or continuance of any duty, or such continuance of existing duty-free or excise treatment, or such additional duties, as the President determines to be required or appropriate to carry out the USIFTA.

8. In order to maintain the general level of reciprocal and mutually advantageous concessions with respect to agricultural trade with Israel, on July 27, 2004, the United States entered into an agreement with Israel concerning certain aspects of trade in agricultural products during the period January 1, 2004, through December 31, 2008 (the ''2004 Agreement'').

9. In Proclamation 7826 of October 4, 2004, consistent with the 2004 Agreement, the President determined, pursuant to section 4(b) of the USIFTA Act, that, in order to maintain the general level of reciprocal and mutually advantageous concessions with respect to Israel provided for by the USIFTA, it was necessary to provide duty-free access into the United States through December 31, 2008, for specified quantities of certain agricultural products of Israel.

10. Each year from 2008 through 2019, the United States and Israel entered into agreements to extend the period that the 2004 Agreement was in force for 1-year periods to allow additional time for the two governments to conclude an agreement to replace the 2004 Agreement.

11. To carry out the extension agreements, the President in Proclamation 8334 of December 31, 2008; Proclamation 8467 of December 23, 2009; Proclamation 8618 of December 21, 2010; Proclamation 8770 of December 29, 2011; Proclamation 8921 of December 20, 2012; Proclamation 9072 of December 23, 2013; Proclamation 9223 of December 23, 2014; Proclamation 9383 of December 21, 2015; Proclamation 9555 of December 15, 2016; Proclamation 9687 of December 22, 2017; Proclamation 9834 of December 21, 2018; and Proclamation 9974 of December 26, 2019, modified the Harmonized Tariff Schedule of the United States (''HTS'') to provide duty-free access into the United States for specified quantities of certain agricultural products of Israel, each time for an additional 1-year period.

12. On December 3, 2020, the United States entered into an agreement with Israel to extend the period that the 2004 Agreement is in force through December 31, 2021, and to allow for further negotiations on an agreement to replace the 2004 Agreement.

13. Pursuant to section 4(b) of the USIFTA Act, I have determined that it is necessary, in order to maintain the general level of reciprocal and mutually advantageous concessions with respect to Israel provided for by the USIFTA, to provide duty-free access into the United States through the close of December 31, 2021, for specified quantities of certain agricultural products of Israel, as provided in Annex I of this proclamation.

14. Section 604 of the Trade Act (19 U.S.C. 2483) authorizes the President to embody in the HTS the substance of the relevant provisions of that Act, and of other Acts affecting import treatment, and actions thereunder, including removal, modification, continuance, or imposition of any rate of duty or other import restriction.

15. The Caribbean Basin Economic Recovery Act, as amended (the ''CBERA''), (title II of Public Law 98–67, 97 Stat. 384 (19 U.S.C. 2701 *et seq.*)), instituted a duty preference program that applies to a product of a Caribbean Basin country that has been designated by the President as a beneficiary country. On October 10, 2020, the President signed into law the Extension of the Caribbean Basin Economic Recovery Act (Public Law 116–164, 134 Stat. 758), which extends certain preferential tariff treatment accorded under the CBERA to September 30, 2030. I have determined, pursuant to section 604 of the Trade Act, that it is necessary to modify the HTS to reflect the extension of the CBERA.

16. On August 21, 2020, in accordance with section 103(a)(2) of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 (the ''Trade Priorities Act'') (title I of Public Law 114–26, 129 Stat. 319, 333 (19 U.S.C. 4202(a)(2))), I notified the Congress that I intended to enter into an agreement regarding tariff barriers with the European Union under section 103(a) of the Trade Priorities Act. On November 20, 2020, the United States entered into such an agreement with the European Union.

17. Section 103(a)(1) of the Trade Priorities Act authorizes the President to proclaim such modification of any existing duty as the President determines to be required or appropriate to carry out a trade agreement entered into under section 103(a). The President generally may proclaim such modification provided that the modification does not reduce the rate of duty to a rate that is less than 50 percent of the rate of such duty that applied on June 29, 2015; does not reduce the rate of duty below that applicable under the Uruguay Round Agreements or a successor agreement on any import-sensitive agricultural product; and does not increase the rate of duty above the rate of such duty that applied on June 29, 2015.

18. Pursuant to section 103(a) of the Trade Priorities Act, I have determined that it is required and appropriate to modify existing duties with respect to certain goods to carry out the agreement regarding tariff barriers with the European Union for such time as the European Union carries out the agreement.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, acting under the authority vested in me by the Constitution and the laws of the United States of America, including section 506A(a)(1) and section 604 of the Trade Act; sections 111(a) and 112(c) of the AGOA; section 6002 of the Africa Investment Incentive Act of 2006; section 4(b) of the USIFTA Act; and section 103(a) of the Trade Priorities Act, do proclaim that:

(1) The DRC is designated as a beneficiary sub-Saharan African country for purposes of section 506A of the Trade Act.

(2) In order to reflect this designation in the HTS, general note 16(a) to the HTS is modified by inserting in alphabetical sequence in the list of beneficiary sub-Saharan African countries ''Democratic Republic of the Congo''.

(3) For purposes of section 112(c) of the AGOA, the DRC is a lesser developed beneficiary sub-Saharan African country.

(4) In order to provide the tariff treatment intended under section 112(c) of the AGOA, note 2(d) to subchapter XIX of chapter 98 of the HTS is modified by inserting in alphabetical sequence in the list of lesser developed beneficiary sub-Saharan African countries ''Democratic Republic of the Congo''.

(5) The modifications to the HTS set forth in paragraphs (1) through (4) of this proclamation shall be effective with respect to articles that are entered for consumption, or withdrawn from warehouse for consumption, on or after January 1, 2021.

(6) In order to implement United States tariff commitments under the 2004 Agreement through December 31, 2021, the HTS is modified as provided in Annex I of this proclamation.

(7) The modifications to the HTS set forth in Annex I of this proclamation shall be effective with respect to eligible agricultural products of Israel that are entered for consumption, or withdrawn from warehouse for consumption, on or after January 1, 2021.

(8) The provisions of subchapter VIII of chapter 99 of the HTS, as modified by Annex I of this proclamation, shall continue in effect through December 31, 2021.

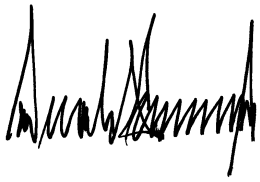
(9) In order to reflect in the HTS the provisions of the extension of the CBERA, general note 17(f)(i) is modified by deleting ''September 30, 2020'' and inserting, in lieu thereof, ''September 30, 2030''.

(10) In order to modify duties on certain goods to carry out the agreement regarding tariff barriers with the European Union, the HTS is modified as set forth in Annex II to this proclamation.

(11) The modifications to the HTS set forth in Annex II to this proclamation shall enter into effect on the dates indicated in Annex II and remain in

effect until the date on which the European Union ceases to carry out the agreement, as determined by the United States Trade Representative (USTR) in a notice published in the *Federal Register*. The HTS shall be modified to revert to the duty rate in effect on July 31, 2020, for each subheading identified in Annex II, effective on that date as determined by the USTR. The USTR shall publish notice of such a determination in the *Federal Register*.

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



Billing code 3295–F1–P

ANNEX I

TEMPORARY EXTENSION OF CERTAIN PROVISIONS OF THE HARMONIZED TARIFF SCHEDULE OF THE UNITED STATES

Effective with respect to eligible agricultural products of Israel which are entered for consumption, or withdrawn from warehouse for consumption, on or after January 1, 2021, and through the close of December 31, 2021, subchapter VIII of chapter 99 of the Harmonized Tariff Schedule of the United States is hereby modified as follows:

1. U.S. note 1 to such subchapter is modified by striking "December 31, 2020," and by inserting in lieu thereof "December 31, 2021".

2. U.S. note 3 to such subchapter is modified by adding at the end of the "Applicable time period" column in the table "Calendar year 2021" and by adding at the end of the "Quantity (kg)" column opposite such year the quantity "466,000".

3. U.S. note 4 to such subchapter is modified by adding at the end of the "Applicable time period" column in the table "Calendar year 2021" and by adding at the end of the "Quantity (kg)" column opposite such year the quantity "1,304,000".

4. U.S. note 5 to such subchapter is modified by adding at the end of the "Applicable time period" column in the table "Calendar year 2021" and by adding at the end of the "Quantity (kg)" column opposite such year the quantity "1,534,000".

5. U.S. note 6 to such subchapter is modified by adding at the end of the "Applicable time period" column in the table "Calendar year 2021" and by adding at the end of the "Quantity (kg)" column opposite such year the quantity "131,000".

6. U.S. note 7 to such subchapter is modified by adding at the end of the "Applicable time period" column in the table "Calendar year 2021" and by adding at the end of the "Quantity (kg)" column opposite such year the quantity "707,000".

ANNEX II

TO MODIFY THE HARMONIZED TARIFF SCHEDULE OF THE UNITED STATES TO IMPLEMENT AN AGREEMENT BETWEEN THE UNITED STATES OF AMERICA AND THE EUROPEAN UNION

1. Effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after August 1, 2020, for which entry is unliquidated or otherwise not final as of that date, the Harmonized Tariff Schedule is modified as follows:

(a) Subheading 1604.20.05 is modified by deleting from the "Rates of Duty 1-General" subcolumn the rate of duty "10%" and inserting in lieu thereof the duty rate "7%".

(b) Subheading 3214.90.50 is modified by deleting from the "Rates of Duty 1-General" subcolumn the rate of duty "6.5%" and inserting in lieu thereof the duty rate "3.5%".

(c) Subheading 3601.00.00 is modified by deleting from the "Rates of Duty 1-General" subcolumn the rate of duty "6.5%" and inserting in lieu thereof the duty rate "3.5%".

(d) Subheading 7013.41.50 is modified by deleting from the "Rates of Duty 1-General" subcolumn the rate of duty "6%" and inserting in lieu thereof the duty rate "3%".

(e) Subheading 9613.10.00 is modified by deleting from the "Rates of Duty 1-General" subcolumn the rate of duty "8%" and inserting in lieu thereof the duty rate "5%".

(f) Subheading 9613.90.80 is modified by deleting from the "Rates of Duty 1-General" subcolumn the rate of duty "8%" and inserting in lieu thereof the duty rate "5%".

2. Effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after August 1, 2021, the Harmonized Tariff Schedule is modified as follows:

(a) Subheading 1604.20.05 is modified by deleting from the "Rates of Duty 1-General" subcolumn the rate of duty "7%" and inserting in lieu thereof the duty rate "5%".

(b) Subheading 3214.90.50 is modified by deleting from the "Rates of Duty 1-General" subcolumn the rate of duty "3.5%" and inserting in lieu thereof the duty rate "3.25%".

(c) Subheading 3601.00.00 is modified by deleting from the "Rates of Duty 1-General" subcolumn the rate of duty "3.5%" and inserting in lieu thereof the duty rate "3.25%".

(d) Subheading 9613.10.00 is modified by deleting from the "Rates of Duty 1-General" subcolumn the rate of duty "5%" and inserting in lieu thereof the duty rate "4%".

(e) Subheading 9613.90.80 is modified by deleting from the "Rates of Duty 1-General" subcolumn the rate of duty "5%" and inserting in lieu thereof the duty rate "4%".

[FR Doc. 2020–28878

Filed 12–28–20; 8:45 a.m.]

Billing code 7020–02–C

Rules and Regulations

Federal Register

Vol. 85, No. 249

Tuesday, December 29, 2020

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

The Code of Federal Regulations is sold by the Superintendent of Documents.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. APHIS–2018–0041]

RIN 0579–AE48

Amendments to the Pale Cyst Nematode Regulations

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the domestic quarantine regulations for pale cyst nematode by adding procedures that allow persons to review and comment on the protocols for regulating and deregulating quarantined and associated areas. As part of this action, we have made the protocols available online. We are taking these actions in response to a court order requiring the Animal and Plant Health Inspection Service to provide a means for public input on the protocols we use to deregulate fields for pale cyst nematode and to make the protocols publicly available. These changes make the protocols accessible to all and give persons the opportunity to comment on them.

DATES: Effective January 28, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Lynn Evans-Goldner, National Policy Manager, Office of the Deputy Administrator, PPQ, APHIS, 4700 River Road, Unit 137, Riverdale, MD 20737; (301) 851–2286; *lynn.evans-goldner@usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

The pale cyst nematode (PCN, *Globodera pallida*) is a major pest of potato crops in cool-temperature areas throughout the world, causing significant yield losses if left uncontrolled. Other hosts of this destructive pest include tomatoes, eggplants, peppers, and some weeds. The spread of PCN in the United States could result in a significant loss of domestic and foreign markets for U.S. potatoes and other host commodities.

Section 414 of the Plant Protection Act (PPA, 7 U.S.C. 7714) provides that the Secretary of Agriculture may, under certain conditions, hold, seize, quarantine, treat, apply other remedial measures to destroy or otherwise dispose of any plant, plant pest, plant product, article, or means of conveyance that is moving, or has moved into or through the United States or interstate if the Secretary has reason to believe the article is a plant pest or is infested with a plant pest at the time of movement.

On March 4, 2019, we published in the **Federal Register** (84 FR 7304–7306, Docket No. APHIS–2018–0041) a proposal [1] to amend the domestic quarantine regulations for PCN by adding procedures that allow persons to review and comment on the protocols for regulating and deregulating infested and associated areas. We took this action in response to a court order requiring the Animal and Plant Health Inspection Service (APHIS) to facilitate public input into the development of protocols for deregulating fields for PCN.

We solicited comments concerning our proposal for 60 days ending May 3, 2019. We reopened the comment period for 30 days ending July 26, 2019,[2] in response to commenters who experienced technical difficulties with accessing the protocols online.

One commenter stated that, in the proposed rule, we did not adequately include scientific support and source material for our confirmatory and deregulatory field protocols as mandated by the court order. To provide the public with an opportunity to review this material, we published another document [3] on June 5, 2020, in the **Federal Register** announcing a second reopening of the comment period for another 30 days, ending July 6, 2020. In that document, we explained the science underlying each of the field protocols and referenced the significant sources we consulted for developing them.

We received a total of 25 comments during the initial and reopened comment periods. They were from State agricultural officials, potato producers and producer organizations, agronomists, attorneys, and members of the public. A few comments we received expressed general agreement with the rule, while the remainder questioned or criticized specific provisions of the rule, the deregulation protocols, and PCN program activities. Some commenters raised topics concerning PCN program operations outside the scope of the proposal and deregulation protocols. We discuss the relevant comments we received below.

Comment Period

A few commenters stated that web links to the protocols, which we had included in the proposed rule and in a mailing sent to affected growers, were not connecting them to the protocol pages.

We acknowledge that the protocol links were not working during part of the initial comment period, so we reopened the comment period as noted above and provided working protocol links to ensure that stakeholders would have ample opportunity to comment.

One commenter asked that the proposed rule be republished, with the protocols included in the body of the rule.

As we made the protocols available for comment on *Regulations.gov* and the APHIS website throughout the reopened comment periods, we see no need for including them in a republished proposed rule. We also note that in the **Federal Register** document announcing the second comment period reopening, we included details of the scientific support and sources we used to develop the protocols.

Changes to the Regulations

We proposed revising § 301.86–3(c)(1), which designates fields with viable pale cyst nematodes present as being infested, by adding information for accessing the APHIS protocol for designation of infested fields in accordance with criteria established by the Administrator.

We also proposed revising § 301.86–3(d)(1) to read that an infested field will be removed from quarantine for PCN upon a determination that no viable

[1] To view the proposal and comment period reopening documents, the comments we received, and supporting documents, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0041.*

[2] 84 FR 30040.

[3] 85 FR 34537–34541.

PCN is detected in the field. We stated that the determination for removing the field from quarantine will be made in accordance with criteria established by the Administrator and sufficient to support removal of infested fields from quarantine, and that the removal criteria will be presented in an online deregulation protocol.[4] We also proposed revising paragraph (d)(2) for associated fields so that it refers to the deregulation protocol for those fields, also available online.

In paragraph (d)(4), we included the website address for accessing the infested and associated field deregulation protocols and indicated that any subsequent changes we make to them will be announced in a **Federal Register** notice and open to public comment. We proposed these changes to the regulations as a response to the court-mandated requirement that the deregulation protocols be publicly accessible and open to notice and comment in accordance with the Administrative Procedure Act.

Deregulation Biosurvey

Our proposed deregulation protocol for infested and associated fields includes a 3-year biosurvey. Two commenters representing State departments of agriculture disagreed with using the 3-year biosurvey (equivalent to 3 consecutive susceptible potato crops) to evaluate for deregulation of infested and associated fields. Both commenters stated that a 3-year biosurvey of infested fields fails to sufficiently mitigate the risk of PCN spreading to uninfested fields in Idaho and in the commenters' respective States. As support, both commenters cited the results of a study conducted in Norway showing that PCN cysts survived for 12 years in infested fields free of PCN host plants, and one cited a study from Northern Ireland claiming a 30-year survival period for PCN cysts in fields that were out of potato production for 42 years.

We are making no changes to the regulations based on the information provided by these commenters as they appear to be referring to an APHIS deregulation protocol no longer in use. Additionally, these commenters did not consider the effects of eradication treatments on infested fields, which shorten the survival period for PCN. As noted in the proposed rule, we originally included a 3-year deregulation biosurvey as part of an eradication program in a 2007 interim rulemaking[5] that quarantined certain areas of Idaho due to the presence of PCN. The biosurvey required planting PCN host crops in soil from an infested field, in a greenhouse, and sampling the soil for PCN following each of three crop cycles. Negative results for all three cycles would be necessary for APHIS to deregulate the field. In the 2007 interim rulemaking, this biosurvey was the sole criterion for deregulation of infested and associated fields.

However, in response to public comments and subsequent scientific input, we supplemented the 3-year biosurvey requirement with the in-field bioassay test for evaluating infested fields for deregulation. The in-field bioassay requires growing three susceptible host crops in a field with no detections of viable PCN following each crop. Under this current deregulation protocol, infested fields are required to pass a series of laboratory-based viability tests that take at least 3 years to complete. Once a field passes the laboratory-based tests, APHIS requires three host crops to be grown over the entire field while it remains under regulatory control. A field has met requirements for deregulation when full field surveys following each of the host crops are negative for viable PCN.

We do not dispute the studies cited by commenters that PCN cysts can remain viable for years in the absence of a host crop. However, we have determined that the current deregulation protocol, which requires growing a host crop in the field as part of the evaluation, will effectively detect and mitigate viable PCN and ensure that fields are not deregulated prematurely.

Another commenter objected to the deregulation protocol requirement that three potato crops be planted in ''hot spots'' (infestation foci) of a regulated field and that those spots be sampled for viable PCN cysts with each crop, even if the initial sampling of the field indicated no viable cysts. According to the commenter, his field revealed no cysts after APHIS conducted an initial sampling, and on those grounds questioned why a grower whose field showed no cysts after testing could not skip over the required iterations of ''hot spot'' planting and sampling, and instead move directly to the next phase of the protocol.

We are making no changes in response to the commenter. The deregulation protocol provides an alternate testing strategy when cysts are not detected in soil samples for use in laboratory-based tests. Three crops of potatoes over the entire area of the field or within the infestation foci can be substituted for the viability and greenhouse bioassay testing to achieve the same level of detection confidence as the laboratory and in-field bioassay tests together.

Two commenters stated that APHIS has been successful to date in delimiting the extent of PCN infestation in Idaho potato fields under the existing survey and sanitation requirements. Both commenters noted that several fields in Idaho are in the process of completing bioassays this production season that could make them eligible for removal from quarantine under the current deregulation protocol. They asked that APHIS make no bioassay protocol changes until the results of the third bioassay on these fields are determined after the growing season, and added that the results of these bioassays should be used to inform any future consideration of modifications to the bioassay protocol with respect to removal of quarantine status. If the results cast doubt on the ability of three bioassays to detect the presence of viable PCN cysts, they suggested that APHIS consider increasing the number of bioassays required for release from quarantine.

The current deregulation protocol is effective at detecting extremely small populations and APHIS is considering no changes to the bioassay at this time. The commenters are referring to several infested fields in Idaho being evaluated under the greenhouse bioassay to determine whether such fields are eligible to return to potato production. To date, no infested fields have met the testing requirements to be fully deregulated. At this stage in the eradication testing process, the fields remain regulated, with measures in place to mitigate the movement of soil off the field until or unless three crops of potatoes have been grown on the field and no viable nematodes are detected following harvest of each crop. If APHIS finds it necessary to change the deregulation protocol in the future, we would first provide the background and scientific basis for those changes and solicit public comment on the matter. Regardless of the deregulation method, if viable nematodes are detected in the bioassay of a particular field, the field will remain regulated.

A commenter stated that the infested field deregulation protocol includes ''optional PCN program-sponsored eradication treatments'' but that the protocol does not explain what these additional eradication treatments are and whether they are an option for APHIS or for the regulated entity. The

[4] The deregulation protocols are available on the APHIS PCN page at *https://www.aphis.usda.gov/planthealth/pcn.*

[5] September 12, 2007 (72 FR 51975–51988, Docket No. APHIS–2006–0143).

commenter suggested that we clarify this explanation in a new proposed rule.

The optional PCN program-sponsored eradication treatments listed in the protocol documents are available at the option of regulated entities, as long as APHIS has sufficient funding and a ready supply of treatment materials. At present, the treatment options are the soil fumigant 1,3-dichloropropene (Telone II) and the trap crop *Solanum sisymbriifolium* (litchi tomato). We do not agree with the commenter's suggestion that a new proposed rule is necessary for explaining this information further.

A few commenters expressed concerns that practices required in the deregulation protocols could adversely affect the environment. One commenter stated that if PCN eradication treatments include a nematicide such as Telone II, additional environmental analysis should be undertaken regarding its use. Another commenter stated that in-field pressure washing, steam sanitation, soil sampling, and host and trap crop planting have environmental implications and noted that issuance of a final rule in the absence of an environmental analysis will violate the National Environmental Policy Act (NEPA, 42 U.S.C. 4321 *et seq.*) and its implementing regulations.

We are making no changes in response to the commenters. This rule does not require such an analysis under NEPA requirements. The rule adds no provisions and makes no changes to the protocols themselves or how they are applied. We note, however, that we have conducted several environmental assessments [6] to evaluate the use of fumigants, trap crop planting, and other field treatments and mitigations with regard to PCN.

Deregulation of Associated Fields

As noted above, we proposed revising § 301.86–3(d) to indicate that, as with infested fields, criteria for deregulating associated fields are included in a protocol available on the PPQ website. For associated fields remaining in host crop production, the deregulation protocol requires that two host crops be grown, each followed by a full field soil survey. If lab results are negative for PCN in both surveys, the field will be deregulated. Statistical analyses have shown that APHIS' delimiting survey rate of 8,000 cubic centimeters of soil (approximately 20 pounds (lbs) per acre) has a greater than 95 percent probability of detecting small populations of PCN after one host crop, and closer to 99 percent probability of detecting PCN after two host crops.

A commenter expressed concern about inconsistencies in how APHIS determines what land should be regulated for PCN and stated that he has never heard of a clear deregulation plan for associated fields where no nematodes have ever been found.

Complete deregulation protocols for infested and associated fields, including associated fields where no nematodes have been found, are available at *https://www.aphis.usda.gov/planthealth/pcn.* Under § 301.86–3(c)(2) of the regulations, APHIS may designate a field as an associated field if host crops have been grown in that field in the past 10 years and if the field came into contact with a regulated article from a PCN-infested field in the past 10 years. Included among the regulated articles listed in § 301.86–2 is any equipment or conveyance used in an infested or associated field that can carry soil if moved out of the field. Although we proposed no changes to these sections of the regulations, provisions for deregulating associated fields are included in the protocols and for this reason we are responding to comments we received regarding farm equipment and field quarantine status.

A commenter asked if potato seed farms should be regulated when they have an association with an infested field.

If a field used as a potato seed source is suspected of having or confirmed to have a PCN infestation, it will be regulated accordingly. Potato seed produced on a regulated field is considered to be a regulated article and as such is subject to movement restrictions. Any field that has come into contact with a regulated article (such as seed produced on an infested field) will be regulated as an associated field. Any fields that are identified as a seed source for an infested field will be prioritized for survey but are not included as part of the regulated area until or unless survey results are suspect or positive for PCN.

Field Borders and Barriers

Under § 301.86–3(c)(2)(i) of the regulations, APHIS will designate a field as an associated field on the basis of adjacency when PCN host crops have been grown in the field in the last 10 years and the field borders an infested field. Although we proposed no changes to this paragraph, we are responding to comments received regarding field borders and regulatory status because the status of such fields is contingent on the deregulation protocol for associated fields.

To deregulate an associated field under this process, the field owner must establish a buffer zone of uncultivated ground at least 15 yards wide along the entire interface with the infested field. The buffer zone must include a physical barrier, such as a ditch, berm, or fence to discourage transfer of soil or other regulated articles between the two fields. The field must also meet the soil survey requirement for deregulation of an associated field. Establishing a field buffer zone is entirely voluntary for the owner of an adjacent field seeking to expedite the process to deregulate a field.

One commenter stated that the border buffer requirements constitute a taking of the neighbor's property and another commenter agreed, stating that farmers should be compensated for having to take land out of production for buffers. Another commenter noted instances in which APHIS required trenches or other barriers between fields on bordering farms even after a field was released from regulation and stated that barriers encroach on the land of innocent neighbors.

We disagree that establishing buffer zones to mitigate the spread of PCN between fields constitutes a taking of property, particularly as establishing such a zone in an associated field is voluntary on the part of the landowner. Creating an uncultivated buffer zone between an adjacent field and an infested field is a scientifically established means for expediting deregulation of the adjacent field before the infested field is deregulated.

Deregulation of Fields no Longer in Host Crop Production or Agricultural Use

We have made publicly available the deregulation protocols for fields no longer in host crop production and fields no longer in agricultural use. We received comments regarding the deregulation of such fields.

One commenter asked if a change in the use of regulated fields to non-agricultural use—such as for housing or pasture—would allow regulation of those fields to be lifted. Another commenter objected to APHIS continuing to designate a field as associated for PCN even though the property includes a home and grass lawn and is too small for growing a profitable host crop, and cysts have never been found there. The commenter asked whether a change in the use of the property to a non-agricultural use, such as a gravel pit, would be sufficient for APHIS to deregulate it. Another commenter cited the case of a

[6] Available at *https://www.aphis.usda.gov/aphis/ourfocus/planthealth/plant-pest-and-disease-programs/ea/ct_pcn.*

homeowner who asked APHIS to remove land connected to his yard from associated field status but was told he would need to follow the deregulation protocol. The commenter suggested that APHIS allow growers to opt out of the deregulation program for a portion of their ground if they choose to subdivide the property for housing.

We are making no changes based on the comments. The protocols already include provisions for deregulating fields that will not return to host crop production and will transition to other uses such as residential or commercial development or pasture. The exact requirements for deregulating a field that has been taken out of host crop production depend upon the nature of the land's intended future use and the level of PCN risk in the field at the time of deregulation.

Another commenter asked if a former large farming operation on regulated fields now functioning as a hobby farm still needs to be regulated for PCN, particularly as the host crops grown are only sold locally.

As all regulated fields can pose a PCN risk, hobby farms established on regulated fields that produce host crops must follow the same deregulation protocol as large-scale agricultural fields remaining in commercial host crop production.

Sampling and Testing Procedures

We received several comments regarding the soil sampling and testing procedures we use in the field deregulation protocols. We have established in the protocols specific soil sampling rates per acre, the findings of which are used to map the distribution and population of cysts in infested fields. Cysts discovered during sampling are tested for viability.[7]

One commenter asked how we determined soil testing rates, noting that any rates determined from an agreement between the United States and Canada are not based on scientific testing rates.

While survey rates are often listed in agreements between countries, the rates themselves are based primarily on scientific research within APHIS and data from the scientific community.

A commenter asked if soil testing rates were determined by the Technical Working Group, noting that any rates based on the work of that group violate the District Court's order that APHIS may not rely upon the advice or recommendations of the Technical Working Group in any future actions.

As we noted in the document reopening the comment period for the proposal, the methodology for soil testing under the PCN program was drawn from scientific best practices and experience gained from our work in the APHIS Golden Nematode Program.

A commenter stated that our methods of proof of a PCN find are flawed, noting instances of fields where small numbers of nematodes were initially found but which subsequently disappeared without receiving any field treatments.

We disagree with the commenter that our methods for detecting PCN are flawed. The detection and subsequent absence of nematodes in a sample from an untreated field is not an unusual occurrence and cannot be ascribed to a problem with our methodology. Several factors can influence detection of PCN, including the aggregate distribution and infestation level of the pest in a field.

One commenter recommended that the protocol survey regimen of 40 lbs per acre on associated fields could be reduced to the European protocol of 1.28 lbs per acre. Another commenter stated that APHIS' soil sampling requirements for the deregulation protocol are 10 times the world standards and recommended that we use the world standard of 2 lbs maximum. Similarly, a commenter stated that since PCN is on the world eradication list, then Idaho should use the same lower level of soil testing that our trading partners use.

We are making no changes in response to the comments. APHIS' goal is to contain and eradicate PCN in Idaho to protect all U.S. growers from the yield losses experienced by growers in other countries that take different approaches to managing PCN. PCN is managed in Europe because it is endemic and widespread and therefore less intensive surveys are sufficient if the goal is management and not eradication. However, PCN populations in Europe continue to increase and seed potato acreages are reduced annually as a result. The purpose of this program is to ensure the same thing does not occur in the United States. We determined that the current soil testing procedures we use are necessary and appropriate to achieve program goals.

A commenter stated we did not indicate the soil depth at which field samples are to be collected for the deregulation protocol, resulting in uncertainty about APHIS' ability to mitigate the PCN risk. The commenter cited soil samples in Norway and Northern Ireland surveys that were taken at depths of 9 to 17 centimeters and 70 centimeters, respectively. Similarly, two other commenters expressed concern that the methods used to collect samples for testing in APHIS-approved laboratories are scientifically invalid because soil samples are only collected from the top 2 inches of the soil.

Soil samples are collected at the field surface; however, tillage and potato harvest practices in southeast Idaho thoroughly mix the top 30 centimeters (cm) of the soil profile. Therefore, subsequent surface sampling effectively represents the top 30 cm of the soil profile. We consider this soil sampling depth to be adequate to detect the presence of PCN in Idaho, the only State in which PCN is known to exist.

A commenter stated that the nematode soil extraction methods required by APHIS in PCN laboratories are expedited, causing very low recovery rates and further invalidating the confirmatory policy.

We are uncertain as to what specific problem the commenter is citing. APHIS follows extraction protocols based on best practices described in scientific literature, which include a minimum 2-week soil drying period and a quality-controlled laboratory environment in which the samples are processed.

Two commenters stated that growers should be able to have an independent lab conduct soil testing and compare their results with APHIS' findings, with one commenter expressing doubts about the reliability of DNA testing conducted by APHIS.

We do not prohibit a field operator or owner from employing independent PCN testing of their fields. However, we note that as soil in regulated fields is considered a regulated article, it cannot be moved from such fields without APHIS authorization. Moreover, soil testing can only be administered at APHIS-permitted facilities under methods approved by APHIS. For any third-party sampling effort to be recognized by APHIS as a valid comparison, we must provide oversight of field sampling and laboratory extraction to ensure APHIS protocols are followed.

A commenter requested that we no longer require tare dirt testing for exotic nematodes, adding that if APHIS does not require testing from our trading partners then APHIS should not be doing it domestically.

We are making no changes in response to the commenter. Tare soil sampling has never been a requirement of the APHIS PCN domestic program.

[7] More information about sampling rates and cyst viability is included in the comment period reopening document (85 FR 34537–34541, Docket No. APHIS–2018–0041, June 5, 2020), which can be accessed through the link in footnote 1.

Farm Machinery and Nonfarm Conveyances in Regulated Fields

As a regulated article under § 301.86–2, farm equipment and conveyances used in an infested or associated field that can carry soil out of the field are subject to pressure washing and steam sanitation requirements. These requirements constitute part of the deregulation protocols for infested and associated fields.

A few commenters stated these requirements have resulted in damage to the paint and computer components of their farming equipment and requested that APHIS provide them with compensation for damages.

We acknowledge that in the past there have been instances in which sanitation measures necessary for mitigating PCN have impacted farming equipment. However, through years of experience we have developed and applied approaches to sanitizing equipment that minimize or prevent instances of damage.

A commenter stated that equipment sanitation requirements were burdensome because it takes time to sanitize equipment and APHIS will not verify completion in a timely way. One commenter recommended that APHIS employ two sets of equipment cleaning teams at earlier and later hours so the whole day is covered.

We are aware of the time and effort required of growers to fulfill the sanitation requirements but note that doing so is essential to mitigating the spread of PCN. We have worked to make it easier for growers to meet these requirements by expanding our hours of service and implementing a central hotline for requesting sanitation services and scheduling appointments after hours, Saturdays, and on Federal holidays.

Some commenters stated that APHIS is inconsistent and arbitrary in how it establishes and enforces PCN regulations with respect to moving equipment and conveyances in and out of regulated fields. One such commenter noted that straw and alfalfa can be moved off an infested field while combines and other equipment used for harvesting must undergo sanitation as a regulated article, and yet power company equipment and third-party vendors move vehicles in and out of quarantined fields without regulation. Another commenter stated that pressure washing and steam sanitation requirements for infested and associated fields are arbitrarily applied. The commenter stated that his organization has provided APHIS with evidence of arbitrary application, including failure of APHIS to require sanitation of non-farm vehicles and equipment entering regulated fields. Finally, a commenter stated, without providing details, that APHIS has allowed trucks to travel unimpeded in infested fields and onto public roads without being washed or inspected, although harvesters could not do the same.

We disagree with the commenters' contention that APHIS applies sanitation requirements for infested and associated fields ineffectively and arbitrarily. Sanitation and limited permitting are required and enforced for all equipment and vehicles that exit a regulated field. We pursue all reports we receive of equipment moved in violation of the requirements and take action when there is enough evidence to warrant it. We use all records and other information available to us to establish regulated areas and to enforce sanitation requirements for all equipment and vehicles, while recognizing that farm equipment poses the greatest risk for spreading PCN, given its exposure to soil and frequent movement between fields.

A commenter asked how many times a field can be re-associated with an infested field.

There is no limit to the number of times a field can be re-associated. The regulatory status of a field for PCN is dependent on that field meeting any of the criteria for designation of fields as associated fields in § 301.86–3(c)(2).

A commenter noted that a number of external environmental factors, including host plant root diffusates, soil temperature and moisture, soil oxygen, soil microorganisms, minerals, and organic substances can induce or influence cyst hatching, and asked why these options are not used in place of sanitizing equipment.

We acknowledge that these factors can influence cyst hatching but note they are currently in the research phase and not ready to be tried on a production scale. Moreover, the factors listed are not actually sanitizing agents but more allied with pest eradication practices. While we always seek new approaches to controlling pests, sanitation is required to adequately address the risk of spreading PCN on equipment used in infested fields.

One commenter expressed concerns about the difficulty of moving deregulated equipment between fields. The commenter noted an instance in which APHIS told a grower that it was a holiday and their grain combine would have to remain in the field for 3 to 4 days before it could be washed and released.

APHIS understands the impacts of the sanitation requirement on growers and works to minimize delays while still providing services at no cost to growers. We note that sanitation and inspection services have been made available to growers on Federal holidays since 2011. In 2012, we developed a self-certification option with program oversight so growers could work autonomously. Stakeholders have the option of entering into a compliance agreement enabling them to meet washing, inspection, and certification requirements themselves.

A commenter stated that pressure washing equipment on the edge of a regulated field creates muddy conditions, which actually enhances the movement of soil out of the field as the mud clings to the tires of the equipment.

The commenter has provided no evidence that APHIS washes equipment in such a way that enhances movement of soil on equipment. We note that APHIS has broad experience with ensuring that vehicles and equipment that have been in PCN regulated fields are washed appropriately.

Non-Compliance With Court Order

According to one commenter, the proposed rule, economic analysis, and protocols violate the District Court's order that APHIS may not rely upon the advice or recommendations of the Technical Working Group in any future actions, including this rulemaking. The commenter noted that in the Court's 2018 Memorandum Decision and Order in *Mickelsen Farms* v. *APHIS,* there are many instances of APHIS' reliance on the recommendations and findings of the Technical Working Group in the development of the protocols. The commenter stated that the Technical Working Group recommended that farm implements used on any known infested field must be completely sanitized and noted that the deregulation protocols call for pressure washing and steam sanitation. The commenter also pointed out that the Technical Working Group recommended using stain viability assays on eggs, as does the infested field deregulation protocols. Finally, the commenter noted that the Technical Working Group recommended post-eradication treatment monitoring using fixed grid patterns, and the infested field protocol also calls for fixed grid pattern field sampling.

Although we disagree with the commenter's contention that the deregulation protocols were developed based on the work of the Technical Working Group, we acknowledge that the March 2019 proposed rule could have provided the public with a more

detailed explanation to draw its own conclusions on this matter. For this reason, we reopened the comment period on the proposed rule a second time and provided in this June 2020 reopening document [8] additional information about the science and sources we used to develop the protocols. We have responded to comments addressing that information in this final rule.

Other Comments

One commenter said that we provided no evidence to support our statement in the proposal that unmanaged PCN infestations can cause potato yield losses of between 20 and 70 percent, adding that no yield losses have ever been documented as a result of PCN in the State of Idaho.

The percentage range we cited in the proposed rule collectively refers to potato yield losses from a few types of potato cyst nematodes, including PCN. Several studies from around the globe cite similar yield losses in countries where potato cyst nematodes have multiplied unchecked.[9] We note that no losses in potato yields have been documented for PCN in Idaho as in other countries because the infestation was detected and addressed before the pest level could reach the threshold for significant crop yield loss.

Several commenters suggested that APHIS should remove PCN from the U.S. and global quarantine lists.

There are currently 85 countries in addition to the United States that regulate *G. pallida* and 127 other countries that also regulate *G. rostochiensis.* Each of these countries determines its own import requirements for commodities entering their country. We agree with the regulatory and scientific communities that find PCN is capable of threatening Idaho [10] and the global potato industry with costs associated with managing unrestricted PCN populations.

Several commenters questioned the U.S. Department of Agriculture's (USDA's) ability to contain or eradicate PCN, citing instances in which viable nematodes have been dispersed broadly by wind, water, and animals.

While we acknowledge that water, wind, or animals are possible mechanisms for spreading PCN, our experience as well as scientific studies indicate that human-assisted spread is the primary mechanism for spreading PCN between fields. Natural PCN movement within soil, in contrast, has been shown to be generally no greater than 1–2 meters annually.[11] Although some infested fields in Idaho have been detected within close proximity to one another, all such fields to date have been shown to have a history of shared equipment or other human-assisted means of soil movement from another infested field.

We note, moreover, that APHIS regulates associated fields on the basis of adjacency to infested fields for the purpose of detecting any PCN spread by natural means. Our survey data have not supported that PCN is spread in Idaho by wind, water, or animals. APHIS has collected over half a million soil samples outside of infested fields, many from fields adjacent to infested fields, with no detections of PCN.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, without change.

Executive Orders 12866 and 13771 and Regulatory Flexibility Act

This final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget. This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available on the *Regulations.gov* website (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

According to the Small Business Administration, entities whose main activity is potato farming (classified under NAICS 111211) are considered small if they have $750,000 or less in annual receipts. Based on the 2017 Census of Agriculture, there were about 25,000 farms in Idaho, of which around 700 were considered to be primarily potato farms. Bingham and Bonneville Counties had 108 and 40 potato farms, respectively. There were about 1,800 farms in Idaho with farm sales greater than $500,000, of which around 1,070 farms had farm sales greater than $1 million. According to the 2017 Census, 108 of Bingham County's 1,177 farm operations (about 9 percent) had farm sales greater than $500,000, while Bonneville County, 40 of the 1,109 farm operations (about 4 percent) had farm sales greater than $500,000. Although the distribution of potato farms with farm sales above $500,000 (or $750,000) is not known, it is reasonable to conclude that many of the potato farms in northern Bingham and southern Bonneville Counties are small business entities.

However, the final rule would not impose new or additional burdens on small entities as this is an administrative action for which there would be no additional costs.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR chapter IV.)

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

[8] See footnote 1 for a link to the document.

[9] Studies on this topic include: ''Scientists: Unless PCN is eliminated, 'there will be no Scottish potato sector left in 25 years' time.'' *Potato News Today,* August 9, 2019; otton, J. 2014, ''The genome and life-stage specific transcriptomes of *Globodera pallida:* key aspects of plant parasitism by a cyst nematode.'' *Genome Biology* 15: *https://doi.org/10.1186/gb-2014-15-3-r43;* Greco, N. 1988, ''Potato cyst nematodes: *Globodera rostochiensis* and *G. pallida.*'' Nematology Circular 149, Florida Department of Agriculture and Consumer Services, Division of Plant Industry, Gainesville, FL, USA; Dale, M.F.B., 1988, ''The assessment of the tolerance of partially resistant potato clones to damage by the potato cyst nematode *Globodera pallida* at different sites and in different years.'' *Annals* of *Applied Biology* 113, pp. 79–88; and Mai, J. 1977, ''Worldwide Distribution of Potato-Cyst Nematodes and Their Importance in Crop Production.'' *Journal of Nematology,* 9:1, January 1977.

[10] See Koirala, S., Watson, P., McIntosh, C.S. *et al.* ''Economic Impact of Globodera Pallida on the Idaho Economy.'' *American Journal of Potato Research.* 97, 214–220 (2020). *https://doi.org/10.1007/s12230-020-09768-2.*

[11] See, for example, N.C. Banks, et al., ''Dispersal of Potato Cyst Nematodes Measured Using Historical and Spatial Statistical Analyses.'' *Phytopathology* 102(6):620–6, June 2012: *https://apsjournals.apsnet.org/doi/pdfplus/10.1094/PHYTO-08-11-0224;* and Lambert, K. and S. Bekal, ''Introduction to Plant-Parasitic Nematodes.'' *The Plant Health Instructor* (2002, revised 2009). DOI: 10.1094/PHI–I–2002–1218–01.

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 rule as not a major rule, as defined by 5 U.S.C. 804(2).

Paperwork Reduction Act

This final rule contains no reporting, recordkeeping, or third party disclosure requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, we are amending 7 CFR part 301 as follows:

PART 301—DOMESTIC QUARANTINE NOTICES

■ 1. The authority citation for part 301 continues to read as follows:

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 7 CFR 2.22, 2.80, and 371.3. Section 301.75–15 issued under Sec. 204, Title II, Public Law 106–113, 113 Stat. 1501A–293; sections 301.75–15 and 301.75–16 issued under Sec. 203, Title II, Public Law 106–224, 114 Stat. 400 (7 U.S.C. 1421 note).

■ 2. Section 301.86–3 is amended as follows:

■ a. In paragraph (a), by removing ''*http://www.aphis.usda.gov/plant_health/plant_pest_info/potato/pcn.shtml*'' and adding ''*https://www.aphis.usda.gov/planthealth/pcn*'' in its place; and

■ b. By revising paragraphs (c)(1) and (d).

The revisions read as follows:

§ 301.86–3 Quarantined areas.

* * * * *

(c) * * *

(1) *Infested fields.* A field will be designated as an infested field for pale cyst nematode upon a determination that viable pale cyst nematode is present in the field. The determination will be made in accordance with the criteria established by the Administrator for the designation of infested fields. The criteria are presented in a protocol document that may be viewed at *https://www.aphis.usda.gov/planthealth/pcn.* The protocol may also be obtained by request from any local office of Plant Protection and Quarantine; local offices are listed in telephone directories. Any substantive changes we propose to make to the protocol will be published for comment in the **Federal Register**. After we review the comments received, we will publish another notice in the **Federal Register** informing the public of any changes to the protocol.

* * * * *

(d) *Removal of fields from quarantine. (1) Infested fields.* An infested field will be removed from quarantine for pale cyst nematode upon a determination that no viable pale cyst nematode is detected in the field. The determination will be made in accordance with criteria established by the Administrator and sufficient to support removal of infested fields from quarantine. The criteria are presented in a protocol document as provided in paragraph (d)(4) of this section along with information for viewing the protocol.

(2) *Associated fields.* An associated field will be removed from quarantine for pale cyst nematode once surveys are completed and pale cyst nematode is not detected in the field. The determination will be made in accordance with criteria established by the Administrator and sufficient to support removal of associated fields from quarantine. The criteria are presented in a protocol document as provided in paragraph (d)(4) of this section along with information for viewing the protocol.

(3) *Removal of other areas from quarantine.* If the Administrator has quarantined any area other than infested or associated fields because of its inseparability for quarantine enforcement purposes from infested or associated fields, as provided in paragraph (a) of this section, that area will be removed from quarantine when the relevant infested or associated fields are removed from quarantine.

(4) *Protocol for removal of fields from quarantine.* The Administrator will remove infested and associated fields, and other areas as provided in this section, from quarantine for pale cyst nematode in accordance with the protocols published on the Plant Protection and Quarantine website at *https://www.aphis.usda.gov/planthealth/pcn.* The protocols may also be obtained by request from any local office of Plant Protection and Quarantine; local offices are listed in telephone directories. Any substantive changes we propose to make to the protocols will be published for comment in the **Federal Register**. After we review the comments received, we will publish another notice in the **Federal Register** informing the public of any changes to the protocols.

Done in Washington, DC, this 1st day of December 2020.

Michael Watson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2020–26962 Filed 12–28–20; 8:45 am]

BILLING CODE 3410–34–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

[NRC–2017–0151]

RIN 3150–AK07

Reactor Vessel Material Surveillance Program

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is confirming the effective date of February 1, 2021, for the direct final rule that was published in the **Federal Register** on October 2, 2020. The direct final rule amends the NRC's reactor vessel material surveillance program requirements for commercial light-water reactors. The direct final rule revises the requirements associated with the testing of specimens contained within surveillance capsules and reporting the surveillance test results. The direct final rule also clarifies the requirements for the design of surveillance programs and the capsule withdrawal schedules for surveillance capsules in reactor vessels purchased after 1982.

DATES: The effective date of February 1, 2021, for the direct final rule published October 2, 2020 (85 FR 62199), is confirmed.

ADDRESSES: Please refer to Docket ID NRC–2017–0151 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–2017–0151. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: *Dawn.Forder@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *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.*

• *Attention:* The Public Document Room (PDR), where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Stewart Schneider, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–4123, 3453, email: *Stewart.Schneider@nrc.gov,* or On Yee, Office of Nuclear Reactor Regulation, telephone: 301–415–1905, email: *On.Yee@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION: On October 2, 2020 (85 FR 62199), the NRC published a direct final rule amending its regulations in appendix H, ''Reactor Vessel Material Surveillance Program Requirements'' (appendix H), to part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Domestic Licensing of Production and Utilization Facilities,'' to revise the NRC's reactor vessel material surveillance program requirements for commercial light-water reactors. The direct final rule revises the requirements in appendix H to 10 CFR part 50 associated with the testing of specimens contained within surveillance capsules and reporting the surveillance test results. The direct final rule also clarifies the requirements for the design of surveillance programs and the capsule withdrawal schedules for surveillance capsules in reactor vessels purchased after 1982.

In the direct final rule published on October 2, 2020, the NRC stated that if no significant adverse comments were received, the direct final rule would become effective on February 1, 2021. The NRC received and docketed two comment submissions on the companion proposed rule (85 FR 62234; October 2, 2020). Electronic copies of the comments can be obtained from the Federal Rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2017–0151 and are also available in ADAMS under Accession Nos. ML20301A624 and ML20308A229, respectively.

The NRC determined that the two comment submissions addressed issues that were outside the scope of the direct final rule or were not significant nor adverse. One comment submission questioned (1) the use of Charpy V-notch testing procedures, (2) the subsequent license renewal and extended power uprate for Turkey Point Nuclear Generating Units 3 and 4, (3) the use of Integrated Surveillance Programs, and (4) the timing associated with specimen testing and capsule report submittal. With respect to the items 1–3, these issues are outside the scope of this direct final rule. While item 4 is within the scope of the direct final rule, the NRC determined that the comment was not significant nor adverse. The other comment submission is outside the scope of this direct final rule. Therefore the direct final rule will become effective as scheduled.

Paperwork Reduction Act Statement

The direct final rule contains a new or amended collection of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The collections of information were approved by the Office of Management and Budget (OMB), approval number 3150–0011.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

Dated: December 21, 2020.

For the Nuclear Regulatory Commission.

Pamela J. Shepherd-Vladimir,

Acting Chief, Regulatory Analysis and Rulemaking Support Branch, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2020–28814 Filed 12–28–20; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0858; Project Identifier MCAI–2020–00949–T; Amendment 39–21370; AD 2020–26–15]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

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

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2016–07–14, which applied to certain Airbus Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. AD 2016–07–14 required replacing the clips, shear webs, and angles, related investigative actions, and repair if necessary. This AD retains the actions of AD 2016–07–14, and requires modifying (replacing) the clips, shear webs, and angles at a certain rear fuselage area with new parts, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA has also determined that additional airplanes are subject to the unsafe condition. This AD was prompted by fatigue testing that determined that fatigue damage could appear on clips, shear webs, and angles at certain rear fuselage sections and certain frames. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective February 2, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of February 2, 2021.

ADDRESSES: For material incorporated by reference (IBR) in this AD, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this IBR material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

It is also available in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0858.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0858; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT:

Sanjay Ralhan, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223; email *Sanjay.Ralhan@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2020–0153, dated July 10, 2020 (EASA AD 2020–0153) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for certain Airbus Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –215 –216, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. EASA AD 2020–0153 superseded EASA AD 2014–0177, dated July 25, 2014 (which corresponds to FAA AD 2016–07–14, 39–18459 (81 FR 21244, April 11, 2016) (AD 2016–07–14)). Model A320–215 airplanes are not certificated by the FAA and are not included on the U.S. type certificate data sheet; this AD therefore does not include those airplanes in the applicability.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2016–07–14. AD 2016–07–14 applied to certain Airbus Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. The NPRM published in the **Federal Register** on October 1, 2020 (85 FR 61892). The NPRM was prompted by fatigue testing that determined that fatigue damage could appear on clips, shear webs, and angles at certain rear fuselage sections and certain frames. The NPRM proposed to retain the actions of AD 2016–07–14, and require modifying (replacing) the clips, shear webs, and angles at a certain rear fuselage area with new parts, as specified in EASA AD 2020–0153. The NPRM also proposed to apply to additional airplanes subject to the unsafe condition.

The FAA is issuing this AD to address fatigue damage on the clips, shear webs, and angles, which could affect the structural integrity of the airplane. See the MCAI for additional background information.

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The FAA has considered the comments received. United Airlines and an anonymous commenter indicated their support for the NPRM.

Conclusion

The FAA reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule as proposed, except for minor editorial changes. The FAA has determined that these minor changes:

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

Related Service Information Under 1 CFR Part 51

EASA AD 2020–0153 describes procedures for replacement of affected parts (as required by FAA AD 2016–07–14). EASA AD 2020–0153 also describes procedures for a modification by replacing the clips, shear webs, and angles at the rear fuselage area of section 19 at frame 72 and frame 74 with new parts without pilot holes, and installing oversized Hi-Loks, nominal aluminum rivets, and nominal Hi-Loks in certain positions. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 219 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions from AD 2016–07–14 (for 44 airplanes affected).	Up to 110 work-hours × $85 per hour = Up to $9,350.	$10,000	Up to $19,350 ..	Up to $851,400.
New actions	126 work-hours × $85 per hour = $10,710	51,750	62,460	13,678,740.

Authority for This Rulemaking

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

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

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2016–07–14, Amendment 39–18459 (81 FR 21244, April 11, 2016), and

■ b. Adding the following new AD:

2020–26–15 Airbus SAS: Amendment 39–21370; Docket No. FAA–2020–0858; Project Identifier MCAI–2020–00949–T.

(a) Effective Date

This airworthiness directive (AD) is effective February 2, 2021.

(b) Affected ADs

This AD replaces AD 2016–07–14, Amendment 39–18459 (81 FR 21244, April 11, 2016) (AD 2016–07–14).

(c) Applicability

This AD applies to Airbus SAS airplanes specified in paragraphs (c)(1) through (3) of this AD, certificated in any category, as identified in European Union Aviation Safety Agency (EASA) AD 2020–0153, dated July 10, 2020 (EASA AD 2020–0153).

(1) Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes.

(2) Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes.

(3) Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Reason

This AD was prompted by fatigue testing that determined that fatigue damage could appear on clips, shear webs, and angles at certain rear fuselage sections and certain frames. The FAA is issuing this AD to address fatigue damage on the clips, shear webs, and angles, which could affect the structural integrity of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2020–0153.

(h) Exceptions to EASA AD 2020–0153

The ''Remarks'' section of EASA AD 2020–0153 does not apply to this AD.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (i)(2) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(j) Related Information

For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223; email *Sanjay.Ralhan@faa.gov.*

(k) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2020–0153, dated July 10, 2020.

(ii) [Reserved]

(3) For EASA AD 2020–0153, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0858.

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

Issued on December 11, 2020.

Lance T. Gant, Director,

Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–28858 Filed 12–28–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0781; Product Identifier 2018–CE–045–AD; Amendment 39–21369; AD 2020–26–14]

RIN 2120–AA64

Airworthiness Directives; Mitsubishi Heavy Industries, Ltd. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 75–16–20, which applied to all Mitsubishi Heavy Industries, Ltd., Model MU–2B, MU–2B–10, MU–2B–15, MU–2B–20, MU–2B–25, MU–2B–26, MU–2B–30, MU–2B–35, and MU–2B–36 airplanes. AD 75–16–20 required repetitive inspections of the propeller pitch control (PPC) lever for security and proper rigging. This AD requires

modification and repetitive inspections of the PPC lever linkage. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective February 2, 2021.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of February 2, 2021.

ADDRESSES: For Mitsubishi service information identified in this final rule, contact Mitsubishi Heavy Industries America, Inc., c/o Turbine Aircraft Services, Inc., 4550 Jimmy Doolittle Drive, Addison, Texas 75001; phone: (972) 248–3108, ext. 209; fax: (972) 248–3321; website: *https://mu-2aircraft.com.* For Honeywell service information identified in this final AD, contact Honeywell International Inc., 111 S 34th Street, Phoenix, Arizona 85034–2802; phone: 855–808–6500; email: *AeroTechSupport@honeywell.com;* website: *https://aerospace.honeywell.com/en/services/maintenance-and-monitoring.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148. It is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0781.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0781; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: John Turner, Aviation Safety Engineer, Fort Worth ACO Branch, FAA, 10101 Hillwood Parkway, Fort Worth, Texas 76177; phone: (817) 222–4508; fax: (817) 222–5245; email: *johh.r.turner@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 75–16–20, Amendment 39–2294 (40 FR 31751, July 29, 1975) (AD 75–16–20). AD 75–16–20 applied to all Mitsubishi Heavy Industries, Ltd. (Mitsubishi) Models MU–2B, MU–2B–10, MU–2B–15, MU–2B–20, MU–2B–25, MU–2B–26, MU–2B–30, MU–2B–35, and MU–2B–36 airplanes. The NPRM published in the **Federal Register** on August 25, 2020 (85 FR 52281). The NPRM was prompted by reports of the PPC lever linkages disconnecting at the engine and Mitsubishi developing a secondary retention feature to secure the PPC. The NPRM was also prompted by Mitsubishi type certificating additional airplanes that are subject to the unsafe condition. In the NPRM, the FAA proposed to require installation of the secondary retention feature, repetitive inspections of the PPC lever linkage, and reporting inspection results to the FAA.

Comments

The FAA received no comments on the NPRM or on the determination of the costs.

Conclusion

The FAA reviewed the relevant data and determined that air safety requires adoption of the AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for minor editorial changes, this AD is adopted as proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

Mitsubishi has issued MU–2 Service Recommendation No. 049/76–002, dated June 29, 2018, and MU–2 Service Recommendation No. 080, dated June 29, 2018. This service information specifies procedures for installing a PPC lever secondary retention feature to secure the PPC lever. These documents are distinct since they apply to different airplane models and configurations.

Mitsubishi has also issued MU–2 Service Bulletin No. 106/76–004, dated February 24, 2016, and MU–2 Service Bulletin No. 244, dated December 25, 2015. This service information specifies procedures for replacing the PPC lever clamping bolt. These documents are distinct since they apply to different airplane models and configurations.

Honeywell International Inc. has issued Service Bulletin TPE331–72–2190, Revision 0, dated December 21, 2011. The procedures in this service information include instructions for incorporating a threaded hole in the splined end of the shouldered shaft of the PPC assembly and re-identifying the shouldered shaft part number. The threaded hole is used to accommodate a secondary retention method to secure the PPC lever.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

Costs of Compliance

The FAA estimates that this AD affects 260 airplanes of U.S. registry.

The FAA estimates the following costs to comply with this AD. The average labor rate is $85 per work hour.

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Modification	2 work-hours × $85 per hour = $170	$2	$172	$44,720.
Repetitive inspections	1 work-hour × $85 per hour = $85 per inspection cycle.	0	$85 per inspection cycle	$22,100 per inspection cycle.

The FAA estimates the following costs to do any necessary on-condition actions for the incorporation of the threaded hole and reporting requirement. The FAA has no way of determining the number of aircraft that might need these on-condition actions:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Incorporation of threaded hole	4 work-hours × $85 per hour = $340	$1,000	$1,340

ON-CONDITION COSTS—Continued

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

If the PPC lever detaches, the necessary corrective actions could vary significantly from airplane to airplane. The FAA has received no definitive data that would enable estimating the cost to install the PPC lever on each airplane or the number of airplanes that may require this action.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524.

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA has determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 75–16–20, Amendment 39–2294 (40 FR 31751, July 29, 1975); and

■ b. Adding the following new airworthiness directive:

2020–26–14 Mitsubishi Heavy Industries, Ltd.: Amendment 39–21369; Docket No. FAA–2020–0781; Product Identifier 2018–CE–045–AD.

(a) Effective Date

This airworthiness directive (AD) is effective February 2, 2021.

(b) Affected ADs

This AD replaces AD 75–16–20, Amendment 39–2294 (40 FR 31751, July 29, 1975) (AD 75–16–20).

(c) Applicability

This AD applies to all Mitsubishi Heavy Industries, Ltd. (Mitsubishi) Models MU–2B, MU–2B–10, MU–2B–15, MU–2B–20, MU–2B–25, MU–2B–26, MU–2B–26A, MU–2B–30, MU–2B–35, MU–2B–36, MU–2B–36A, MU–2B–40, and MU–2B–60 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 61: Propellers.

(e) Reason

This AD was prompted by propeller pitch control (PPC) lever linkages disconnecting at the engine. The FAA is issuing this AD to address the PPC lever linkage from disconnecting at the engine, which could lead to the inability to control the propeller pitch with the power lever in the cockpit and consequent loss of control of the engine power settings.

(f) Compliance

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

(g) Modification

(1) For all airplanes except Model MU–2B and MU–2B–10 airplanes: Within 100 hours time-in-service (TIS) after the effective date of this AD or within 12 months after the effective date of this AD, whichever occurs first, modify the PPC lever linkage as specified in paragraphs (g)(1)(i) through (iii) of this AD, as applicable.

(i) Replace the PPC lever clamping bolt in accordance with the Accomplishment Instructions, section 2, of Mitsubishi MU–2 Service Bulletin No. 106/76–004, dated February 24, 2016, or Mitsubishi MU–2 Service Bulletin No. 244, dated December 25, 2015, as applicable to your model airplane.

(ii) For airplanes without a threaded hole in the splined end of the shouldered shaft of the PPC assembly, incorporate a threaded hole in accordance with the Accomplishment Instructions, paragraph 3.C.(3)(d)*2,* of Honeywell International Inc. Service Bulletin TPE331–72–2190, Revision 0, dated December 21, 2011.

(iii) Install a secondary retention feature in the threaded end of the PPC input shaft in accordance with the Accomplishment Instructions, section 2, of Mitsubishi MU–2 Service Recommendation No. 049/76–002, dated June 29, 2018, or Mitsubishi MU–2 Service Recommendation No. 080, dated June 29, 2018, as applicable to your model airplane.

(2) For Model MU–2B and MU–2B–10 airplanes: Within 100 hours TIS after the effective date of this AD or within 12 months after the effective date of this AD, whichever

occurs first, replace the PPC lever clamping bolt and install a secondary retention feature in the threaded end of the PPC input shaft using a method approved by the Manager of the Fort Worth ACO Branch, FAA. The Manager's approval letter must specifically refer to this AD.

(h) Repetitive Inspections and Reporting

Within 100 hours TIS after replacing the bolt and installing a secondary retention feature as required by paragraph (g) of this AD and thereafter at intervals not to exceed 100 hours TIS, inspect the security of the PPC lever by pulling the PPC lever upward by hand to ensure it does not detach from the PPC input shaft. If the PPC lever detaches, do the following.

(1) Before further flight, install the PPC lever using a method approved by the Manager of the Fort Worth ACO Branch, FAA. The Manager's approval letter must specifically refer to this AD.

(2) Within 30 days after the PPC lever detachment or within 30 days after the effective date of this AD, whichever occurs later, report the results of the inspection, including airplane model and serial number, to the FAA representative identified in paragraph (l)(2) of this AD.

(i) Special Flight Permit

(1) Special flight permits may be issued for the purpose of operating the airplane to a location where the requirements of paragraph (g) of this AD can be performed with the following limitations: Flights must not carry passengers, must operate in daytime visual meteorological conditions only, and must not operate in areas of known turbulence.

(2) Special flight permits may be issued for the purpose of operating the airplane to a location where the requirements of paragraph (h) of this AD may be performed without limitations.

(j) Paperwork Reduction Act Burden Statement

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. All responses to this collection of information are mandatory as required by this AD; the nature and extent of confidentiality to be provided, if any. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Fort Worth ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the Fort Worth ACO Branch, send it to the attention of the person identified in paragraph (l)(2) of this AD.

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

(l) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Japan Civil Aviation Bureau (JCAB) AD No. TCD–8678–2016, dated February 5, 2016, for related information. This MCAI may be found in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0781.

(2) For more information about this AD, contact John Turner, Aviation Safety Engineer, Fort Worth ACO Branch, FAA, 10101 Hillwood Parkway, Fort Worth, Texas 76177; phone: (817) 222–4508; fax: (817) 222–5245; email: *johh.r.turner@faa.gov.*

(m) Material Incorporated by Reference

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

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

(i) Honeywell International Inc. Service Bulletin TPE331–72–2190, Revision 0, dated December 21, 2011.

(ii) Mitsubishi MU–2 Service Bulletin No. 244, dated December 25, 2015.

(iii) Mitsubishi MU–2 Service Bulletin No. 106/76–004, dated February 24, 2016.

(iv) Mitsubishi MU–2 Service Recommendation No. 049/76–002, dated June 29, 2018.

(v) Mitsubishi MU–2 Service Recommendation No. 080, dated June 29, 2018.

(3) For Mitsubishi service information identified in this AD, contact Mitsubishi Heavy Industries America, Inc., c/o Turbine Aircraft Services, Inc., 4550 Jimmy Doolittle Drive, Addison, Texas 75001; phone: (972) 248–3108, ext. 209; fax: (972) 248–3321; website: *https://mu-2aircraft.com.*

(4) For Honeywell service information identified in this AD, contact Honeywell International Inc., 111 S 34th Street, Phoenix, Arizona 85034–2802; phone: 855–808–6500; email: *AeroTechSupport@honeywell.com;* website: *https://aerospace.honeywell.com/en/services/maintenance-and-monitoring.*

(5) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

(6) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on December 11, 2020.

Lance T. Gant, Director,

Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–28855 Filed 12–28–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–0750; Airspace Docket No. 20–ACE–17]

RIN 2120–AA66

Amendment of the Class E Airspace; Trenton, MO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Class E airspace extending upward from 700 feet above the surface at Trenton Municipal Airport, Trenton, MO. This action is the result of an airspace review caused by the decommissioning of the Trenton non-directional beacon (NDB) navigation information to the instrument procedures at this airport. The geographic coordinates of the airport are also being updated to coincide with the FAA's aeronautical database. Airspace redesign is necessary for the safety and management of instrument flight rules (IFR) operations at this airport.

DATES: Effective 0901 UTC, February 25, 2021. Director of the Federal Register approves this incorporation by reference action under Title 1 Code of Federal Regulations part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and

Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Rebecca Shelby, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5857.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class E airspace extending upward from 700 feet above the surface at Trenton Municipal Airport, Trenton, MO, to support instrument flight rule operations at this airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (85 FR 53310; August 28, 2020) for Docket No. FAA–2020–0750 to amend the Class E airspace extending upward from 700 feet above the surface at Trenton Municipal Airport, Trenton, MO. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 amends the Class E airspace extending upward 700 feet above the surface to within a 6.4-mile radius of Trenton Municipal Airport, Trenton, MO, and removes the Trenton NDB and associated extensions from the airspace legal description; and updates the geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This action is due to an airspace review caused by the decommissioning of the Trenton NDB, which provided navigation information for the instrument procedures at this airport.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ACE MO E5 Trenton, MO [Amended]

Trenton Municipal Airport, MO
(Lat. 40°05′07″ N, long. 93°35′26″ W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Trenton Municipal Airport.

Issued in Fort Worth, Texas, on December 22, 2020.

Steven T. Phillips,

Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2020–28846 Filed 12–28–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–0766; Airspace Docket No. 20–AWP–38]

RIN 2120–AA66

Modification of Class D and Establishment of Class E Airspace; Hayward, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies the Class D airspace, establishes Class E airspace extending upward from the surface and establishes Class E airspace as an

extension to the Class D and Class E surface areas at Hayward Executive Airport, Hayward, CA. After a biennial review of the airspace, the FAA found it necessary to amend the existing airspace for the safety and management of Instrument Flight Rules (IFR) operations at this airport. This action updates the airport name, amends the geographical coordinates for Hayward Executive Airport and Metropolitan Oakland International Airport to match the FAA's database and makes a minor editorial change replacing the outdated term Airport/Facility Directory with the term Chart Supplement.

DATES: Effective 0901 UTC, February 25, 2021. The Director of the Federal Register approves this incorporation by reference action under Title 1 Code of Federal Regulations part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA).

For information on the availability of FAA Order 7400.11E at NARA, email *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Richard Roberts, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–2245.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code (U.S.C.). Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies the Class D airspace, establishes Class E airspace to support IFR operations at Hayward Executive Airport under standard instrument approach and departure procedures at the airport, for the safety and management of aircraft within the National Airspace System. Additionally, an editorial change is being made to the legal description replacing ''Airport/Facility Directory'' with the term ''Chart Supplement'' and updating the name of the airport to match the FAA aeronautical database.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (85 FR 57170; September 15, 2020) for Docket No. FAA–2020–0766 to amend the Class D surface airspace, establish a Class E surface area and establish a Class E extension to the Class D and Class E surface areas in support of IFR operations. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. One substantive comment was received from an anonymous contributor. The commenter was concerned with the impact an expansion of .5 miles to the Class D would have on controller workload and traffic navigating on the flyway to the west of the Hayward class D. The FAA agrees. The expansion to the Class D was proposed to accommodate expanded circling criteria and update the airspace to the higher standard. However, because the procedures at Hayward have not yet been upgraded the FAA will review the procedures and see if a more acceptable approach can be identified when the circling is updated to include expanded circling. Therefore, the Class D and Class E airspace extending upward from the surface is established within 3.5 miles of Hayward Executive Airport excluding the portion in the Metropolitan Oakland Airspace. In addition, the portion 1.8 miles each side of the 119° bearing is eliminated, as it is no longer needed.

Class D and Class E airspace designations are published in paragraph 5000, 6002 and 6004 of FAA Order 7400.11E, dated July 21, 2020 and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class D and Class E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

The FAA is amending 14 CFR part 71 by removing the Class D extension 1.8 miles each side of the 119° bearing to the southeast, as it is no longer needed for operations.

Class E airspace extending upward from the surface is established within 3.5 miles of Hayward Executive Airport excluding the portion that extends into Metropolitan Oakland International Airport Airspace. These lateral dimensions match the Class D lateral boundary. This provides improved safety for operations within this area when the Airport Traffic Control Tower is not staffed.

Class E airspace as an extension to the Class D and Class E surface areas is established to capture aircraft as they descend through 1,000 feet AGL outside the lateral dimensions of the surface area, while using the RNAV Approach to runway 28L.

In addition, the term Airport Facility/Directory is replaced with Chart Supplement and the name of the Hayward Executive Airport and the geographical coordinates for both Hayward Executive Airport and Metropolitan Oakland International Airport are updated to match the FAA's National Airspace System Resource (NASR) database.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order (E.O.) 12866; (2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant

economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July, 21, 2020 and effective September 15, 2020, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

AWP CA D Hayward, CA [Amended]

Hayward Executive Airport, CA
(Lat. 37°39′32″ N, long. 122°07′18″ W)
Metropolitan Oakland International Airport
(Lat. 37°43′17″ N, long. 122°13′16″ W)

That airspace extending upward from the surface to, but not including, 1,500 feet MSL within a 3.5-mile radius of the Hayward Executive Airport, Hayward CA excluding that portion within the Metropolitan Oakland International Airport, Class C airspace. This Class D airspace is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6002 Class E Airspace Designated as Surface Areas.

* * * * *

AWP CA E2 Hayward, CA [New]

Hayward Executive Airport, CA
(Lat. 37°39′32″ N, long. 122°07′18″ W)
Metropolitan Oakland International Airport
(Lat. 37°43′17″ N, long. 122°13′16″ W)

That airspace extending upward from the surface to but not including 1,500 feet MSL within a 3.5-mile radius of the Hayward Executive Airport, Hayward CA excluding that portion within the Metropolitan Oakland International Airport, Class C airspace. This Class E airspace is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6004 Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

AWP CA E4 Hayward, CA [New]

Hayward Executive Airport, CA
(Lat. 37°39′32″ N, long. 122°07′18″ W)

That airspace extending upward from the surface 1.2 miles each side of the 120° bearing from the Hayward Executive Airport extending from the Class D and E2 airspace 3.5-mile radius to 9 miles from the airport.

Issued in Seattle, Washington, on December 21, 2020.

Brian Ochs,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2020–28637 Filed 12–28–20; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 200

[Release No. 33–10900; 34–90623; IA–5644; IC–34134]

Delegation of Authority to Director of the Division of Enforcement

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission (''Commission'') is revising its regulations with respect to the delegations of authority to the Director of the Division of Enforcement. These revisions are the result of the Commission's experience with its nonpublic investigations, litigation in Federal court, and disgorgement and Fair Fund plans in administrative and cease-and-desist proceedings instituted by the Commission. The revisions are intended to conserve Commission resources and make Commission operations more efficient by delegating to the Director the discretion to take the actions described below.

DATES: Effective December 29, 2020.

FOR FURTHER INFORMATION CONTACT: Joseph K. Brenner, Chief Counsel, at (202) 551–5055, Division of Enforcement, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–6553.

SUPPLEMENTARY INFORMATION:

Background

The Commission is revising its delegations of authority to the Director of the Division of Enforcement as a result of its experience with its nonpublic investigations, litigation in Federal court, and disgorgement and Fair Fund plans in administrative and cease-and-desist proceedings instituted by the Commission. The revisions are intended to conserve Commission resources and make Commission operations more efficient. Congress has authorized such delegation by Public Law 87–592, 76 Stat. 394, 15 U.S.C. 78d–1(a), which provides that the Commission ''shall have the authority to delegate, by published order or rule, any of its functions to . . . an employee or employee board, including functions with respect to hearing, determining, ordering, certifying, reporting, or otherwise acting as to any work, business or matter.''

The Commission is authorized to bring actions in United States District Court seeking injunctive and other relief for violations of the Federal securities laws and regulations. *See* Section 20(b) of the Securities Act of 1933 (15 U.S.C. 77t(b)); Section 21(d)(1) of the Securities Exchange Act of 1934 (15 U.S.C. 78u(d)(1)); Section 42(d) of the Investment Company Act of 1940 (15 U.S.C. 80a–41(d)); Section 209(d) of the Investment Advisers Act of 1940 (15 U.S.C. 80b–9(d)). With respect to Federal court litigation, the Commission routinely authorizes its staff to commence litigation against particular parties seeking particular relief. The addition of 17 CFR 200.30–4(a)(18) will allow the Director to carry out these authorizations more efficiently by taking the following actions: (i) Dismissing claims against entities that are defunct, the subject of bankruptcy proceedings, or without material assets; and (ii) dismissing claims against persons or entities that are duplicative of other pending claims against those persons or entities.

The Commission is authorized to conduct investigations concerning potential violations of the Federal securities laws and regulations and, as part of those investigations, to require the production of records. *See* Section 19(c) of the Securities Act of 1933 (15 U.S.C. 77s(c)); Section 21(b) of the Securities Exchange Act of 1934 (15 U.S.C. 78u(b)); Section 42(b) of the Investment Company Act of 1940 (15

U.S.C. 80a–41(b)); Section 209(b) of the Investment Advisers Act of 1940 (15 U.S.C. 80b–9(b)). Pursuant to Section 21(h)(4)(A) of the Securities Exchange Act of 1934, (15 U.S.C. 78u(h)(4)(A)), United States District Courts are authorized to issue orders delaying prior notice of a subpoena for records subject to the Right to Financial Privacy Act (12 U.S.C. 3401 *et seq.*) and prohibiting financial institutions from disclosing that records have been sought or obtained. The addition of 17 CFR 200.30–4(a)(19) will authorize the Director to file applications in United States District Court with respect to such orders.

The Commission is authorized to deny, suspend the effective date of, suspend for a period not exceeding 12 months, or revoke the registration of a security if the Commission finds, on the record after notice and opportunity for hearing, that the issuer of the security has failed to comply with the Federal securities laws or regulations. *See* Section 12(j) of the Securities Exchange Act of 1934 (15 U.S.C. 78*l*(j)). The Commission also is authorized to suspend trading in any security (other than an exempted security) for a period not exceeding ten business days if, in its opinion, the public interest and protection of investors so require. *See* Section 12(k)(1)(A) of the Securities Exchange Act of 1934 (15 U.S.C. 78*l*(k)(1)(A)). The addition of 17 CFR 200.30–4(a)(20) will authorize the Director to institute public administrative proceedings pursuant to Section 12(j) with respect to a security based on the issuer's alleged failure to file required periodic reports and, in connection with the institution of such proceedings, issue an order pursuant to Section 12(k)(1)(A).

In administrative and cease-and-desist proceedings instituted by the Commission to enforce the Federal securities laws, the Commission, in the exercise of its discretion, may distribute to investor victims amounts collected as disgorgement, prejudgment interest, and civil money penalties. *See* Section 308 of the Sarbanes-Oxley Act of 2002 (15 U.S.C. 7261). The addition of § 200.30–4(a)(21) will improve the efficiency of the Commission's distribution processes by authorizing the Director to: (i) Grant extensions of time to submit proposed distribution plans to the Commission; (ii) appoint tax administrators, pursuant to a Commission-approved omnibus order; (iii) publish notice of proposed plans, including plans that omit elements required by 17 CFR 201.1101, Rule 1101 of the Commission's Rules on Fair Fund and Disgorgement Plans; (iv) issue orders adopting plans as to which no negative comments have been received; (v) approve disbursements to investors in accordance with the plans; (vi) approve payment of the fees and expenses of administration; and (vii) approve final fund accountings.

The Division of Enforcement will report periodically to the Commission on the Director's use of these delegations. Notwithstanding these delegations, the Director may submit any matter he or she believes appropriate to the Commission. Furthermore, any action taken by the Director pursuant to delegated authority is subject to Commission review as provided by 17 CFR 201.430 and 201.431 and 15 U.S.C. 78d–1(b), Rules 430 and 431 of the Commission's Rules of Practice.

Administrative Law Matters

The Commission finds, in accordance with the Administrative Procedure Act (''APA''), that this amendment relates solely to agency organization, procedure, or practice. Title 5 U.S.C. 553(b)(3)(A). Accordingly, the APA's provisions regarding notice of rulemaking and opportunity for public comment are not applicable. These changes are therefore effective on December 29, 2020. In accord with the APA, we find that there is good cause to establish an effective date less than 30 days after publication of these rules. 5. U.S.C. 553(d). These rules do not substantially affect the rights or obligations of non-agency parties and pertain to increasing efficiency of internal Commission operations. For the same reasons, the provisions of the Small Business Regulatory Enforcement Fairness Act are not applicable. *See* 5 U.S.C. 804(3)(C) (the term ''rule'' does not include ''any rule of agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties''). Additionally, the provisions of the Regulatory Flexibility Act, 5 U.S.C. 60 *et seq.,* which apply only when notice and comment are required by the APA or other law, are not applicable. *See* 5 U.S.C. 601(2). These amendments do not contain any collection of information requirements as defined by the Paperwork Reduction Act of 1995. *See* 5 CFR 1320.3. Further, because these amendments impose no new burdens on private parties, the Commission does not believe that the amendments will have any impact on competition for purposes of Section 23(a)(2) of the Exchange Act. 15 U.S.C. 78w(a)(2).

Statutory Authority

This rule is adopted pursuant to statutory authority granted to the Commission, including Section 19 of the Securities Act, 15 U.S.C. 77s; Sections 4A, 4B, and 23 of the Exchange Act, 15 U.S.C. 78d–1, 78d–2, and 78w; Section 38 of the Investment Company Act, 15 U.S.C. 80a–37; Section 211 of the Investment Advisers Act, 15 U.S.C. 80b–11; and Section 3 of the Sarbanes-Oxley Act, 15 U.S.C. 7202.

List of Subjects in 17 CFR Part 200

Administrative practice and procedure, Authority delegations (Government agencies).

Text of Amendments

For the reasons set out in the preamble, the Commission is amending title 17, chapter II of the Code of Federal Regulations as follows:

PART 200—ORGANIZATION; CONDUCT AND ETHICS; AND INFORMATION AND REQUESTS

Subpart A—Organization and Program Management

■ 1. The authority citation for part 200, subpart A, continues to read, in part, as follows:

Authority: 15 U.S.C. 77c, 77o, 77s, 77z–3, 77sss, 78d, 78d–1, 78d–2, 78o–4, 78w, 78*ll*(d), 78mm, 80a–37, 80b–11, 7202, and 7211 *et seq.,* unless otherwise noted.

* * * * *

■ 2. Section 200.30–4 is amended by adding paragraphs (a)(18) through (21) to read as follows:

§ 200.30–4 Delegation of authority to Director of Division of Enforcement.

* * * * *

(a) * * *

(18) With respect to enforcement proceedings in Federal court, to:

(i) Dismiss claims against entities that are defunct, the subject of Federal or foreign bankruptcy proceedings, or without material assets; and

(ii) Dismiss claims against persons or entities that duplicate or overlap with other pending claims against those persons or entities, unless the dismissal would involve claims requiring a higher level of intent than that required by the remaining claims, result in a reduction of disgorgement available for the claims in the Commission's complaint, or eliminate the statutory basis for a bar sought in the Commission's complaint.

(19) To file applications in Federal court to seek an order pursuant to section 21(h)(2) of the Securities Exchange Act of 1934 (15 U.S.C. 78u(h)(2)) in connection with

investigations pursuant to section 19(c) of the Securities Act of 1933 (15 U.S.C. 77s(c)), section 21(b) of the Securities Exchange Act of 1934 (15 U.S.C. 78u(b)), section 42(b) of the Investment Company Act of 1940 (15 U.S.C. 80a–42(b)), and section 209(b) of the Investment Advisers Act of 1940 (15 U.S.C. 80b–9(b)).

(20) To institute proceedings pursuant to section 12(j) of the Securities Exchange Act of 1934 (15 U.S.C. 78*l*(j)) with respect to a security based on the issuer's alleged failure to file required periodic reports and, in connection with the institution of such proceedings, issue orders pursuant to section 12(k)(1)(A) of the Securities Exchange Act of 1934 (15 U.S.C. 78*l*(k)(1)(A)).

(21) With respect to disgorgement funds and Fair Fund plans established in administrative or cease-and-desist proceedings instituted by the Commission pursuant to the Federal securities laws, to:

(i) Grant extensions of time to submit proposed distribution plans to the Commission;

(ii) Appoint tax administrators, pursuant to a Commission-approved omnibus order;

(iii) Publish notice of proposed plans, including plans that omit elements required by § 201.1101 of this chapter (Rule 1101 of the Rules on Fair Fund and Disgorgement Plans);

(iv) Issue orders adopting plans as to which no negative comments have been received;

(v) Approve disbursements to investors in accordance with the plans;

(vi) Approve payment of the fees and expenses of administration; and

(vii) Approve final fund accountings.

* * * * *

By the Commission.

Dated: December 10, 2020.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2020–27537 Filed 12–28–20; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Parts 4, 5, and 7

[Docket Nos. TTB–2019–0004 and TTB–2019–0005; T.D. TTB–165; Re: Notice Nos. 182, 183, and 184]

RIN 1513–AB56 and 1513–AC45

Addition of New Standards of Fill for Wine and Distilled Spirits; Amendment of Distilled Spirits and Malt Beverage Net Contents Labeling Regulations

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Final rule; Treasury decision.

SUMMARY: This final rule amends the Alcohol and Tobacco Tax and Trade Bureau (TTB) regulations that govern wine and distilled spirits containers to add seven new standards of fill for wine and distilled spirits. Although TTB had originally proposed to generally eliminate the standards of fill for wine and distilled spirits, TTB is not adopting that proposal at this time. The amendments described in this final rule will provide bottlers with flexibility by allowing the use of the added container sizes, and will facilitate the movement of goods in domestic and international commerce, while also providing consumers broader purchasing options.

TTB is also amending the labeling regulations for distilled spirits and malt beverages to reflect current policy by specifically stating in the regulations that distilled spirits may be labeled with the equivalent standard United States (U.S.) measure in addition to the mandatory metric measure, and that malt beverages may be labeled with the equivalent metric measure in addition to the mandatory U.S. measure.

DATES: This final rule is effective December 29, 2020.

FOR FURTHER INFORMATION CONTACT: Jennifer Berry, Alcohol and Tobacco Tax and Trade Bureau, Regulations and Rulings Division; telephone 202–453–1039, ext. 275.

SUPPLEMENTARY INFORMATION:

Background

TTB Authority

The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers regulations setting forth standards of fill for containers of wine and distilled spirits products distributed within the United States. For wine, the authority to establish these standards is based on section 105(e) of the Federal Alcohol Administration Act (FAA Act), codified at 27 U.S.C. 205(e), which authorizes the Secretary of the Treasury to prescribe regulations relating to the ''packaging, marking, branding, and labeling and size and fill'' of alcohol beverage containers ''as will prohibit deception of the consumer with respect to such products or the quantity thereof * * *.'' For distilled spirits, the authority to establish standards of fill is based on two provisions of law: (1) Section 205(e) of the FAA Act as discussed above, and (2) section 5301(a) of the Internal Revenue Code of 1986 (IRC), codified at 26 U.S.C. 5301(a). Section 5301(a) of the IRC authorizes the Secretary of the Treasury to prescribe regulations ''to regulate the kind, size, branding, marking, sale, resale, possession, use, and reuse of containers (of a capacity of not more than 5 wine gallons) designed or intended for use for the sale of distilled spirits * * *'' when the Secretary determines that such action is necessary to protect the revenue. TTB administers these IRC and FAA Act provisions pursuant to section 1111(d) of the Homeland Security Act of 2002, as codified at 6 U.S.C. 531(d). In addition, the Secretary of the Treasury has delegated certain administrative and enforcement authorities to TTB through Treasury Order 120–01.

Current Standards of Fill for Wine

The standards of fill for wine are contained in subpart H of part 4 of the TTB regulations (27 CFR part 4). The term ''standard of fill'' is used in the TTB regulations and in this document to refer to the authorized amount of liquid in the container, rather than the size or capacity of the container itself. For better readability, however, this document sometimes uses the terms ''size'' or ''container size'' and ''standards of fill'' interchangeably. Within subpart H, paragraph (a) of § 4.72 (27 CFR 4.72(a)) authorizes the use of the following metric standards of fill for containers other than those described in paragraph (b) of that section:

- 3 liters;
- 1.5 liters;
- 1 liter;
- 750 milliliters;
- 500 milliliters;
- 375 milliliters;
- 187 milliliters;
- 100 milliliters; and
- 50 milliliters.

Paragraph (b) of § 4.72 states that wine may be bottled or packed in containers of 4 liters or larger if the containers are filled and labeled in quantities of even liters (4 liters, 5 liters, 6 liters, etc.).

Current Headspace Requirements for Wine

Requirements for headspace, the empty space between the top of the wine and the top of the container, are also contained in subpart H of 27 CFR part 4. Within subpart H, paragraph (a)(3) of § 4.71 (27 CFR 4.71(a)(3)) states that a standard wine container must be made and filled so as to have a headspace not in excess of 6 percent of the total capacity of the container after closure if the net content of the container is 187 milliliters or more and, in the case of all other wine containers, a headspace not in excess of 10 percent of such capacity.

Current Standards of Fill for Distilled Spirits

The standards of fill for distilled spirits are contained in subpart E of part 5 of the TTB regulations (27 CFR part 5). Within subpart E, paragraph (a)(1) of § 5.47a (27 CFR 5.47a(a)(1)) specifies the following metric standards of fill for containers other than those described in paragraph (a)(2) of that section:

- 1.75 liters;
- 1 liter;
- 750 milliliters;
- 500 milliliters (authorized only until June 30, 1989);
- 375 milliliters;
- 200 milliliters;
- 100 milliliters; and
- 50 milliliters.

In the case of distilled spirits in metal containers that have the general shape and design of a can, that have a closure which is an integral part of the container, and that cannot be readily reclosed after opening, paragraph (a)(2) of § 5.47a authorizes the use of the following metric standards of fill:

- 355 milliliters;
- 200 milliliters;
- 100 milliliters; and
- 50 milliliters.

In addition to the metric standards specified above, § 5.47a contains provisions regarding tolerances (discrepancies between actual and stated fill), unreasonable shortages in fill, and distilled spirits bottled or imported before January 1, 1980, and marketed or released from customs custody on or after that date (the date on which the U.S. volumetric standards were replaced by the § 5.47a metric standards, as discussed in more detail below).

Current Headspace Requirements for Distilled Spirits

Requirements for headspace are contained in 27 CFR 5.46(b), which states that a standard liquor bottle of a capacity of 200 milliliters or more shall be held to be misleading if it has a headspace in excess of 8 percent of the total capacity of the bottle after closure.

Malt Beverages

Unlike wine and distilled spirits, there are no standards of fill prescribed for malt beverages under the FAA Act. However, in the case of malt beverages, § 7.22(a)(4) of the TTB regulations (27 CFR 7.22(a)(4)) requires the display of net contents on the brand label as mandatory label information.

Notices of Proposed Rulemaking

On July 1, 2019, TTB published Notice Nos. 182 and 183 in the **Federal Register** (84 FR 31257 and 84 FR 31264).

Notice No. 182 proposed to eliminate all but a minimum standard of fill for wine containers. The minimum container size was retained to ensure the container would be of sufficient size to accommodate required labeling. The notice also proposed, in response to a petition, to increase the minimum headspace from not in excess of 10 percent of the container's capacity to not in excess of 30 percent for clear containers 100 milliliters or less. Finally, TTB also sought comments on alternatives to eliminating the standards of fill, including authorizing some or all of the petitioned-for sizes that were discussed in the notice, and developing an expedited administrative process for adding new standards in the future.

Notice No. 183 proposed to eliminate all but minimum and maximum standards of fill for distilled spirits. Retaining the minimum was proposed to ensure the container would be of sufficient size to accommodate required labeling, while the maximum maintains the distinction between bottled and bulk products. The FAA Act at 27 U.S.C. 206(c) establishes a bulk distilled spirits container as one having a capacity in excess of one wine gallon, while paragraphs (a) and (b) of section 206 do not permit the retail sale of distilled spirits in bulk containers to consumers.

In Notice No. 183, TTB also proposed to amend the labeling regulations for distilled spirits and malt beverages to reflect current policy by specifically stating that distilled spirits may be labeled with the equivalent standard U.S. measure in addition to the mandatory metric measure, and that malt beverages may be labeled with the equivalent metric measure in addition to the mandatory U.S. measure. Similar labeling is authorized for wine labels in 27 CFR 4.37(b) and has been authorized for distilled spirits and malt beverage labels as a matter of policy, but has not been explicitly stated in the distilled spirits and malt beverage regulations.

As in Notice No. 182, in Notice No. 183 TTB also sought comments on alternatives to eliminating the standards of fill, including authorizing some or all of the petitioned-for sizes that were discussed in the notice, and developing an expedited administrative process for adding new standards in the future.

In Notice Nos. 182 and 183, TTB provided reasons for proposing the elimination of the standards of fill, including the following:

1. It would address several petitions TTB had received on this issue, would eliminate the need for industry members to petition for additional authorizations if marketplace conditions favor different standards in the future, and would eliminate restrictions on competition and the movement of goods in domestic and international commerce.
2. It would address concerns that the current standards of fill unnecessarily limit manufacturing options and consumer purchasing options, particularly where consumers may seek smaller containers to target a specific amount of consumption.
3. TTB believed that the current and proposed labeling requirements regarding net contents (see 27 CFR 4.32(b)(2) and 4.37, 27 CFR 5.32(b)(3) and 5.38) and those regarding the design and fill of containers (see 27 CFR 4.71 and 27 CFR 5.46) provide consumers with adequate information about container contents, so standards of fill are not necessary to prevent consumer confusion.
4. Limiting standards of fill is no longer necessary to ensure accurate calculation of tax liabilities or to protect the revenue.
5. TTB's current experience with malt beverages, for which there is no Federal standard of fill requirement, shows no disproportionate level of revenue compliance or consumer deception issues related to bottle sizes.

The comment periods for Notice Nos. 182 and 183 originally closed on August 30, 2019, but TTB reopened and extended the comment periods at the request of commenters (see Notice No. 184, 84 FR 39786). The extended comment periods ended October 30, 2019. Because Notice Nos. 182 and 183 proposed similar regulatory amendments and the substance of the comments received were similar, TTB is finalizing the two notices in one final rule.

Comments

TTB received 644 comments in response to Notice No. 182 and 603

comments in response to Notice No. 183, for a total of 1,247 comments. Commenters included producers, wholesale distributers, retailers, trade associations (domestic and foreign), members of Congress, foreign government entities, and members of the public.

TTB also considered 79 comments concerning standards of fill that were submitted in response to Notice No. 176, Modernization of the Labeling and Advertising Regulations for Wine, Distilled Spirits, and Malt Beverages, published in the **Federal Register** (83 FR 60562) on November 26, 2018. When these additional comments are taken into account, TTB reviewed 1,326 comments regarding standard of fill issues as summarized below.

Comments on the Proposed Elimination of the Standards of Fill

Of the 1,326 comments TTB received, 1,251 comments address the proposed elimination of the standards of fill. A total of 110 comments support the proposal—40 comments to Notice No. 182, 40 comments to Notice No. 183, and 30 comments to Notice No. 176. Of the 1,141 comments opposed to eliminating the standards of fill—575 commenters to Notice No. 182, 560 commenters to Notice No. 183, and 6 comments to Notice No. 176—960 are nearly identical form letters, a majority of which are associated with three wholesale distributing companies and their employees.

Commenters supporting the elimination of the standards of fill generally state that the standards are unnecessary, restrictive to producers, and out-of-date. They note that there are no standards of fill for malt beverages or for other consumer products, and state that this does not cause difficulties. They contend that eliminating the standards of fill will result in lower costs for producers, will facilitate international trade, and will provide consumers with more options in beverage alcohol packaging. The American Craft Spirits Association (Notice No. 183, comment 78) states that it surveyed its membership concerning the rulemaking and ''found overwhelming support for elimination of the current standards.'' It adds that ''[i]n order to promote innovation within the industry and competitively enter products into the global marketplace, smaller spirits producers must have maximum flexibility to quickly meet consumer demand as well as diverse regulatory standards.''

Several of the wine commenters who support elimination of the standards of fill cite the fact that they are unable to use certain can sizes to package wine because they are not among the authorized standard sizes. For example, Senator Charles Schumer (Notice No. 182, comment 12) cites the inability of New York wineries to package their wine in 250 milliliter and 355 milliliter cans as grounds for eliminating the standard of fill regulations. The Senator argues that these sizes are popular single serving sizes that are readily available to producers since they are already mass produced for beer and soda.

Commenters opposing the elimination of the standards of fill cite a number of reasons to retain the standards. The most often cited argument is that the standards of fill prevent consumer confusion. For example, commenters state that eliminating the standards of fill will cause a proliferation of sizes, making it difficult for consumers to compare prices on similar products. The Wine Institute (Notice No. 182, comment 162) states ''consumers may not be able to tell the difference between a 750 milliliter wine bottle and a 700 milliliter bottle, which could create an opportunity for producers to reduce costs and taxes while not necessarily reducing their prices. The current federal standards of fill allow consumers to shop by cost comparison without needing to calculate the price per milliliter.''

A handful of commenters cite the European Union's (EU) experience prior to 1990, when it had no standards of fill for distilled spirits. Drinks Ireland (Notice No. 183, comment 77) states that without standards of fill the market situation was ''complex, expensive, and confusing for consumers.'' The American Distilled Spirits Association (Notice No. 183, comment 111), citing comments submitted in response to the Bureau of Alcohol, Tobacco and Firearm's 1987 Advance Notice of Proposed Rulemaking (Notice No. 633, June 24, 1987, 52 FR 23685) on standards of fill, notes that the EU's lack of standards resulted in ''a confusing array of bottle sizes being sold side-by-side on retail shelves creating an environment ripe for consumer confusion.''

A number of commenters state that eliminating the standards of fill is inconsistent with the FAA Act. A letter signed by 52 members of the Congressional Wine Caucus states it would ''run directly counter to TTB's stated mission of prohibiting consumer deception'' (Notice No. 182, comment 168). Similar comments include that of the Wine Institute, which comments that eliminating the standards of fill ''would lead to the chaotic consumer marketplace that the FAA Act was intended to prevent.'' Six industry associations filing jointly (Notice No. 183, comment 108) state that retaining the standards of fill is consistent with TTB's statutory authority under the FAA Act to protect consumers.

Opposing comments also argued that eliminating the standards of fill will result in conflicting State requirements. These commenters report that a number of States defer to the Federal standard of fill requirements, so elimination could result in a patchwork of different State rules. The Congressional Wine Caucus states: ''38 states defer to the federal standard and if it is eliminated, these states will be forced to enact new container size requirements. This will create serious disruption to business as wineries would have to overhaul their sales, marketing, and compliance models to adjust to 38 varying state regulations.''

No State entity submitted comments to either notice, although TTB did request comments in Notice Nos. 182 and 183 from State regulators on whether the proposal would present regulatory issues at a State level. However, TTB did receive a comment from the National Alcohol Beverage Control Association (NABCA), which represents jurisdictions, including States, which directly control the distribution and sale of beverage alcohol within their borders. NABCA (Notice No. 182, comment 64; Notice No. 183, comment 55) opposes the elimination of the standards of fill and comments that the States currently using the Federal standards will enact new standard of fill requirements that could be different in each State.

Numerous commenters state that a proliferation in sizes will cause harm to distributors and retailers. According to many of these commenters, more sizes will result in additional SKUs, which will increase costs for these industry members. Southern Glazer's Wine & Spirits (Notice No. 183, comment 66) states that the increase in SKUs ''will have cascading economic ramifications throughout the entire value chain—from supplier to wholesaler to retailer to the end consumer. It will require major wholesalers, for example, to invest in elevated inventory levels, enhanced material handling capabilities, and increased storage space.'' The California Grocers Association (Notice No. 182, comment 169) states that ''Eliminating the regulation on standard wine and spirits sizes will increase our costs,'' and provides examples relating to such things as shelf space and inventory.

Opponents also contend that eliminating the standards of fill will

cause an increase in counterfeit and gray market imports that are currently prevented because the standards do not include some common international sizes, most specifically the 700 milliliter size. A large number of commenters state that adulterated products could more easily enter the country, resulting in injury and possibly death to consumers. This concern is expressed by Moët Hennessy USA, Inc. (Notice No. 183, comment 100) in its comment: ''* * * we wish to express a serious concern that will be impacted by changes to the existing standards—unauthorized importation of distilled spirits and wine products * * *. Allowing unauthorized imports robs Moët Hennessy USA and other authorized importers of the opportunity to protect against those risks and to ensure that our products are being sold in the intended state and manner. U.S. consumers should never face the risk of injury or death due to untraceable adulterated or counterfeit product brought in by an unauthorized importer.''

Finally, a few commenters argue that malt beverages are different in meaningful ways from wine and distilled spirits, and the fact that there are no standards of fill for malt beverages does not imply that there should not be standards of fill for wine and distilled spirits. These commenters state that because of historical practices consumers have different expectations for malt beverages than they do for wine and spirits. Additionally, Sazerac (Notice No. 183, comment 67) reports that a number of States mandate specific standards of fill for malt beverages, which it argues has driven standardization nationally. Heaven Hill Brands (Notice No. 183, comment 96) notes that in most states malt beverage distributors have the ability to distribute directly. It contends that ''[t]his direct distribution by suppliers allows for more flexibility in size due to fewer limitations resulting from a distributor's management of malt beverage inventory. Distilled spirits, however, must go through the distributor tier and have a much longer shelf life creating long periods of storage.''

Comments Regarding the Addition of Specific Sizes

Both Notice Nos. 182 and 183 stated that TTB was also considering maintaining the standards of fill, but ''liberalizing the existing regulatory scheme'' by adding certain additional standards of fill. In the respective notices, TTB listed sizes for which it had received a petition as 200, 250, 355, 620, and 700 milliliters and 2.25 liters for wine, and 700, 720, 900 milliliter and 1.8 liters for distilled spirits. A large number of commenters expressed support for the addition of specific petitioned-for sizes as follows:

Wine—250 milliliter: This size was supported by 51 commenters. Proponents of this size note that some wines are currently being sold in aggregate packages of four 250 milliliter cans, which together equal one liter, an authorized standard of fill. Industry members state that the 250 milliliter is popular with consumers as a single serving size, with some further stating that this size promotes portion control and responsible drinking. In his comment, Senator Schumer states that ''a recent wine consumer survey by WICResearch.com concluded that 'the total wine market will grow in order to satisfy consumer preferences,' if TTB permitted sales of wine-in-a-can in a single 250 milliliter size, which the survey revealed is the single-serve size most popular with consumers.'' Wine Institute notes that 250 milliliter containers are ''ideal serving containers for consumption at certain licensed venues such as stadiums, parks and other locations where glass or larger containers are not viable,'' and retailers wish to sell them individually in such venues.

Some commenters report that retailers often separate the containers from the aggregate packages, causing trade enforcement issues at the State level. To remedy this, these commenters recommend TTB approve the 250 milliliter size as an authorized standard of fill.

Wine—355 milliliter (12 oz.): This size was supported by 38 commenters. Several cider producers state that since the 355 milliliter (12 oz) can size is standard in the beer industry, their customers want and expect that size, making it critical to their commercial success. These producers note that, in the production of cider, apples often naturally ferment to an alcohol by volume (abv) level just above 7.4%, so producers often take steps to lower the abv below 7% so that the standards of fill regulations will not apply, enabling them to use 355 milliliter containers. They state that sugar levels in apples vary widely depending on climate and other factors, making final alcohol levels difficult to predict. They argue that being able to use the 355 milliliter container size will eliminate this uncertainty.

Wine—200 milliliter: This size was supported by 23 commenters. Several cider industry members state that their customers are seeking products in this size. The Vermont Grape and Wine Council (Notice No. 182, comment 74) and Presque Isle Wine Cellars (Notice No. 182, comment 37) state that this size is good for ice wine and is the size used in Canada for ice wine. Other commenters note that this size is authorized in Europe, so its approval will facilitate trade.

Other wine sizes: The other container sizes proposed in Notice No. 182—620 milliliter and 700 milliliter—were supported by two comments and one comment, respectively. TTB received no comments specifically addressing the proposed 2.25 liter size. However, TTB received comments proposing additional wine sizes that had not been proposed in Notice No. 182: 20 milliliter, 180 milliliter, 225 milliliter, 255 milliliter, 300 milliliter, 360 milliliter, 473 milliliter (16 oz), 475 milliliter, 550 milliliter, 568 milliliter, 650 milliliter, 720 milliliter, 1.8 liters, and 3.5 liters. Several of these sizes were suggested in Notice No. 176 by cider producers who contend that the sizes are important for their industry's success. Other proponents state that their proposed sizes are authorized in another country, so approval will facilitate trade.

Distilled spirits—700 milliliter: This size was supported by 18 commenters, who generally state that the 700 milliliter size is popular in other countries, so approval will facilitate trade and allow U.S. consumers more options in imported distilled spirits. However, several other commenters specifically cite the 700 milliliter size as a size that should not be approved. These commenters state that 700 milliliter is too close to the currently approved 750 milliliter size, and also contend that the size is the most popular bottle size worldwide with counterfeiters. Constellation Brands, Inc. (Notice No. 183, comment 107) states that the ''existence of both a 750 ml and 700 ml size in the marketplace could lead to consumer confusion and allow for confusing or misleading pricing practices. The addition of a 700 ml size could also enable sales by unauthorized importers.'' Moet Hennessy USA, Inc. (Notice No. 183, comment 100) states that the prohibition against the 700 milliliter size has kept many unauthorized spirits imports out. Approval, it believes, ''will 'open the floodgates' for unauthorized spirits imports into the U.S.'' It further states that ''unreputable operators * * * refill used spirits bottles with different liquid, causing potential serious risk to consumers.''

Other distilled spirits sizes: Three of the petitioned-for sizes—720 milliliter, 900 milliliter, and 1.8 liters—received

support from three Japanese trade associations and the Japanese National Tax Agency. Several other additional distilled spirits sizes were proposed by commenters that had not been proposed in Notice No. 183: 20 milliliter, 250 milliliter, 350 milliliter, 355 milliliter, 500 milliliter, 1.5 liters, 2 liters, 3 liters, 3.75 liters, and 5 gallons. Five commenters proposed the 1.5 liters size, stating that the size is used in other countries, so its approval will align the standards of fill more closely with the global marketplace. The EU referenced all nine of its authorized sizes (100 milliliter, 200 milliliter, 350 milliliter, 500 milliliter, 700 milliliter, 1 liter, 1.5 liters, 1.75 liters and 2 liters) in its comment. The proponents of these sizes cite their usage in other countries and state that their approval will facilitate trade and offer additional options to U.S. consumers.

Comments Opposing Addition of Any New Sizes

Numerous commenters to both notices opposed the approval of any new sizes, stating that the existing standards of fill already provide a wide variety of package sizes. Some of these commenters are not against the addition of new sizes per se, but rather believe that the current rulemaking did not provide enough opportunity for the public to focus on the petitioned-for sizes. E. & J. Gallo Winery (Notice No. 182, comment 146) states that ''[e]ach proposed new standard of fill should be the subject of a separate rulemaking proceeding so that commenters can review each in the context of existing standards of fill and any other proposals under consideration. Among other things, those rulemakings should address whether a proposed new standard of fill should replace an existing standard of fill or whether it should be limited to a particular package type such as cans or Tetra Paks. This type of deliberation is not possible in the current rulemaking.''

Comments on Proposal for an Expedited Approval Process

Both Notice Nos. 182 and 183 proposed the option of instituting an expedited approval process for standards of fill were TTB to continue to approve individual standards. A total of 33 comments from both notices specifically address this proposal.

Only four comments express complete support for an expedited approval process. The U.S. Association of Cider Makers (Notice No. 182, comment 158) supports an expedited process because ''the industry and marketplace change faster than the existing proposed rulemaking process can react, and we believe it is unreasonable to rely on NPRMs to quickly respond to market innovations.'' The National Association of Beverage Importers (Notice No. 182, comment 136 and Notice No. 183, comment 105) states that an administrative process would ''enable TTB to 'test the waters' of multiple sizes.'' It could, for example, permit the optional use of a 700 milliliter distilled spirits bottle for a limited period of time to determine how consumers react and the industry implements the introduction of this standard size from the global market.

Thirteen comments express complete opposition to any administrative approval process. These commenters generally state that new sizes should be approved by rulemaking, which will allow for public comments and transparency. Some of them also comment that it is not clear how such a process would work. Sazerac Company, Inc. (Notice No. 182, comment 85) states that ''the public should be given a meaningful opportunity to comment on potential changes as this should not be merely an administrative decision. Without sufficiently clear, publically-available standards, these standards could change over time without public input as officials change.'' Sazerac also states that it believes comment would be required under the Administrative Procedure Act (APA) because the standards of fill are binding on industry.

An additional 16 comments express support for an expedited process if it includes a public comment period or an opportunity for ''open consultation'' with all stakeholders before new sizes are approved. Several of these commenters also state that they would like additional information about how an expedited process would work.

Other Comments

No comments were received regarding the Notice No. 182 proposal to increase the minimum headspace for wine containers from not in excess of 10 percent of the container's capacity to not in excess of 30 percent for clear containers 100 milliliters or less.

Comments on Labeling Distilled Spirits With U.S. Measure and Malt Beverages With Metric Measure

Five comments to Notice No. 183 opposed the proposal to amend the labeling regulations for distilled spirits and malt beverages to specifically provide that distilled spirits may be labeled with the equivalent standard U.S. measure in addition to the mandatory metric measure, and that malt beverages may be labeled with the equivalent metric measure in addition to the mandatory U.S. measure. Such labeling has been allowed under TTB policy, but it has not been explicitly authorized in the regulations. These commenters state that such dual labeling is unnecessary and will cause ''label clutter.'' Six comments to Notice No. 182 expressed opposition to allowing U.S. units on wine labels, even though TTB made no proposal on the issue in Notice No. 182, as the wine labeling regulations already state that wine may be labeled with the equivalent U.S. unit in addition to the mandatory metric unit. See 27 CFR 4.37(b).

TTB Analysis

As discussed above, TTB received 110 comments that expressed support for eliminating the standards of fill, asserting that eliminating the standards will provide them with greater flexibility to meet consumer demands and grow their businesses. TTB received 1,141 comments that oppose eliminating the standards of fill (including the 937 nearly identical comments from individuals associated with three industry members). These commenters contended that eliminating the standards of fill would cause consumer confusion and potentially lead to a proliferation of differing State container size requirements that could cause further consumer confusion. Commenters also expressed concern about significant market disruption.

Based upon these comments, particularly those with regard to the potential consumer confusion, TTB believes that the appropriate action at this time is not to eliminate all standards of fill but instead to identify and authorize specific standards of fill from among those sizes that were the subject of notice and comment and for which TTB received sufficient information to make a determination.

TTB notes that, while some commenters expressed support for eliminating of the standards of fill (including Senator Charles Schumer), the comments themselves focused specifically upon ensuring that certain can sizes, such as 250 milliliter and 355 milliliter for wine, were authorized. TTB believes that its authorization of these sizes largely addresses these commenters' concerns.

Commenters expressed considerable support for most of the sizes TTB included in its proposals. However, few commenters supported authorizing the 620 milliliter, 700 milliliter, and 2.25 liter sizes for wine (which received specific support from 2, 1, and 0 commenters respectively).

The 700 milliliter size for distilled spirits was the only proposed size, for either wine or distilled spirits, for which some expressed opposition. With regard to the 700 milliliter size, TTB received supportive comments from industry members who state that approval of the 700 milliliter size for distilled spirits will facilitate trade for U.S. exporters and importers, because it is commonly used in other countries, and none of the commenters opposed to the 700-milliliter size provided information that would support a finding that the 700-milliliter size will be any more misleading to consumers than the other sizes supported by commenters generally. While some commenters noted that the 700-milliliter size is close to the already authorized 750-milliter size, as noted above, commenters supported approving the 355-milliliter size for wine, although 375-milliter is already an authorized size, and no commenters suggested that the closeness in size would lead to confusion. Additionally, although TTB understands the concern that commenters raised with regard to the potential for counterfeit products in the 700-milliliter size, TTB believes it is appropriate to continue to apply enforcement measures to deal with counterfeit products of any size.

In light of this, TTB believes that the addition of most of the petitioned-for sizes will result in many of the same benefits that were intended when it proposed eliminating the standards of fill—providing bottlers with more flexibility, facilitating the movement of goods in domestic and international commerce, and providing additional purchasing options to consumers, but without causing the disruption commenters expressed concerns over regarding the proposed elimination of standards of fill.

U.S.–Japan Trade Agreement

On October 7, 2019, the United States and Japan reached an agreement (the Agreement) on market access for certain agriculture and industrial goods. On December 30, 2019, a **Federal Register** notice (84 FR 72187) was issued to implement the Agreement. As part of the Agreement, the United States reached a side letter agreement with Japan dated October 7, 2019, which addresses issues related to alcohol beverages, including standards of fill (''Side Letter''). See *https://ustr.gov/sites/default/files/files/agreements/japan/Letter_Exchange_on_Alcoholic_Beverages.pdf.* The Side Letter states that the U.S. Department of the Treasury will take final action on Notice Nos. 182 and 183. If the final action does not address certain sizes—180, 300, 360, 550, 720 milliliters, and 1.8 liters for wine, and 700, 720, 900 milliliters, and 1.8 liters for distilled spirits—then the U.S. Department of the Treasury shall propose new rulemaking to allow for those sizes. The Side Letter took effect with the U.S.-Japan Trade Agreement, which entered into force on January 1, 2020.

In Notice No. 183, TTB referenced the distilled spirits sizes listed in the Side Letter. It described the petitions from three Japanese trade associations and a Japanese government agency for those sizes. These entities submitted comments that supported the elimination of the standards of fill, but further stated that, if the standards are not eliminated, they support the approval of their petitioned-for sizes. These proposed sizes for distilled spirits are discussed in Notice No. 183. Because TTB had not received petitions for the wine sizes listed in the Side Letter, TTB did not reference those sizes for wine in Notice No. 182. Nevertheless, TTB did receive comments from a Japanese trade association and a Japanese government agency proposing the approval of those sizes. The two comments support the elimination of the standards of fill, but requested the approval of the 180, 300, 360, 550, 720 milliliters, and 1.8 liters sizes for wine if the standards of fill for wine are not eliminated.

Administrative Approval Process

TTB requested comments regarding whether it should include in the new regulations an expedited administrative approval process that would replace the requirement for separate rulemaking in order to add new sizes to the standards of fill. This expedited approval process was offered as a quicker and less burdensome way to facilitate the expansion of bottled sizes without creating unnecessary industry burden. However, few commenters supported the process unless it included a public comment period or other means to consult with the industry, similar to the existing rulemaking process. Other commenters expressed support for an administrative approval process provided that TTB establishes criteria for approving additional sizes, and stated that TTB had not identified appropriate criteria for such a procedure. Consequently, TTB believes that an administrative procedure for approving new standards of fill is not appropriate at this time.

TTB Finding

After careful analysis of the comments discussed above, TTB has decided not to eliminate the standards of fill for wine and distilled spirits. Rather, TTB is adding certain sizes for which TTB had aired petitions in Notice Nos. 182 and 183. Based upon the comments received to those notices, TTB is authorizing the addition of the 200, 250, and 355 milliliters sizes for wine to § 4.72, and the 700, 720, 900 milliliters, and 1.8 liters sizes for distilled spirits to § 5.47a.

At this time, TTB is not adding the 620 milliliters, 700 milliliters, and 2.25 liter wine sizes for which it had aired petitions, because comments received regarding these sizes did not provide sufficient information for TTB to determine that they should be authorized standards of fill. TTB will consider including these sizes and any new petitions for additional sizes in subsequent rulemaking. Moreover, TTB is not adding a 2-milliliter size for distilled spirits that was the subject of a petition because, as discussed in Notice No. 183, TTB believes that a minimum size of 50 milliliters is needed to ensure sufficient space on the container for required labeling.

TTB is adopting the proposal in Notice No. 182 to increase the minimum headspace in wine containers from not in excess of 10 percent of the container's capacity to not in excess of 30 percent for clear containers 100 milliliters or less. TTB is likewise adopting the Notice No. 183 proposal to amend the labeling regulations for distilled spirits and malt beverages to specifically provide that distilled spirits may be labeled with the equivalent standard U.S. measure in addition to the mandatory metric measure, and that malt beverages may be labeled with the equivalent metric measure in addition to the mandatory U.S. measure.

TTB will conduct rulemaking to propose the addition of new standards of fill for wine, including the 180, 300, 360, 550, 720 milliliters, and 1.8 L sizes that Japanese government entities and Japanese industry associations requested during the comment period, and which were included in the Side Letter signed as part of the U.S.-Japan Trade Agreement discussed above.

Regulatory Analysis and Notices

Regulatory Flexibility Act

TTB certifies that this final rule will not have a significant economic impact on a substantial number of small entities. This final rule will provide wine and distilled spirits bottlers and importers with additional flexibility to use new bottle sizes if they so choose. This proposed regulation does not impose any new reporting,

recordkeeping, or other administrative requirements. Accordingly, a regulatory flexibility analysis is not required.

Paperwork Reduction Act

The collection of information in this rule has been previously approved by the Office of Management and Budget (OMB) under the title ''Labeling and Advertising Requirements Under the Federal Alcohol Administration Act,'' and assigned control number 1513–0087. This regulation will not result in a substantive or material change in the previously approved collection action, since the nature of the mandatory information that must appear on labels affixed to the container remains unchanged.

Executive Order 12866

It has been determined that this final rule is not a significant regulatory action as defined in Executive Order 12866 of September 30, 1993. Therefore, a regulatory assessment is not necessary.

Inapplicability of the Delayed Effective Date Requirement

Because these regulations relieve a restriction by providing wine and distilled spirits bottlers and importers with additional flexibility to use new bottle sizes if they so choose, and do not impose any new reporting, recordkeeping, or other administrative requirements, it has been determined, pursuant to 5 U.S.C. 553(d)(1), that these regulations will be issued without a delayed effective date.

Drafting Information

Jennifer Berry of the Regulations and Rulings Division drafted this document, along with other Department of the Treasury personnel.

List of Subjects

27 CFR Part 4

Advertising, Alcohol and alcoholic beverages, Consumer protection, Customs duties and inspection, Export, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements, Wine.

27 CFR Part 5

Advertising, Alcohol and alcoholic beverages, Consumer protection, Customs duties and inspection, Exports, Imports, Labeling, Liquors, Packaging and containers, Reporting and recordkeeping requirements.

27 CFR Part 7

Advertising, Alcohol and alcoholic beverages, Beer, Customs duties and inspection, Exports, Imports, Labeling, Malt beverages, Packaging and containers. Reporting and recordkeeping requirements.

Amendment to the Regulations

For the reasons discussed in the preamble, TTB is amending 27 CFR parts 4, 5, and 7 as follows:

PART 4—LABELING AND ADVERTISING OF WINE

■ 1. The authority citation for part 4 continues to read as follows:

Authority: 27 U.S.C. 205, unless otherwise noted.

■ 2. Section 4.71(a)(3) is revised to read as follows:

§ 4.71 Standard wine containers.

(a) * * *

(3) *Headspace.* It must be designed and filled so that the headspace, or empty space between the top of the wine and the top of the container, meets the following specifications:

(i) *187 mL or more.* If the net contents stated on the label are 187 milliliters or more, the headspace must not exceed 6 percent of the container's total capacity after closure.

(ii) *Less than 187 mL.* If the net contents stated on the label are less than 187 milliliters, except as described in (a)(3)(iii) of this section, the headspace must not exceed 10 percent of the container's total capacity after closure.

(iii) *Exception.* Wine bottled in clear containers with the contents clearly visible, with a net content stated on the label of 100 milliliters or less, may have a headspace that does not exceed 30 percent of the container's total capacity after closure.

■ 3. In § 4.72, amend the table in paragraph (a) by adding to the list of authorized standards of fill three new sizes after the entry for 375 milliliters, to read as follows:

§ 4.72 Metric standards of fill.

(a) * * *

* * * * *

355 milliliters.
250 milliliters.
200 milliliters.

* * * * *

PART 5—LABELING AND ADVERTISING OF DISTILLED SPIRITS

■ 4. The authority citation for part 5 continues to read as follows:

Authority: 26 U.S.C. 5301, 7805, 27 U.S.C. 205.

■ 5. In § 5.38, revise paragraph (a) to read as follows:

§ 5.38 Net Contents.

(a) *Standards of fill.* The net contents of distilled spirits shall be stated in metric measure. The equivalent standard U.S. measure may also be stated on the container in addition to the metric measure. *See* § 5.47a of this part for tolerances and for regulations pertaining to unreasonable shortages.

* * * * *

■ 6. In § 5.47a, amend paragraph (a)(1) by adding to the list of authorized standards of fill four new entries in numeric order, to read as follows:

§ 5.47a Metric standards of fill (distilled spirits bottled after December 31, 1979).

(a) * * *

(1) * * * 8 liters.

* * * * *

900 milliliters.

* * * * *

720 milliliters.
700 milliliters.

* * * * *

PART 7—LABELING AND ADVERTISING OF MALT BEVERAGES

■ 7. The authority citation for part 7 continues to read as follows:

Authority: 27 U.S.C. 205.

■ 8. In § 7.27, the introductory text of paragraph (a) is revised to read as follows:

§ 7.27 Net contents.

(a) Net contents shall be stated in standard U.S. measure as follows, and the equivalent metric measure may also be stated:

* * * * *

Signed: December 22, 2020.

Elisabeth C. Kann,

Acting Administrator.

Approved: December 22, 2020.

Timothy E. Skud,

Deputy Assistant Secretary, Tax, Trade, and Tariff Policy.

[FR Doc. 2020–28747 Filed 12–28–20; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2020–0719]

RIN 1625–AA00

Safety Zone; Oakland Ship-to-Shore Crane Arrival, San Francisco Bay, Oakland, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the navigable waters of the San Francisco Bay during the transit of the M/V ZHEN HUA 35, scheduled to arrive between December 24, 2020 and January 10, 2021. This safety zone is necessary to protect personnel, vessels, and the marine environment from hazards associated with the arms of three ship-to-shore gantry cranes, which will extend more than 200 feet out from the transiting vessel when the arms are lowered, and from the vessel's stability condition due to an air draft greater than 300 feet when the cranes are in the up position. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zone without permission of the Captain of the Port San Francisco or a designated representative.

DATES: This rule is effective without actual notice from December 29, 2020 through 11:59 p.m. on January 10, 2021. For the purposes of enforcement, actual notice will be used from 12:01 a.m. December 24, 2020 through December 29, 2020.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2020–0719 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LT Anthony Solares, Waterways Management, U.S. Coast Guard; telephone (415) 399–7443, email *SFWaterways@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port San Francisco
DHS Department of Homeland Security
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking with respect to this rule because it is impracticable. The Coast Guard did not receive details for the vessel's arrival and transit until December 20, 2020. The Coast Guard must establish this safety zone by December 24, 2020 and lacks sufficient time to provide a reasonable comment period and consider those comments before issuing the rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. It is contrary to the public interest to delay the effective date of this rule because the safety zone must be effective by December 24, 2020 to protect vessels and persons from the dangers associated with the M/V ZHEN HUA 35 as it transits a busy waterway between December 24, 2020 and January 10, 2021.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port San Francisco has determined that potential hazards associated with the transit of the M/V ZHEN HUA 35 between December 24, 2020 and January 10, 2021, will be a safety concern for anyone within a 500-foot radius of the vessel during its transit to Oakland, Berth 58, while the vessel is within the San Francisco Bay and areas shoreward of the line drawn between San Francisco Main Ship Channel Lighted Bell Buoy 7 and San Francisco Main Ship Channel Lighted Whistle Buoy 8 (LLNR 4190 & 4195) in positions 37°46.9′ N, 122°35.4′ W and 37°46.5′ N, 122°35.2′ W, respectively. For this reason, a safety zone is needed to protect personnel, vessels, and the marine environment in the navigable waters around the M/V ZHEN HUA 35 during its transit to Berth 58 at the Oakland International Container Terminal in Oakland, CA.

IV. Discussion of the Rule

This rule establishes a safety zone from 12:01 a.m. on December 24, 2020 until 11:59 p.m. on January 10, 2021, during the inbound transit of the M/V ZHEN HUA 35. While the M/V ZHEN HUA 35 is within the San Francisco Bay and areas shoreward of the line drawn between San Francisco Main Ship Channel Lighted Bell Buoy 7 and San Francisco Main Ship Channel Lighted Whistle Buoy 8 (LLNR 4190 & 4195) in positions 37°46.9′ N, 122°35.4′ W and 37°46.5′ N, 122°35.2′ W, respectively, the safety zone will encompass the navigable waters around and under the vessel, from surface to bottom, within a circle formed by connecting all points 500 feet out from the vessel. The safety zone is needed to protect personnel, mariners, and vessels from hazards associated with ship-to-shore gantry crane arms which will extend more than 200 feet out from the transiting vessel. This loading configuration is necessary in order for the vessel to pass safely under the Golden Gate Bridge and the San Francisco-Oakland Bay Bridge.

The M/V ZHEN HUA 35 will make a temporary stop in Anchorage 9 during its transit to the Oakland International Container Terminal. The vessel will stop temporarily for the crew to make adjustments to the cargo so the vessel can safely moor at Berth 58 in Oakland, CA. The cargo adjustments will include raising three ship-to-shore crane arms to an upright position which will facilitate mooring.

The effect of the safety zone is to restrict navigation in the vicinity of the M/V ZHEN HUA 35. Except for persons or vessels authorized by the COTP or the COTP's designated representative, no person or vessel may enter or remain in the restricted area. ''Designated representative'' means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel or a Federal, State, or local officer designated by or assisting the Captain of the Port San Francisco (COTP) in the enforcement of the safety zone.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the limited duration and

narrowly tailored geographic area of the safety zone. This safety zone impacts a 500-foot-radius area of the San Francisco Bay in San Francisco, CA for a limited duration. While the safety zone encompasses a two week period to account for uncertain transit delays of the M/V ZHEN HUA 35, the safety zone will only be enforced for the duration of the vessel's inbound transit, which is expected to last less than 24 hours, and that period will be announced via Broadcast Notice to Mariners. Vessels desiring to transit through the safety zone may do so upon express permission from the COTP or the COTP's designated representative.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the temporary safety zone may be small entities, for the reasons stated in section V.A. above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect 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. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and U.S. Coast Guard Environmental Planning Policy, COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone which prevents entry to a 500-foot radius area of the San Francisco Bay for a limited period of time during a vessel's inbound transit. It is categorically excluded from further review under paragraph L60(a) in Table 3–1 of Department of Homeland Security Directive 023–01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T11–035 to read as follows:

§ 165.T11–045 Safety Zone; Oakland Ship-to-Shore Crane Arrival, San Francisco Bay, Oakland, CA.

(a) *Location.* The following area is a safety zone: all navigable waters of the San Francisco Bay, from surface to bottom, within a circle formed by connecting all points 500 feet out from the vessel, M/V ZHEN HUA 35, during the vessel's inbound transit from a line drawn between San Francisco Main Ship Channel Lighted Bell Buoy 7 and San Francisco Main Ship Channel Lighted Whistle Buoy 8 (LLNR 4190 & 4195) in positions 37°46.9′ N, 122°35.4′ W (NAD 83) and 37°46.5′ N, 122°35.2′ W (NAD 83), respectively, to Berth 58 at the Oakland International Container Terminal in Oakland, CA. This transit includes a stop at Anchorage 9 to reposition the vessel's cargo.

(b) *Definitions.* As used in this section, ''designated representative''

means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel or a Federal, State, or local officer designated by or assisting the Captain of the Port San Francisco (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or the COTP's designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or the COTP's designated representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative. Persons and vessels may request permission to enter the safety zone on VHF–23A or through the 24-hour Command Center at telephone (415) 399–3547.

(d) *Enforcement period.* This section will be enforced between 12:01 a.m. on December 24, 2020 until 11:59 p.m. on January 10, 2021 during the inbound transit of the M/V ZHEN HUA 35, or as announced via Broadcast Notice to Mariners.

(e) *Information broadcasts.* The COTP or the COTP's designated representative will notify the maritime community of periods during which this zone will be enforced, in accordance with 33 CFR 165.7.

Dated: December 22, 2020.

Marie B. Byrd,

Captain, U.S. Coast Guard, Captain of the Port, San Francisco.

[FR Doc. 2020–28874 Filed 12–28–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 4

RIN 2900–AP88

Schedule for Rating Disabilities: Musculoskeletal System and Muscle Injuries; Correction

AGENCY: Department of Veterans Affairs.

ACTION: Final rule; correction.

SUMMARY: The Department of Veterans Affairs (VA) is making correcting amendments to the final rule published on November 30, 2020. The final rule amends the Department of Veterans Affairs (VA) Schedule for Rating Disabilities (''VASRD'' or ''rating schedule'') by revising the portion of the rating schedule that addresses the musculoskeletal system.

DATES: Effective February 7, 2021.

FOR FURTHER INFORMATION CONTACT: Gary Reynolds, M.D., Regulations Staff (211C), Compensation Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 461–9700. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: VA is correcting its final rule, ''RIN 2900–AP88; Schedule for Rating Disabilities: Musculoskeletal System and Muscle Injuries'', that was published on November 30, 2020, in the **Federal Register** at 38 CFR, Vol. 85, No. 230, 76453. The first error is with instruction 2(a), in which we intended to revise diagnostic code 5003. We are correcting this error by revising the entire diagnostic code 5003. The second error contains inaccurate diagnostic codes for Prosthetic implants in appendix C. We are correcting this error by revising the entry for Prosthetic implants.

Jeffrey M. Martin,

Assistant Director, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

In FR Doc. 2020–25450 appearing on page 76453 in the **Federal Register** of Monday, November 30, 2020, the following corrections are made:

§ 4.71a [Corrected]

■ 1. On page 76460, in § 4.71a, the entry for diagnostic code 5003 is correctly revised to read as follows:

§ 4.71a Schedule of ratings—musculoskeletal system.

ACUTE, SUBACUTE, OR CHRONIC DISEASES

	Rating
* * * * * * *	
5003 Degenerative arthritis, other than post-traumatic:	
Degenerative arthritis established by X-ray findings will be rated on the basis of limitation of motion under the appropriate diagnostic codes for the specific joint or joints involved (DC 5200 etc.). When however, the limitation of motion of the specific joint or joints involved is noncompensable under the appropriate diagnostic codes, a rating of 10 pct is for application for each such major joint or group of minor joints affected by limitation of motion, to be combined, not added under diagnostic code 5003. Limitation of motion must be objectively confirmed by findings such as swelling, muscle spasm, or satisfactory evidence of painful motion. In the absence of limitation of motion, rate as below:	
With X-ray evidence of involvement of 2 or more major joints or 2 or more minor joint groups, with occasional incapacitating exacerbations	20
With X-ray evidence of involvement of 2 or more major joints or 2 or more minor joint groups	10
Note (1): The 20 pct and 10 pct ratings based on X-ray findings, above, will not be combined with ratings based on limitation of motion.	
Note (2): The 20 pct and 10 pct ratings based on X-ray findings, above, will not be utilized in rating conditions listed under diagnostic codes 5013 to 5024, inclusive.	
* * * * * * *	

Appendix C to Part 4 [Corrected]

■ 2. On page 76469, in appendix C to part 4, the entry for ''Prosthetic implants'' is correctly revised to read as follows:

Appendix C to Part 4—Alphabetical Index of Disabilities

	Diagnostic code
* * * * * * *	
Prosthetic implants:	
Ankle replacement	5056
Elbow replacement	5052
Hip, resurfacing or replacement	5054
Knee, resurfacing or replacement	5055
Shoulder replacement	5051
Wrist replacement	5053
* * * * * * *	

[FR Doc. 2020–26907 Filed 12–28–20; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1, 13, 17 and 97

[WT Docket No. 19–212; FCC 20–126; FRS 17235]

Completing the Transition to Electronic Filing, Licenses and Authorizations, and Correspondence in the Wireless Radio Services

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this Report and Order, the Commission finalizes its transition to electronic interactions for licenses in the Wireless Radio Services. Specifically, the E-Licensing Report and Order: Eliminates existing exemptions to electronic filing in the FCC's Universal Licensing System and require electronic filing in the Antenna Structure Registration system; requires electronic filing (and delivery of service) of pleadings related to these systems; requires applicants, licensees, and registrants to provide an email address on related FCC Forms; and shifts from paper to electronic delivery of Commission correspondence generated from these systems. Together, these changes will decrease costs for consumers and the Commission, enhance transparency of and public access to data, and save a substantial amount of paper annually.

DATES: Effective June 29, 2021.

FOR FURTHER INFORMATION CONTACT: Katherine Patsas Nevitt, Wireless Telecommunications Bureau, Mobility Division, (202) 418–0638 or *katherine.nevitt@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the *Report and Order* in WT Docket No. 19–212, FCC 20–126, adopted September 16, 2020, and released September 17, 2020. The full text of the *Report and Order* is available for public inspection at the following internet address: *https://docs.fcc.gov/public/attachments/FCC-20-126A1_Rcd.pdf.* Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format), by sending an email to *FCC504@fcc.gov* or calling the Consumer and Governmental Affairs Bureau at 202–418–0530 (voice) or 202–418–0432 (TTY).

Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act of 1980, as amended (RFA), requires that an agency prepare a regulatory flexibility analysis for notice and comment rulemakings, unless the agency certifies that ''the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.'' Accordingly, the Commission has prepared a Final Regulatory Flexibility Analysis (FRFA) concerning the possible impact of the rule changes contained in this *Report and Order* on small entities. As required by the Regulatory Flexibility Act, an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the *notice of proposed rulemaking* (*NPRM*) (84 FR 51502, Sept. 30, 2019) released in September 2019 in this proceeding. The Commission sought written public comment on the proposals in the *NPRM,* including comments on the IRFA. No comments were filed addressing the IRFA. This FRFA conforms to the RFA. The Commission will send a copy of the *Report and Order, Order of Proposed Modification, and Orders,* including the FRFA, to the Chief Counsel for Advocacy of the Small Business Administration.

Paperwork Reduction Act

This document does not contain new or modified information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

Congressional Review Act

The Commission will send a copy of the *Report and Order* to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

Synopsis

I. Introduction

1. In the Report and Order, the Commission finalizes its transition to electronic interactions for licenses in the Wireless Radio Services. Specifically, the E-Licensing Report and Order: (1) Eliminates existing exemptions to electronic filing in the FCC's Universal Licensing System and require electronic filing in the Antenna Structure Registration system; (2) requires electronic filing (and delivery of service) of pleadings related to these systems; (3) requires applicants, licensees, and registrants to provide an email address on related FCC Forms; and (4) shifts from paper to electronic delivery of Commission correspondence generated from these systems. Together, these changes will decrease costs for consumers and the Commission, enhance transparency of and public access to data, and save a substantial amount of paper annually.

II. Background

2. The Commission manages applications for all Wireless Radio Service licenses through ULS. Related systems accept filings and work in conjunction with or alongside of ULS: The Antenna Structure Registration (ASR) System, the Tower Construction Notification System (TCNS), and the Electronic Section 106 (E–106) System. To promote safety in aircraft navigation, the Commission requires the owners of antenna structures to register with the

ASR System if their structures are above 200 feet in height or are in close proximity to an airport's runway. TCNS and the E–106 System advance the goal of the National Historic Preservation Act to protect historic properties, including Tribal religious and cultural sites. Collectively, these systems provide an efficient and transparent means to accept, review, and take action on the Commission's Wireless Radio Service applications.

3. The majority of applications filed in ULS today are electronic, as required by rule. But exceptions to mandatory electronic filing remain for the following services: (i) Part 90 Private Land Mobile Radio services for shared spectrum, spectrum in the public safety pool below 746 MHz, and spectrum in the public safety allocation above 746 MHz, except those filed by FCC-certified frequency coordinators; (ii) part 97 Amateur Radio Service, except those filed by Volunteer Examination Coordinators; (iii) part 95 General Mobile Service and Personal Radio Service, excluding 218–219 MHz service; (iv) part 80 Maritime Services, excluding VHF 156–162 MHz Public Coast Stations; (v) part 87 Aviation Services; (vi) part 13 Commercial Radio Operators (individual applicants only); and (vii) certain part 101 licensees who also fall under the exempted groups.

4. Similarly, the overwhelming majority of ASR applications are filed electronically; however, applicants have the choice to file manually or electronically. Pleadings related to applications in ULS and ASR, such as petitions to deny, may be filed electronically through a pleadings portal in ULS, but there is no mandatory electronic filing requirement. TCNS is an electronic-only system, so all interactions with it are electronic by design. While communications facility notifiers generally use TCNS as the vehicle to fulfill their obligation to identify and contact Tribal Nations and Native Hawaiian Organizations, they are not required to use it if a Tribe or NHO expressed a preference for being contacted in another manner. In addition, while communications facility notifiers can provide information to State Historic Preservation Officers via certain FCC Forms, there is no requirement that they use the E–106 system to submit these forms or otherwise file them electronically.

III. Report and Order

A. Electronic Filing

1. Electronic Filing in ULS

5. We find it in the public interest to eliminate the exemptions in § 1.913 of our rules that allow manual filings by applicants and licensees, and we instead mandate electronic filing for all Wireless Radio Services. This action furthers several longstanding Commission goals, including reducing regulatory burdens and environmental waste while streamlining our wireless services application process. It is also consistent with our Commission-wide efforts to digitize our systems and create efficient, user-friendly interactions with the agency.

6. ULS currently provides licensees and applicants electronic filing capability for the vast majority of applications in the Wireless Radio Services, but there are a few limited categories of submissions that ULS is unable to accept electronically. The Wireless Telecommunications Bureau recently has implemented a solution that allows all such applications to be filed in the Commission's Electronic Comment Filing System (ECFS). Thus, it is now possible for all applications in the Wireless Radio Services to be submitted electronically through one of the appropriate Commission e-filing systems.

2. Electronic Filing in the ASR System

7. We also require mandatory electronic filing of all applications in the ASR system. We believe there are many benefits to relying exclusively on electronic filing in the ASR system. Electronic submission is faster and less burdensome for applicants, less prone to errors resulting from processing of paper submissions. We agree that electronic filing in ASR is efficient, cost-effective, and reduces waste by eliminating unnecessary paper processes. Combined with the fact that the Commission already receives an overwhelming majority of ASR submissions electronically today, it is evident that a paper filing option is unnecessary. Accordingly, we revise the Commission's rules to specify mandatory electronic filing in the ASR system.

3. Reducing Paper Created by TCNS and E–106

8. The Commission developed TCNS and E–106 as tools for meeting its obligations under the National Historic Preservation Act. The Commission delegates the responsibility to licensees and applicants for initiating the Section 106 review process for the proposed facilities and for identifying and assessing potential adverse effects on historic properties. This process requires the Commission to consult with the appropriate State Historic Preservation Officers and Tribal Nations that have expressed an interest in the area of potential effect of a proposed project. Tribal Historic Preservation Officers may act in lieu of State Historic Preservation Officers for projects on Tribal lands. TCNS provides Tribes with preliminary electronic notification of proposed tower projects that potentially could impact historic properties of religious and cultural significance to Tribal Nations and Native Hawaiian Organizations. The E–106 System supports TCNS by allowing applicants to electronically submit the forms and cultural resources reports necessary for participating State Historic Preservation Officers, Tribal Historic Preservation Officers and consulting parties to complete the review process, as provided for in the Commission's Nationwide Programmatic Agreement.

9. We find that the existing TCNS and E–106 electronic filing systems, although voluntary, already automate and expedite the exchange of information and correspondence. In an effort to maximize the numerous benefits associated with electronic communications, however, we find that we can further reduce paperwork associated with these electronic systems. Accordingly, for State Historic Preservation Officers, we eliminate the paper mailing option for the Weekly Notice of Tower Construction Notification System Filings and will now deliver these courtesy notifications solely by email. With respect to E–106, we eliminate the courtesy paper mailing option of the Informational Notice of Section 106 Filings that summarizes proposed projects for applicants, consultants, and State Historic Preservation Officers that choose to use the E–106 system to review FCC Forms 620 and 621 electronically. This notice will now be delivered solely by email, except in instances where Tribes or Native Hawaiian Organizations have requested paper notification preferences.

B. E-Pleadings and E-Service for Wireless Radio Services Applications and Licenses

10. The Commission adopts rules mandating electronic filing for all pleadings related to ULS and ASR licenses and applications and requiring electronic service of those pleadings where service is mandated. We find that requiring electronic filing of pleadings will provide several benefits to wireless licensees, applicants, and stakeholders, including cost savings, convenience, and speed. Electronic filing reduces paper, printing, and delivery expenses. It also is more convenient: Users can file documents nearly 24 hours a day, 7

days a week through the non-docketed pleadings module on the ULS homepage. In addition, electronic filings are transmitted nearly instantaneously, which facilitates faster communications with the Commission and makes those pleadings simultaneously available to other interested parties. Electronic filing also allows users to create a digital record and establish proof of delivery.

11. Consistent with changes we make for electronic pleadings, we also require interested parties to submit electronically petitions, complaints, and requests for environmental review of proposed wireless communications facilities filed in accordance with the Commission's NEPA rules. While we are confident that the vast majority of participants in the NEPA review process will have the capability to participate electronically, we recognize that some members of the public may lack internet access. We believe that the Commission's waiver process is sufficient to provide relief from the requirement to electronically file such documents where parties are unable to file electronically or would be otherwise unreasonably burdened by such a requirement. Parties seeking such a waiver should include as part of their paper submission a request for waiver of the electronic filing requirement, and send that submission to the appropriate mailing address for the Commission Secretary. Parties should explain in their waiver requests why they are unable to file electronically or why it would be unreasonably burdensome for them to do so.

12. Consistent with our decision to mandate electronic filings of pleadings, the Commission adopts rules mandating electronic service, where service is required. Specifically, we require all petitions, pleadings, and other documents associated with licensing matters in the Wireless Radio Services to be served electronically upon a party, his attorney, or other duly constituted agent to the email address listed in ULS. Given that all parties will be required to provide valid email addresses, service by email to such an address may be considered complete upon sending. A party that has failed to provide a valid email address may not object to the adequacy of service. We revise various part 1 rules to effectuate these changes.

C. Email Address for Applications, Registrations, and Notifications

13. We find it in the public interest to require the inclusion of email addresses for all new ULS and ASR applicants and all existing ULS licensees and ASR registrants that modify, renew, or otherwise touch their existing licenses and registrations. We encourage existing licensees and tower owners to update their licenses and registrations with an email address in order to receive electronically courtesy letters from the Commission going forward. This approach is consistent with the Commission's efforts to modernize its legacy filing, communications, and information retention systems and is necessary to effectuate the rules we adopt in this document requiring electronic delivery of all correspondence between the Commission and ULS and ASR applicants and registrants.

14. Having valid, up-to-date email addresses on file will ensure that the Commission can shift its current process of delivering correspondence generated by ULS and the ASR System from postal mail to email. We also find that requiring an email address is not unduly burdensome for applicants and licensees. Rather, this action reflects a practice already adopted by the vast majority of our system's users and would otherwise pose a minor change in practices for the few filers who have not yet adopted such practices. Once an email address is required on the relevant FCC Forms, the Commission may dismiss as defective an application if an email address is not included.

15. To increase the number of email addresses on file and expand the Commission's use of electronic correspondence, we encourage existing licensees and tower owners to complete administrative updates to existing licenses and registrations in order to receive courtesy letters from the Commission. With the rules adopted in this document, courtesy letters will only be sent electronically to licensees and tower owners with email addresses on file; those without email addresses on file will not receive any courtesy letters. Licensees and tower owners seeking to receive such courtesy letters should therefore complete administrative updates to their existing licenses and registrations to continue receiving such correspondence. Beyond courtesy letters, we also find that encouraging licensees and tower owners to update their existing licenses and registrations will facilitate the Commission's transition to electronic correspondence more broadly.

D. Electronic Notices, Correspondence, and Alerts

16. In this Report and Order, the Commission adopts rules mandating electronic delivery for all ULS and ASR compulsory and courtesy correspondence and eliminating the ability to request the Commission to mail hard copies of authorization and letters. We find it in the public interest to transition to electronic correspondence, which reduces regulatory burdens and environmental waste and makes interactions with the Commission more accessible and efficient. Mandating e-correspondence and eliminating the ability to request that Bureaus mail hard copies of authorizations produces several benefits with no offsetting costs, given that users can access and download their official authorizations, leases, registrations, and all related correspondence from the ULS and ASR System at any time.

17. The Commission's previous actions transitioning to e-correspondence produced several benefits, which we expand upon in this document by shifting from mail to electronic delivery of correspondence generated by ULS and the ASR system. We find that shifting to electronic correspondence is timely and reasonable, reduces costs and increases efficiency. Most businesses operate electronically, and electronic correspondence is an expedient and reliable form of communication and ensures a streamlined and efficient process. In addition, we find it in the public interest to replace our traditional physical mailing processes with less expensive electronic alternatives to reduce the Commission's expenses.

18. Substance of Email Delivery.—We find that including the actual substance of the correspondence in the email is the most efficient way to transmit critical Commission communications and will increase the accessibility and speed of communications with our systems' users. We find that including the actual substance of the communications in the email itself is more efficient than proposed alternatives, and is supported by the record. Therefore, all email correspondence will include the in the body of the message: (1) Applicant name(s), (2) FCC Registration Numbers, (3) any applicable file numbers, (4) a list of any applicable call signs, (5) the subject of the communication (*e.g.,* application return, construction notification reminder, etc.), and (6) the disposition of the action. In other words, the Commission is taking the same correspondence that was previously in a mailed letter and shifting the content of that letter to the email message.

19. To ensure that an email is received by the appropriate recipient, users may list up to two email addresses associated with their license or application. Allowing up to two email addresses is consistent with the current

practice in ULS today; as the Commission continues to modernize its ULS platform going forward, it will consider the ability to allow more than two email addresses, as some commenters recommend. For the same reasons, we also will continue to allow users to designate a ''primary'' and ''secondary'' address for all or certain correspondence.

20. To reduce the risk that a message is mistaken as phishing or junk mail, the subject line of the email will include the description of the action and application type. We find that providing this information in the subject line, along with the Sender's address ending in ''*fcc.gov,*'' will help assure recipients that the message is official Commission correspondence and reduce the risk that an email is mistaken as phishing or junk mail. We remind users that they may adjust their email settings to recognize Commission messages to ensure that Commission messages are not erroneously diverted to junk mail. The information contained in these emails can also be independently verified by logging into ULS, and consumers are familiar with these practices through dealings with all major banks and businesses. Copies of all such correspondence are contained in ULS or ASR under ''Automated Letters'' or ''Letters'' for the relevant application or license, which provides another way for users to verify their authenticity. Users responding to such Commission communication will do so by filing applications (or amending pending applications) in ULS and ASR, not via email.

21. The Commission's longstanding practice of reviewing the message for errors and attempting to deliver the message a second time has proven successful when physical mail is returned as undeliverable, and we find that the same approach is appropriate for handling undeliverable emails. We are putting in place rules that will allow the Bureaus to offer enhanced capabilities in the future and will consider and weigh the benefits and costs of such an alerting system or other mechanisms going forward as we continue to modernize ULS.

E. Transition Deadline

22. As of the effective date of this Order, we will no longer print and mail paper authorizations. All notification preferences will be automatically set or reset to receive electronic licenses, and all licensees can download and print official copies of their licenses in ULS License Manager. We otherwise set a transition deadline for the decisions in this document regarding mandatory e-filing, mandatory email address submission, and the Bureaus' shift to electronic correspondence, of six months from the effective date of this Report and Order.

IV. Procedural Matters

23. Regulatory Flexibility Analysis. The Regulatory Flexibility Act of 1980, as amended (RFA) requires that an agency prepare a regulatory flexibility analysis for notice and comment rulemakings, unless the agency certifies that ''the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.'' Accordingly, the Commission has prepared a Final Regulatory Flexibility Analysis (FRFA) relating to the possible impact of the rule changes contained in the Report and Order. The FRFA is set forth in Appendix C of the Report and Order.

24. Paperwork Reduction Analysis. This Report and Order does not contain new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4).

25. Congressional Review Act. The Commission will submit this draft Report & Order to the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget, for concurrence as to whether this rule is ''major'' or ''non-major'' under the Congressional Review Act, 5 U.S.C. 804(2). The Commission will send a copy of this Report and Order to Congress and the Government Accountability Office pursuant to 5 U.S.C. 801(a)(1)(A).

V. Ordering Clauses

26. Accordingly, *It Is Ordered* that, pursuant to the authority found in sections 1, 4(i), and 303 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 303, this Report and Order *Is Hereby Adopted*.

27. *It Is Further Ordered* that parts 1, 13, 17, and 97 of the Commission's rules, 47 CFR parts 1, 13, 17, and 97, *Are Amended* as set forth in the Final Rules, and such rule amendments shall be effective six months after the date of publication in the **Federal Register**.

28. *It Is Further Ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *Shall Send* a copy of this Report and Order, including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

29. *It Is Further Ordered* that the Commission *Shall Send* a copy of this Report and Order in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Parts 1, 13, 17, and 97

Administrative practice and procedure, Amateur radio service, Antenna structure registration, Commercial radio operators, Environmental impact statements, National Environmental Policy Act, Radio, Telecommunications, Wireless radio service applications.

Federal Communications Commission.

Marlene Dortch,

Secretary.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR parts 1, 13, 17, and 97 as follows:

PART 1—PRACTICE AND PROCEDURE

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

Authority: 47 U.S.C. chs. 2, 5, 9, 13; 28 U.S.C. 2461, unless otherwise noted.

Subpart A—General Rules of Practice and Procedure

■ 2. Amend § 1.5 by revising paragraph (a) to read as follows:

§ 1.5 Mailing address furnished by licensee.

(a) Each licensee shall furnish the Commission with an address to be used by the Commission in serving documents or directing correspondence to that licensee. Unless any licensee advises the Commission to the contrary, the address contained in the licensee's most recent application will be used by the Commission for purposes of this paragraph (a). For licensees in the Wireless Radio Services, each licensee shall also furnish the Commission with an email address to be used by Commission for serving documents or directing correspondence to that licensee; correspondence sent to such email address is deemed to have been served on the licensee.

* * * * *

■ 3. Revise § 1.12 to read as follows:

§ 1.12 Notice to attorneys of Commission documents.

In any matter pending before the Commission in which an attorney has appeared for, submitted a document on behalf of or been otherwise designated by a person, any notice or other written communication pertaining to that matter issued by the Commission and which is required or permitted to be furnished to the person will be communicated to the attorney, or to one of such attorneys if more than one is designated. If direct communication with the party is appropriate, a copy of such communication will be mailed to the attorney; or for matters involving Wireless Radio Services, emailed to the attorney instead of mailed.

■ 4. Section 1.41 is revised to read as follows:

§ 1.41 Informal requests for Commission action.

Except where formal procedures are required under the provisions of this chapter, requests for action may be submitted informally. Requests should set forth clearly and concisely the facts relied upon, the relief sought, the statutory and/or regulatory provisions (if any) pursuant to which the request is filed and under which relief is sought, and the interest of the person submitting the request. In application and licensing matters pertaining to the Wireless Radio Services, as defined in § 1.904, such requests must be submitted electronically, via the ULS, and the request must include an email address for receiving electronic service. See § 1.47(d).

■ 5. Revise the introductory text of § 1.45 to read as follows:

§ 1.45 Pleadings; filing periods.

Except as otherwise provided in this chapter, pleadings in Commission proceedings shall be filed in accordance with the provisions of this section. Pleadings associated with licenses, applications, waivers, and other documents in the Wireless Radio Services must be filed via the ULS, and persons other than applicants or licensees filing pleadings in ULS must provide an email address to receive electronic service. *See* § 1.47(d).

* * * * *

■ 6. Amend § 1.47 by revising paragraphs (a) and (d) through (g) to read as follows:

§ 1.47 Service of documents and proof of service.

(a) Where the Commission or any person is required by statute or by the provisions of this chapter to serve any document upon any person, service shall (in the absence of specific provisions in this chapter to the contrary) be made in accordance with the provisions of this section. Documents that are required to be served by the Commission in agency proceedings (*i.e.,* not in the context of judicial proceedings, Congressional investigations, or other proceedings outside the Commission) may be served in electronic form. Documents associated with licenses, applications, waivers, and other requests in the Wireless Radio Services that are required to be served by the Commission in agency proceedings must be served in electronic form. In proceedings involving a large number of parties, and unless otherwise provided by statute, the Commission may satisfy its service obligation by issuing a public notice that identifies the documents required to be served and that explains how parties can obtain copies of the documents.

Note 1 to paragraph (a): Paragraph (a) of this section grants staff the authority to decide upon the appropriate format for electronic notification in a particular proceeding, consistent with any applicable statutory requirements. The Commission expects that service by public notice will be used only in proceedings with 20 or more parties.

* * * * *

(d) Except in formal complaint proceedings against common carriers under §§ 1.720 through 1.740 and proceedings related to the Wireless Radio Services under subpart F of this part, documents may be served upon a party, his attorney, or other duly constituted agent by delivering a copy or by mailing a copy to the last known address. Documents that are required to be served must be served in paper form, even if documents are filed in electronic form with the Commission, unless the party to be served agrees to accept service in some other form. Petitions, pleadings, and other documents associated with licensing matters in the Wireless Radio Services must be served electronically upon a party, his attorney, or other duly constituted agent by delivering a copy by email to the email address listed in the Universal Licensing System (ULS). If a filer is not an applicant or licensee, the document must include an email address for receiving electronic service.

(e) Delivery of a copy pursuant to this section means handing it to the party, his attorney, or other duly constituted agent; or leaving it with the clerk or other person in charge of the office of the person being served; or, if there is no one in charge of such office, leaving it in a conspicuous place therein; or, if such office is closed or the person to be served has no office, leaving it at his dwelling house or usual place of abode with some person of suitable age and discretion then residing therein. For pleadings, petitions, and other documents associated with licensing matters in the Wireless Radio Services, delivery of a copy pursuant to this section is complete by sending it by email to the email addresses listed in the ULS, or to the email address of the applicant's or licensee's attorney provided in a pleading or other document served on the filer.

(f) Service by mail is complete upon mailing. Service by email is complete upon sending to the email address listed in the ULS for a particular license, application, or filing.

(g) Proof of service, as provided in this section, shall be filed before action is taken. The proof of service shall show the time and manner of service, and may be by written acknowledgement of service, by certificate of the person effecting the service, or by other proof satisfactory to the Commission. Failure to make proof of service will not affect the validity of the service. The Commission may allow the proof to be amended or supplied at any time, unless to do so would result in material prejudice to a party. Proof of electronic service shall show the email address of the person making the service, in addition to that person's residence or business address; the date and time of the electronic service; the name and email address of the person served; and that the document was served electronically.

* * * * *

■ 7. Amend § 1.49 by revising paragraph (e) to read as follows:

§ 1.49 Specifications as to pleadings and documents.

* * * * *

(e) Petitions, pleadings, and other documents associated with licensing matters in the Wireless Radio Services must be filed electronically in ULS. *See* § 22.6 of this chapter for specifications.

* * * * *

■ 8. Amend § 1.51 by revising paragraphs (f) and (h) to read as follows:

§ 1.51 Number of copies of pleadings, briefs, and other papers.

* * * * *

(f) For application and licensing matters involving the Wireless Radio Services, pleadings, briefs or other documents must be filed electronically in ULS.

* * * * *

(h) Pleadings, briefs or other documents filed electronically in ULS by a party represented by an attorney shall include the name, street address, email address, and telephone number of at least one attorney of record. Parties not represented by an attorney that files electronically in ULS shall provide their name, street address, email address, and telephone number.

■ 9. Section 1.52 is amended by adding a sentence after the first two sentences to read as follows:

§ 1.52 Subscription and verification.

* * * Pleadings, petitions, and other documents related to licensing matters in the Wireless Radio Services shall be signed by at least one attorney of record in his individual name or by the party who is not represented by an attorney and shall include his email and physical mailing address.

* * * * *

■ 10. Section 1.85 is revised to read as follows:

§ 1.85 Suspension of operator licenses.

Whenever grounds exist for suspension of an operator license, as provided in section 303(m) of the Communications Act, the Chief of the Wireless Telecommunications Bureau, with respect to amateur and commercial radio operator licenses, may issue an order suspending the operator license. No order of suspension of any operator's license shall take effect until 15 days' notice in writing of the cause for the proposed suspension has been given to the operator licensee, who may make written application to the Commission at any time within the said 15 days for a hearing upon such order. The notice to the operator licensee shall not be effective until actually received by him, and from that time he shall have 15 days in which to email the said application. In the event that conditions prevent emailing of the application before the expiration of the 15-day period, the application shall then be emailed as soon as possible thereafter, accompanied by a satisfactory explanation of the delay. Upon receipt by the Commission of such application for hearing, said order of suspension shall be designated for hearing by the Chief, Wireless Telecommunications Bureau and said suspension shall be held in abeyance until the conclusion of the hearing. Upon the conclusion of said hearing, the Commission may affirm, modify, or revoke said order of suspension. If the license is ordered suspended, the operator shall send his operator license to the Mobility Division, Wireless Telecommunications Bureau, in Washington, DC, on or before the effective date of the order, or, if the effective date has passed at the time notice is received, the license shall be sent to the Commission forthwith.

■ 11. Amend § 1.87 by revising paragraphs (a) and (b) to read as follows:

§ 1.87 Modification of license or construction permit on motion of the Commission.

(a) Whenever it appears that a station license or construction permit should be modified, the Commission shall notify the licensee or permittee in writing of the proposed action and reasons therefor, and afford the licensee or permittee at least thirty days to protest such proposed order of modification, except that, where safety of life or property is involved, the Commission may by order provide a shorter period of time.

(b) The notification required in paragraph (a) of this section may be effectuated by a notice of proposed rulemaking in regard to a modification or addition of an FM or television channel to the Table of Allotments (§§ 73.202 and 73.504 of this chapter) or Table of Assignments (§ 73.606 of this chapter). The Commission shall send a copy of any such notice of proposed rulemaking to the affected licensee or permittee by email. For modifications involving Wireless Radio Services, the Commission shall notify the licensee or permittee by email of the proposed action and reasons therefor, and afford the licensee or permittee at least thirty days to protest such proposed order of modification, except that:

(1) Where safety of life or property is involved, the Commission may by order provide a shorter period of time; and

(2) Where the notification required in paragraph (a) of this section is effectuated by publication in the **Federal Register**, the Commission shall afford the licensee or permittee at least thirty days after publication in the **Federal Register** to protest such proposed order of modification.

* * * * *

■ 12. Amend § 1.106 by revising paragraphs (i) and (o) to read as follows:

§ 1.106 Petitions for reconsideration in non-rulemaking proceedings.

* * * * *

(i) Petitions for reconsideration, oppositions, and replies shall conform to the requirements of §§ 1.49, 1.51, and 1.52 and, except for those related to licensing matters in the Wireless Radio Service and addressed in paragraph (o) of this section, shall be submitted to the Secretary, Federal Communications Commission, Washington, DC 20554, by mail, by commercial courier, by hand, or by electronic submission through the Commission's Electronic Comment Filing System or other electronic filing system (such as ULS). Petitions submitted only by electronic mail and petitions submitted directly to staff without submission to the Secretary shall not be considered to have been properly filed. Parties filing in electronic form need only submit one copy.

* * * * *

(o) Petitions for reconsideration of licensing actions, as well as oppositions and replies thereto, that are filed with respect to the Wireless Radio Services, must be filed electronically via ULS.

* * * * *

Subpart F—Wireless Radio Services Applications and Proceedings

■ 13. Amend § 1.913 by removing and reserving paragraph (d) and revising paragraphs (e) and (f) to read as follows:

§ 1.913 Applications and notification forms; electronic filing.

* * * * *

(e) *Applications requiring prior coordination.* Parties filing applications that require frequency coordination shall, prior to filing, complete all applicable frequency coordination requirements in service-specific rules contained within this chapter. After appropriate frequency coordination, such applications must be electronically filed via ULS. Applications filed by the frequency coordinator on behalf of the applicant must be filed electronically.

(f) *Applications for amateur licenses.* Each candidate for an amateur radio operator license which requires the applicant to pass one or more examination elements must present the administering Volunteer Examiners (VE) with all information required by this section prior to the examination. The VEs may collect the information required by this section in any manner of their choosing, including creating their own forms. Upon completion of the examination, the administering VEs will immediately grade the test papers and will then issue a certificate for successful completion of an amateur radio operator examination (CSCE) if the applicant is successful. The VEs will send all necessary information regarding a candidate to the Volunteer-Examiner Coordinator (VEC) coordinating the examination session. Applications filed with the Commission by VECs and all other applications for amateur service licenses must be filed electronically via ULS. Feeable requests for vanity call signs must be filed in accordance with

§ 0.401 of this chapter or electronically filed via ULS.

* * * * *

■ 14. Amend § 1.917 by revising paragraph (d) to read as follows:

§ 1.917 Who may sign applications.

* * * * *

(d) ''Signed,'' as used in this section, means, for manually filed applications only, an original hand-written signature or, for electronically filed applications only, an electronic signature. An electronic signature shall consist of the name of the applicant transmitted electronically via ULS or any other electronic filing interface the Commission may designate and entered on the application as a signature.

■ 15. Amend § 1.923 by revising paragraph (i) to read as follows:

§ 1.923 Content of applications.

* * * * *

(i) *Email address.* Unless an exception is set forth elsewhere in this chapter, each applicant must specify an email address where the applicant can receive electronic correspondence. This email address will be used by the Commission to serve documents or direct correspondence to the applicant. Any correspondence sent to the email address currently on file shall be deemed to have been served on the applicant. Each applicant should also provide a United States Postal Service address.

■ 16. Amend § 1.929 by revising paragraph (k)(3) to read as follows:

§ 1.929 Classification of filings as major or minor.

* * * * *

(k) * * *

(3) Any email or physical mailing address and/or telephone number changes;

* * * * *

■ 17. Amend § 1.939 by revising paragraph (b) to read as follows:

§ 1.939 Petitions to deny.

* * * * *

(b) *Filing of petitions.* Petitions to deny and related pleadings must be filed electronically via ULS. Petitions to deny and related pleadings must reference the file number of the pending application that is the subject of the petition.

* * * * *

■ 18. Amend § 1.947 by revising paragraph (b) to read as follows:

§ 1.947 Modification of licenses.

* * * * *

(b) Licensees may make minor modifications to station authorizations, as defined in § 1.929 (other than pro forma transfers and assignments), as a matter of right without prior Commission approval. Where other rules in this part permit licensees to make permissive changes to technical parameters without notifying the Commission (*e.g.,* adding, modifying, or deleting internal sites), no notification is required. For all other types of minor modifications (*e.g.,* name, email or physical mailing address, point of contact changes), licensees must notify the Commission by filing FCC Form 601 within thirty (30) days of implementing any such changes.

* * * * *

Subpart I—Procedures Implementing the National Environmental Policy Act of 1969

■ 19. Section 1.1304 is revised to read as follows:

§ 1.1304 Information, assistance, and waiver of electronic filing and service requirements.

(a) For general information and assistance concerning the provisions of this subpart, the Office of General Counsel may be contacted, (202) 418–1700. For more specific information, the Bureau responsible for processing a specific application should be contacted.

(b) All submissions relating to this subpart shall be made electronically. If an interested party is unable to submit or serve a filing electronically, or if it would be unreasonably burdensome to do so, such party may submit its filing on paper to the appropriate address for the Commission Secretary and serve the filing on other parties by mail. Such party should include as part of its paper submission a request for waiver of the electronic filing requirement. Such waiver request must contain an explanation addressing the requestor's inability to file electronically or why electronic filing would be unreasonably burdensome. Either showing will be sufficient to obtain a waiver under this section.

■ 20. Amend § 1.1307 by:

■ a. Revising paragraph (b) introductory text;

■ b. In paragraph (c), revising the first sentence, adding a sentence after the first sentence, and revising the parenthetical sentence; and

■ c. Revising the first sentence of paragraph (d).

The revisions read as follows:

§ 1.1307 Actions that may have a significant environmental effect, for which Environmental Assessments (EAs) must be prepared.

* * * * *

(b) In addition to the actions listed in paragraph (a) of this section, Commission actions granting construction permits, licenses to transmit or renewals thereof, equipment authorizations or modifications in existing facilities, require the preparation of an Environmental Assessment (EA) if the particular facility, operation, or transmitter would cause human exposure to levels of radiofrequency radiation in excess of the limits in §§ 1.1310 and 2.1093 of this chapter. Applications to the Commission for construction permits, licenses to transmit or renewals thereof, equipment authorizations or modifications in existing facilities must contain a statement confirming compliance with the limits unless the facility, operation, or transmitter is categorically excluded, as discussed in paragraphs (b)(1) through (3) of this section. Technical information showing the basis for this statement must be electronically submitted to the Commission upon request. Such compliance statements may be omitted from license applications for transceivers subject to the certification requirement in § 25.129 of this chapter.

* * * * *

(c) If an interested person alleges that a particular action, otherwise categorically excluded, will have a significant environmental effect, the person shall electronically submit to the Bureau responsible for processing that action a written petition setting forth in detail the reasons justifying or circumstances necessitating environmental consideration in the decision-making process. If an interested person is unable to submit electronically or if filing electronically would be unreasonably burdensome, such person may submit the petition by mail, with a request for waiver under § 1.1304(b). (See § 1.1313). * * *

(d) If the Bureau responsible for processing a particular action, otherwise categorically excluded, determines that the proposal may have a significant environmental impact, the Bureau, on its own motion, shall require the applicant to electronically submit an EA. * * *

* * * * *

■ 21. Section 1.1309 is revised to read as follows:

§ 1.1309 Application amendments.

Applicants are permitted to amend their applications to reduce, minimize,

or eliminate potential environmental problems. Amendments shall be made electronically. As a routine matter, an applicant will be permitted to amend its application within thirty (30) days after the Commission or the Bureau informs the applicant that the proposal will have a significant impact upon the quality of the human environment (*see* § 1.1308(c)). The period of thirty (30) days may be extended upon a showing of good cause.

■ 22. Amend § 1.1312 by revising paragraph (b) to read as follows:

§ 1.1312 Facilities for which no preconstruction authorization is required.

* * * * *

(b) If a facility covered by paragraph (a) of this section may have a significant environmental impact, the information required by § 1.1311 shall be submitted electronically by the licensee or applicant and ruled on by the Commission, and environmental processing (if invoked) shall be completed, see § 1.1308, prior to the initiation of construction of the facility.

* * * * *

■ 23. Section 1.1313 is revised to read as follows:

§ 1.1313 Objections.

(a) In the case of an application to which section 309(b) of the Communications Act applies, objections based on environmental considerations shall be filed electronically as petitions to deny. If the interested person is unable to file electronically or if filing electronically would be unreasonably burdensome, such person may submit the petition by mail, with a request for waiver under § 1.1304(b).

(b) Informal objections which are based on environmental considerations must be filed electronically prior to grant of the construction permit, or prior to authorization for facilities that do not require construction permits, or pursuant to the applicable rules governing services subject to lotteries. If the interested person is unable to file electronically or if filing electronically would be unreasonably burdensome, such person may submit the objection by mail, with a request for waiver under § 1.1304(b).

■ 24. Amend § 1.1314 by revising paragraph (f) to read as follows:

§ 1.1314 Environmental impact statements (EISs).

* * * * *

(f) The Application, the EA, the DEIS, and the FEIS and all related documents, including the comments filed by the public and any agency, shall be part of the administrative record and will be routinely available for public inspection. All documents and comments shall be filed electronically.

* * * * *

■ 25. Amend § 1.1315 by revising paragraphs (b) through (e) to read as follows:

§ 1.1315 The Draft Environmental Impact Statement (DEIS); Comments.

* * * * *

(b) When a DEIS and supplements, if any, are prepared, the Commission shall file the Statement with the Office of Federal Activities, Environmental Protection Agency, consistent with its procedures. Public Notice of the availability of the DEIS will be published in the **Federal Register** by the Environmental Protection Agency.

(c) When copies or summaries of the DEIS are sent to the Environmental Protection Agency, the copies or summaries will be electronically mailed with a request for comment to Federal agencies having jurisdiction by law or special expertise, to the Council on Environmental Quality, to the applicant, to individuals, groups and state and local agencies known to have an interest in the environmental consequences of a grant, and to any other person who has requested a copy. If an interested person lacks access to electronic mail and requests a hard copy or summary of the DEIS, it must be provided by mail.

(d) Any person or agency may comment on the DEIS and the environmental effect of the proposal described therein within 45 days after notice of the availability of the statement is published in the **Federal Register**. A copy of those comments shall be electronically mailed to the applicant by the person who files them pursuant to § 1.47 and filed electronically with the Commission. If the interested person is unable to file electronically or mail the copy electronically, or if it would be unreasonably burdensome to do so, such person may submit the comments to the Commission and the applicant by mail, with a request for waiver under § 1.1304(b). If a person submitting comments is especially qualified in any way to comment on the environmental impact of the facilities, a statement of his or her qualifications shall be set out in the comments. In addition, comments submitted by an agency shall identify the person(s) who prepared them.

(e) The applicant may electronically file reply comments within 15 days after the time for filing comments has expired. Reply comments shall be filed with the Commission and served by the applicant on persons or agencies which filed comments.

* * * * *

PART 13—COMMERCIAL RADIO OPERATORS

■ 26. The authority citation for part 13 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

■ 27. Amend § 13.9 by revising paragraph (c) to read as follows:

§ 13.9 Eligibility and application for new license or endorsement.

* * * * *

(c) Each application for a new General Radiotelephone Operator License, Marine Radio Operator Permit, Radiotelegraph Operator License, Ship Radar Endorsement, GMDSS Radio Operator's License, Restricted GMDSS Radio Operator's License, GMDSS Radio Maintainer's License, or GMDSS Radio Operator/Maintainer License must be accompanied by the required fee, if any, and submitted in accordance with § 1.913 of this chapter. The application must include an electronic copy of the official PPC(s) from a COLEM(s) showing that the applicant has passed the necessary examination Element(s) within the previous 365 days when the applicant files the application. If a COLEM files the application on behalf of the applicant, an official copy of the PPC(s) is not required. However, the COLEM must keep the PPC(s) on file for a period of 1 year. When acting on behalf of qualified examinees, the COLEM must forward all required data to the FCC electronically.

* * * * *

■ 28. Section 13.10 is revised to read as follows:

§ 13.10 Licensee address.

In accordance with § 1.923 of this chapter, all applicants (except applicants for a Restricted Radiotelephone Operator Permit or a Restricted Radiotelephone Operator Permit-Limited Use) must specify an email address where the applicant can receive electronic correspondence. Suspension of the operator license may result when correspondence from the FCC is returned as undeliverable because the applicant failed to provide the correct email address.

PART 17—CONSTRUCTION, MARKING, AND LIGHTING OF ANTENNA STRUCTURES

■ 29. The authority citation for part 17 continues to read as follows:

Authority: 47 U.S.C. 154, 301, 303, 309.

■ 30. Amend § 17.4 by revising paragraphs (b), (c)(1)(ii) and (iv), (c)(5)(ii), (e), and (f) to read to read as follows:

§ 17.4 Antenna structure registration.

* * * * *

(b) Except as provided in paragraph (e) of this section, each owner of an antenna structure described in paragraph (a) of this section must electronically file FCC Form 854 with the Commission. Additionally, each owner of a proposed structure referred to in paragraph (a) of this section must submit a valid FAA determination of ''no hazard.'' In order to be considered valid by the Commission, the FAA determination of ''no hazard'' must not have expired prior to the date on which FCC Form 854 is received by the Commission. The height of the structure will be the highest point of the structure including any obstruction lighting or lightning arrester. If an antenna structure is not required to be registered under paragraph (a) of this section and it is voluntarily registered with the Commission after October 24, 2014, the registrant must note on FCC Form 854 that the registration is voluntary. Voluntarily registered antenna structures are not subject to the lighting and marking requirements contained in this part.

(c) * * *

(1) * * *

(ii) For a reduction in height of an antenna structure or an increase in height that does not constitute a substantial increase in size as defined in paragraph I(E)(1)–(3) of appendix B to part 1 of this chapter, provided that there is no construction or excavation more than 30 feet beyond the existing antenna structure property;

* * * * *

(iv) For replacement of an existing antenna structure at the same geographic location that does not require an Environmental Assessment (EA) under § 1.1307(a) through (d) of this chapter, provided the new structure will not use a less preferred lighting style, there will be no substantial increase in size as defined in paragraph I(E)(1)–(3) of appendix B to part 1 of this chapter, and there will be no construction or excavation more than 30 feet beyond the existing antenna structure property;

* * * * *

(5) * * *

(ii) *Content.* An Environmental Request must state why the interested person or entity believes that the proposed antenna structure or physical modification of an existing antenna structure may have a significant impact on the quality of the human environment for which an Environmental Assessment must be considered by the Commission as required by § 1.1307 of this chapter, or why an Environmental Assessment submitted by the prospective Antenna Structure Registration (ASR) applicant does not adequately evaluate the potentially significant environmental effects of the proposal. The Request must be submitted as a written petition filed electronically, setting forth in detail the reasons supporting Requester's contentions. If the filer is unable to submit electronically, or if filing electronically would be unreasonably burdensome, the Request may be submitted by mail, with a request for waiver under § 1.1304(b) of this chapter.

* * * * *

(e) If the owner of the antenna structure cannot file FCC Form 854 because it is subject to a denial of Federal benefits under the Anti-Drug Abuse Act of 1988, 21 U.S.C. 862, the first tenant licensee authorized to locate on the structure (excluding tenants that no longer occupy the structure) must register the structure electronically using FCC Form 854, and provide a copy of the Antenna Structure Registration (FCC Form 854R) to the owner. The owner remains responsible for providing to all tenant licensees and permittees notification that the structure has been registered, consistent with paragraph (f) of this section, and for posting the registration number as required by paragraph (g) of this section.

(f) The Commission shall issue to the registrant FCC Form 854R, Antenna Structure Registration, which assigns a unique Antenna Structure Registration Number. The antenna structure owner shall immediately provide to all tenant licensees and permittees notification that the structure has been registered, along with either a copy of Form 854R or the Antenna Structure Registration Number and a link to the FCC antenna structure website: *http://wireless.fcc.gov/antenna/*. This notification must be done electronically.

* * * * *

■ 31. Amend § 17.6 by revising paragraph (c) to read as follows:

§ 17.6 Responsibility for painting and lighting compliance.

* * * * *

(c) If the owner of the antenna structure cannot file FCC Form 854 because it is subject to a denial of Federal benefits under the Anti-Drug Abuse Act of 1988, 21 U.S.C. 862, the first tenant licensee authorized to locate on the structure (excluding tenants that no longer occupy the structure) must electronically register the structure using FCC Form 854, and provide a copy of the Antenna Structure Registration (FCC Form 854R) to the owner. The owner remains responsible for providing to all tenant licensees and permittees notification that the structure has been registered, consistent with § 17.4(f), and for posting the registration number as required by § 17.4(g).

■ 32. Section 17.57 is revised to read as follows:

§ 17.57 Report of radio transmitting antenna construction, alteration, and/or removal.

The owner of an antenna structure for which an Antenna Structure Registration Number has been obtained must notify the Commission within 5 days of completion of construction by filing FCC Form 854–R and/or dismantlement by filing FCC Form 854. The owner must also notify the Commission within 5 days of any change in structure height or change in ownership information by filing FCC Form 854. FCC Forms 854 and 854–R, and all related amendments, modifications, and attachments, shall be filed electronically.

PART 97—AMATEUR RADIO SERVICE

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

Authority: 47 U.S.C. 151–155, 301–609, unless otherwise noted.

■ 34. Amend § 97.21 by revising paragraph (a)(1) to read as follows:

§ 97.21 Application for a modified or renewed license grant.

(a) * * *

(1) Must apply to the FCC for a modification of the license grant as necessary to show the correct mailing and email address, licensee name, club name, license trustee name, or license custodian name in accordance with § 1.913 of this chapter. For a club or military recreation station license grant, the application must be presented in document form to a Club Station Call Sign Administrator who must submit the information thereon to the FCC in an electronic batch file. The Club Station Call Sign Administrator must retain the collected information for at least 15 months and make it available to the FCC upon request. A Club Station Call Sign Administrator shall not file with the Commission any application to modify a club station license grant that was submitted by a person other than the trustee as shown on the license grant,

except an application to change the club station license trustee. An application to modify a club station license grant to change the license trustee name must be submitted to a Club Station Call Sign Administrator and must be signed by an officer of the club.

* * * * *

■ 35. Section 97.23 is revised to read as follows:

§ 97.23 Mailing and email addresses.

Each license grant must show the grantee's correct name, mailing address, and email address. The email address must be an address where the grantee can receive electronic correspondence. Revocation of the station license or suspension of the operator license may result when correspondence from the FCC is returned as undeliverable because the grantee failed to provide the correct email address.

[FR Doc. 2020–28779 Filed 12–28–20; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. NHTSA–2020–0111]

RIN 2127–AM31

Federal Motor Vehicle Safety Standards; Side Impact Protection, Ejection Mitigation; Technical Corrections

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Final rule; technical corrections.

SUMMARY: This final rule corrects errors in Federal Motor Vehicle Safety Standard (FMVSS) No. 214, ''Side impact protection,'' and in FMVSS No. 226, ''Ejection mitigation.'' The error occurred in FMVSS No. 214 when an amendment to FMVSS No. 214 was transcribed into the Code of Federal Regulations. The error to FMVSS No. 226 arose as a result of a drafting error when NHTSA issued FMVSS No. 226. This final rule amends the standards to reflect the intent of the Agency when it issued the standards.

DATES: This rule is effective December 29, 2020.

FOR FURTHER INFORMATION CONTACT: Mr. Vincent Wu or Mr. James Myers, NHTSA Office of Crashworthiness Standards, telephone 202–366–1740. Mailing address: 1200 New Jersey Avenue SE, West Building, Washington, DC 20590.

SUPPLEMENTARY INFORMATION: This document corrects minor errors in FMVSS No. 214, ''Side impact protection,'' and FMVSS No. 226, ''Ejection mitigation.'' The first error resulted when the **Federal Register** transcribed regulatory text for FMVSS No. 214. The second error occurred when the Agency drafted the regulatory text for FMVSS No. 226 in establishing the standard.

FMVSS No. 214

On September 11, 2007, NHTSA published a final rule that incorporated a vehicle-to-pole test in FMVSS No. 214, ''Side impact protection.'' [1] In response to petitions for reconsideration of the rule,[2] NHTSA published a final rule on March 15, 2010 that, among other matters, corrected unit conversion errors in S6.1.2 and S6.1.3 of the standard.[3] The March 15, 2010 final rule set forth the regulatory text for S6.1.3, ''Peak crush resistance'' as follows: ''The peak crush resistance shall not be less than two times the curb weight of the vehicle or 31,138 N (7,000 lb), *whichever is less.*'' 75 FR at 12140, col. 1 (emphasis added). Similar language was also included in the revised S6.2.3, which stated, ''Peak crush resistance. The peak crush resistance shall not be less than three and one half times the curb weight of the vehicle or 53,378 N (12,000 lb), whichever is less.'' *Id.* However, the phrase ''whichever is less'' was not included in S6.1.3 as published in the Code of Federal Regulations, though the phrase was included in S6.2.3 (49 CFR 571.214).

The door crush force requirements establish threshold protections for occupants from injury-causing intrusion into the occupant space that can occur during a side impact. The phrase ''whichever is less'' in S6.1.3 was meant to clarify which of the maximum door crush force levels applies to vehicles, depending upon the vehicle's curb weight.[4] However, when the phrase was mistakenly eliminated, it created ambiguity and potentially implied that S6.1.3 required higher forces to be used than NHTSA had intended. Without the phrase, there is potential for manufacturer confusion and the possibility that some may certify to an overly stringent door crush force requirement than NHTSA intended. NHTSA (and, we believe, industry as a whole) has applied S6.1.3 with the understanding and effect that the ''whichever is less'' language was meant to be as it is in S6.2.3—see, *e.g.,* NHTSA's test procedure (TP) manual for FMVSS No. 214 issued by NHTSA's Office of Vehicle Safety Compliance for testing vehicles to Standard No. 214. The TP has always aligned with the correct original regulatory text.[5] That said, the absence of the phrase reduces the clarity of S6.1.3 and introduces an unintended ambiguity that NHTSA would like to correct. This technical amendment corrects the error by adding ''whichever is less'' back in S6.1.3.

FMVSS No. 226

On January 19, 2011, NHTSA published a final rule establishing FMVSS No. 226, ''Ejection mitigation.'' The final rule intended to exclude from the applicability of the standard vehicles with no doors or with doors that are designed to be easily attached or removed so the vehicle can be operated without doors. In the notice of proposed rulemaking (NPRM) preceding the final rule, the Agency requested comment on whether ''[v]ehicles that have no doors, or exclusively have doors that are designed to be easily attached or removed so that the vehicle can be operated without doors'' were still being produced.[6] NHTSA further explained that, ''Assuming the vehicles are being manufactured, NHTSA proposes excluding the vehicles on practicability grounds,'' and requested comment on the issue.[7] Subsequently, in the final rule, NHTSA proceeded to exclude the vehicles in the text of the preamble. The Agency made its intent to exclude the vehicles in the final rule clear, explaining in the preamble that: ''Comments were requested but none were received on whether vehicles are still being manufactured that have no doors, or exclusively have doors that are designed to be easily attached or removed so that the vehicle can be operated without doors. NHTSA

[1] 72 FR 51908.

[2] March 15, 2010, 75 FR 12140. This was the second response to petitions for reconsideration of the 2007 final rule.

[3] S6.1.2 and S6.1.3 relate to Standard No. 214's door crush resistance requirements.

[4] Prior to the error, a vehicle with a curb weight less than 3,500 lb (''vehicle A'') could have met a force requirement of 2 times the vehicle curb weight, which would be a load of less than 7,000 lb. Similarly, prior to the error, a vehicle with a curb weight greater than 3,500 lb (''vehicle B'') could have met a force requirement of 7,000 lb. After the error, the option was removed, so under S6.1.3, vehicle A was also subject to a test with a load of 7,000 lb, and vehicle B was also subject to a load of two times its curb weight. NHTSA did not intend for the vehicles to have to be certified to both a force requirement of two times the curb weight and a 7,000 lb requirement.

[5] *https://one.nhtsa.gov/DOT/NHTSA/Vehicle%20Safety/Test%20Procedures/Associated%20Files/TP-214-s05.pdf.*

[6] 74 FR 63180, 63220; December 2, 2009.

[7] *Id.*

proposed excluding these vehicles on practicability grounds. This final rule adopts the exclusion.'' [8]

However, notwithstanding the Agency's clear intent expressed by that preamble text, NHTSA inadvertently did not include this exclusion in the final rule's regulatory text, so it is not reflected in FMVSS No. 226 as set forth in the CFR (49 CFR 571.226). The practical effect of this error is likely inconsequential, because since the effective date of FMVSS No. 226, NHTSA has applied the standard as excluding such vehicles from FMVSS No. 226. Regardless, even if the practical effect of the error is inconsequential, NHTSA would like to correct this drafting error by adding the exclusion of the vehicles to S2, ''Application,'' of the standard.

Effective Date

NHTSA is making the changes effective on publication in the **Federal Register**. NHTSA is issuing these corrections in a final rule because NHTSA finds that notice and comment are unnecessary. The amendment to FMVSS No. 214 corrects an error that arose with publication of the standard in the CFR. The correction to FMVSS No. 226 is made to correct NHTSA's drafting error when the Agency issued the standard. The correcting amendments simply make technical corrections to align the regulatory text with NHTSA's expressed intent when the Agency issued the standards concerning the performance standard in No. 214 and the application of No. 226. The practical effect of these corrections is inconsequential. For the above reasons, NHTSA finds good cause for making this correcting amendment effective on publication in the **Federal Register**.

Regulatory Notices and Analyses

Executive Orders 12866 and 13563 and DOT Rulemaking Procedures

NHTSA has considered the impact of this final rule under Executive Orders (E.O.) 12866 and 13563, as well as under the Department of Transportation's administrative rulemaking procedures set forth in 49 CFR part 5, subpart B. This final rule makes technical corrections and is not considered significant under these Executive orders. The rule corrects the regulatory text to align it with the Agency's intent in drafting the language at issue. There are no costs or benefits associated with this technical correction because the Agency has been operating as if the language changes included in this final rule have been in effect since the publication of the earlier final rules.

Executive Order 13771 (Regulatory Reform)

As this final rule is nonsignificant, it is not subject to the offset requirements of E.O. 13771.

National Environmental Policy Act

This final rule correcting the standards at issue will not have an adverse impact on the quality of the human environment.

Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, I certify that this final rule will not have a significant impact on a substantial number of small entities. This rule simply makes technical corrections and is not expected to have an impact on any entities.

Executive Orders 13132 (Federalism)

NHTSA has examined today's final rule pursuant to E.O. 13132 (64 FR 43255, August 10, 1999) and concluded that no additional consultation with States, local governments or their representatives is mandated beyond the rulemaking process. This final rule simply makes technical corrections and does not have sufficient federalism implications to warrant consultation with State and local officials or the preparation of a federalism summary impact statement. The rule 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.

Executive Order 12988 (Civil Justice Reform)

When promulgating a regulation, E.O. 12988, ''Civil Justice Reform'' (61 FR 4729; February 7, 1996), specifically requires that the Agency must make every reasonable effort to ensure that the regulation, as appropriate: (1) Specifies in clear language the preemptive effect; (2) specifies in clear language the effect on existing Federal law or regulation, including all provisions repealed, circumscribed, displaced, impaired, or modified; (3) provides a clear legal standard for affected conduct rather than a general standard, while promoting simplification and burden reduction; (4) specifies in clear language the retroactive effect; (5) specifies whether administrative proceedings are to be required before parties may file suit in court; (6) explicitly or implicitly defines key terms; and (7) addresses other important issues affecting clarity and general draftsmanship of regulations.

Pursuant to this order, NHTSA notes as follows. The preemptive effect of this final rule is discussed above in connection with E.O. 13132. This rule simply makes technical corrections and does not have any retroactive effect. There is no requirement that individuals submit a petition for reconsideration or pursue other administrative proceedings before they may file suit in court.

Executive Order 13609: Promoting International Regulatory Cooperation

This final rule simply makes technical corrections and will have no effect on international regulatory cooperation.

National Technology Transfer and Advancement Act

This final rule simply makes technical corrections. There are no voluntary consensus standards that apply to this final rule.

Unfunded Mandates Reform Act

This final rule only makes technical corrections and is not subject to the Unfunded Mandates Reform Act of 1995. There are no costs associated with this rule.

Paperwork Reduction Act

There are no Paperwork Reduction Act requirements associated with this technical correction.

Regulation Identifier Number (RIN)

The Department of Transportation assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. You may use the RIN contained in the heading at the beginning of this document to find this action in the Unified Agenda.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an organization, business, labor union, etc.). You may review DOT's complete Privacy Act statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *http://www.dot.gov/privacy.html.*

[8] 76 FR 3291.

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles, Rubber and rubber products, Tires.

Accordingly, 49 CFR part 571 is amended by making the following correcting amendments:

PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

■ 1. The authority citation for part 571 of title 49 continues to read as follows:

Authority: 49 U.S.C. 322, 30111, 30115, 30117, and 30166; delegation of authority at 49 CFR 1.95.

■ 2. Section 571.214 is amended by revising S6.1.3 to read as follows:

§ 571.214 Standard No. 214; Side impact protection.

* * * * *

S6.1.3 *Peak crush resistance.* The peak crush resistance shall not be less than two times the curb weight of the vehicle or 31,138 N (7,000 lb), whichever is less.

* * * * *

■ 2. Section 571.226 is amended by revising S2 to read as follows:

§ 571.226 Standard No. 226; Ejection mitigation.

* * * * *

S2. *Application.* This standard applies to passenger cars, and to multipurpose passenger vehicles, trucks and buses with a gross vehicle weight rating of 4,536 kg or less, except walk-in vans, modified roof vehicles, convertibles, and vehicles with no doors or with doors that are designed to be easily attached or removed so the vehicle can be operated without doors. Also excluded from this standard are law enforcement vehicles, correctional institution vehicles, taxis and limousines, if they have a fixed security partition separating the 1st and 2nd or 2nd and 3rd rows and if they are produced by more than one manufacturer or are altered (within the meaning of 49 CFR 567.7).

* * * * *

Issued in Washington, DC, under authority delegated in 49 CFR 1.95.

James C. Owens,

Deputy Administrator.

[FR Doc. 2020–27543 Filed 12–28–20; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 21

[Docket No. FWS–HQ–MB–2019–0103; FF09M22000–201–FXMB1232090000]

RIN 1018–BE67

Migratory Bird Permits; Management of Conflicts Associated With Double-Crested Cormorants (Phalacrocorax auritus) Throughout the United States

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: The U.S. Fish and Wildlife Service (Service) establishes a new permit for State and federally recognized Tribal (hereafter ''Tribe'' or ''Tribal'') fish and wildlife agencies for the management of double-crested cormorants (*Phalacrocorax auritus;* hereafter ''cormorants''). The new permit authorizes specific take activities that are normally prohibited and are intended to relieve or prevent impacts from cormorants on lands or in waters managed by State or Tribal fish and wildlife agencies to address conflicts related to the following issues: Wild and publicly stocked fish managed by State fish and wildlife agencies or federally recognized Tribes; Tribal- and State-owned or operated aquaculture facilities (including hatcheries); human health and safety; State- or Tribal-owned property and assets; and threatened and endangered species (listed under the Endangered Species Act of 1973, as amended, or identified in State- or Tribal-specific legislation as threatened or endangered) or those listed as Species of Greatest Conservation Need in State Wildlife Action Plans. The Service retains ultimate authority for regulating the take of cormorants. States and Tribes have the discretion to determine whether, when, where, and for which of the above purposes they conduct lethal take within limits and allocations set by the Service.

DATES: This rule takes effect on February 12, 2021.

Supplementary Documents: The Environmental Protection Agency will announce the availability of the Final Environmental Impact Statement (FEIS) associated with this rulemaking action. The Service will execute a Record of Decision no sooner than 30 days from the date of publication of the notice of availability of the FEIS by the Environmental Protection Agency.

Information Collection Requirements: If you wish to comment on the information collection requirements in this rule, please note that the Office of Management and Budget (OMB) is required to make a decision concerning the collection of information contained in this rule between 30 and 60 days after the date of publication of this rule in the **Federal Register**. Therefore, comments should be submitted to OMB by January 28, 2021.

ADDRESSES: You may inspect comments received on the draft environmental impact statement and associated proposed rule and view the final environmental impact statement and other documents associated with this rulemaking action at *http://www.regulations.gov* in Docket No. FWS–HQ–MB–2019–0103.

Information Collection Requirements: Written comments and suggestions on the information collection requirements should be submitted within 30 days of publication of this document to *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. Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, MS: PRB (JAO/3W), Falls Church, VA 22041–3803 (mail); or *Info_Coll@fws.gov* (email). Please reference OMB Control Number 1018–0175 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: Jerome Ford, U.S. Fish and Wildlife Service, Department of the Interior, (202) 208–1050.

SUPPLEMENTARY INFORMATION:

Background

The Service is the Federal agency delegated with the primary responsibility for managing migratory birds. Our authority derives from the Migratory Bird Treaty Act of 1918 (MBTA; 16 U.S.C. 703–712), as amended, which implements conventions with Great Britain (for Canada), Mexico, Japan, and Russia. We implement the provisions of the MBTA through the regulations in parts 10, 13, 20, 21, 22, and 92 of title 50 of the Code of Federal Regulations (CFR). The MBTA protects migratory birds (listed in 50 CFR 10.13) from take, except as authorized under the MBTA. Regulations pertaining to specific migratory bird permit types are at 50 CFR parts 21 and 22. The Service works on migratory bird conservation in partnership with four Flyway Councils (Atlantic, Mississippi, Central, and Pacific), which include representatives

of State, provincial, and territorial agencies.

The double-crested cormorant is a fish-eating migratory bird that is distributed across a large portion of North America. There are five different breeding populations, variously described by different authors as the Alaska, Pacific (or Western), Interior, Atlantic, and Southern populations. Although these populations are described by their breeding ranges, the birds commingle to various extents on their migration and wintering areas, with birds from populations closer to each other overlapping more than those that are more distant.

Cormorant populations have increased over both the short term (2005–2015) and long term (1966–2015) (United States Geological Survey 2020). Permits issued by the Service to take birds are one method available to reduce conflicts. However, prior to applying for permits to take cormorants, individuals and entities experiencing conflicts with cormorants should attempt nonlethal techniques (*e.g.,* hazing, habitat modification) to alleviate the conflict. Nonlethal techniques combined with lethal take should be more effective and may ultimately result in less need for lethal take in the future.

In response to ongoing damage at aquaculture facilities and other damage and conflicts associated with increasing cormorant populations, the Service administered regulations that included, in addition to Depredation Permits (located at 50 CFR 21.41), an Aquaculture Depredation Order (which was located at 50 CFR 21.47) beginning in 1998 and a Public Resource Depredation Order (which was located at 50 CFR 21.48), which began in 2003. Both of these regulations were in place until May 2016 when they were vacated by Court order (see more information, below).

The Aquaculture Depredation Order eliminated individual permit requirements in 13 States for private individuals, corporations, State agencies, and Federal agencies taking cormorants at aquaculture facilities. The Public Resource Depredation Order enabled States, Tribes, and the U.S. Department of Agriculture (USDA) Wildlife Services in 24 States, without the need for individual depredation permits, to take cormorants found committing or about to commit, and to prevent, depredations on the public resources of fish (including hatchery stock at Federal, State, and Tribal facilities), wildlife, plants, and their habitats.

In May 2016, these depredation orders were vacated by the United States District Court for the District of Columbia. The Court concluded that the Service failed to consider a reasonable range of alternatives in its 2014 environmental assessment (EA) and directed the Service to take ''a hard look'' at the effects of the depredation orders on double-crested cormorant populations and other affected resources. Finally, the Court ordered that the Service perform a new and legally adequate EA or environmental impact statement (EIS) under the National Environmental Policy Act of 1969, as amended (NEPA; 42 U.S.C. 4321–4347). Following the Court ruling, the Service prepared an EA in 2017 to address continuing conflicts with cormorants (USFWS 2017). The authority for authorizing lethal take of depredating cormorants reverted to the issuance of individual depredation permits pursuant to 50 CFR 21.41. Under the 2017 EA, cormorants could lethally be taken only to address conflicts with aquaculture, human health and safety, threatened and endangered species (as listed under the Endangered Species Act of 1973 (ESA), 16 U.S.C. 1531 *et seq.*) and State-listed species of management concern, and personal property (under the 2017 EA, take of cormorants to protect wild and publicly stocked fisheries would only be allowed to protect threatened or endangered species).

Conflicts in aquatic systems continue to exist between cormorants and fish stocks managed by Federal, State, and Tribal agencies as recreational and/or commercial fisheries. Conflicts also exist between cormorants and conservation of other species and habitats in some areas. As fish-eating birds, cormorant predation of fish occurs not only at aquaculture facilities, but also in private recreational ponds and large aquatic ecosystems. While conflicts exist between cormorants and some stakeholders, birders and other interested parties value cormorants for their aesthetic and existence values.

The Service is responsible for balancing the lethal take of cormorants to alleviate conflicts where available data support such take and maintaining sustainable populations of cormorants and minimizing the regulatory burden on Federal and State agencies, Tribes, and individual citizens. In making decisions, the Service strives to use an effective and transparent decision-making process that ensures input from migratory bird and fisheries management programs and other stakeholders, fulfills requirements under NEPA, and addresses key biological uncertainties. When determining allowable take, the Service must consider uncertainty related to cormorant population dynamics, estimated maximum sustainable lethal take, and risk of over-exploitation. Furthermore, the Service must identify monitoring requirements that could be used to assess the effects of lethal take on cormorant populations and to ensure take is commensurate with population status. Monitoring can also improve future decisions regarding allowable take and how that allowable take could be determined. States, Tribes, and other stakeholders can provide assistance and information. The Service will formally convene meetings with the Flyway Councils and other relevant stakeholders to develop a specific cormorant population monitoring plan.

History of Management and Conflicts

Cormorants are migratory waterbirds protected by the MBTA. They are native to North America and range widely across the continent, typically inhabiting wetlands and adjacent upland habitats. Cormorants also are found in some human-modified environments including airport airfields and aquaculture ponds. As described previously, the bird-management community generally accepts that there are five different breeding populations: The Alaska, Pacific (Western), Interior, Atlantic, and Southern populations.

Cormorant abundance in North America has increased dramatically since the 1960s and 1970s, mostly due to the growth of the Interior and Atlantic populations. The current estimate of cormorant abundance in the continental United States and Canada is 871,001 to 1,031,757 birds (USFWS 2020).

Prior to 1998, the sole method for authorizing the lethal take of depredating cormorants to alleviate damage and conflicts was through the issuance of depredation permits pursuant to 50 CFR 21.41, which allows the take of migratory birds that are injuring ''crops or other interests.'' In 1998, the Service published a final rule (63 FR 10550–10561, March 4, 1998) establishing a depredation order that authorized commercial freshwater aquaculture producers in 13 States to take cormorants without the need for a depredation permit when cormorants were found committing or about to commit depredations on aquaculture stocks. That rule was located at 50 CFR 21.47. The Service continued to issue depredation permits to address damage and conflicts to property, natural resources, and threats to human health and safety pursuant to 50 CFR 21.41. Any individual or entity conducting lethal take of cormorants under

depredation permits or the depredation order was required to submit a report detailing the take to the Service annually.

The increase in cormorant abundance across areas of North America and the subsequent range expansion of cormorants has been well documented along with concerns of the negative impacts associated with the expanding population (*e.g.,* Taylor and Dorr 2003, Hunter et al. 2006, Atlantic Flyway Council and Mississippi Flyway Council 2010, Pacific Flyway Council 2012). In response to increasing requests for depredation permits to alleviate damage and conflicts associated with cormorants, the Service issued a final environmental impact statement (FEIS) pursuant to NEPA and made changes to the regulations governing the take of cormorants in 2003. The 2003 FEIS considered direct, indirect, and cumulative effects of alternatives for cormorant management in the United States and discussed mitigating measures. In October 2003, based on analysis in the FEIS and review of public and agency comments, the Service published a final rule and notice of record of decision (68 FR 58022–58037, October 8, 2003) that modified the existing depredation order for aquaculture facilities (previously located at 50 CFR 21.47). The regulations became effective in November 2003. The modified depredation order for aquaculture facilities eliminated the need for private individuals, corporations, State agencies, and Federal agencies to obtain a depredation permit to take cormorants at aquaculture facilities in 13 States. It also authorized USDA Wildlife Services' employees to take cormorants at roost sites in the vicinity of aquaculture facilities during October, November, December, January, February, March, and April.

That final rule in 2003 also established a depredation order that authorized Federal agencies, State fish and wildlife agencies, and Tribes in 24 States to take cormorants to reduce damage and conflicts with public resources without the need for a depredation permit. At that time, the Service defined a public resource as a natural resource managed and conserved by public agencies, which included fish (*i.e.,* wild fish and stocked fish at Federal, State, and Tribal hatcheries that are intended for release in public or Tribal waters), wildlife, plants, and their habitats. The depredation order for public resources was previously located at 50 CFR 21.48. As with previous regulations, any individual or entity conducting lethal take of cormorants under depredation permits or the depredation orders was required to submit a report detailing the take to the Service annually.

To evaluate the potential effects on the cormorant population from the implementation of the two depredation orders, a mitigating measure required by the 2003 FEIS was to review and renew, if warranted, the two depredation orders every 5 years. Subsequently, the Service developed an EA pursuant to NEPA in 2009 and again in 2014 that determined that a 5-year extension of the expiration date of the two depredation orders would not threaten cormorant populations and that activities conducted under the two depredation orders would not have a significant impact on the human environment. Therefore, from October 2003 through May 2016, the Service authorized the take of cormorants pursuant to the two depredation orders (which covered certain States), through the issuance of depredation permits for activities in States not addressed in the two depredation orders, and through the issuance of scientific collecting permits (50 CFR 21.23).

Since the Court's vacating of the depredation orders in May 2016 as discussed above, the Service has been reviewing and issuing individual depredation permits in the central and eastern lower 48 States pursuant to two separate analyses conducted under NEPA. Individuals or entities apply for these permits to address site-specific conflicts, and each application is logged, evaluated, and acted upon (approved or rejected) on a case-by-case basis based on the merits of the permit application.

The 2017 EA (USFWS 2017) evaluated issuing depredation permits to take cormorants for specific circumstances across 37 central and eastern States and the District of Columbia. The selected alternative (Reduced Take Alternative) authorized the average annual take of cormorants that occurred during 2010–2015 (51,571cormorants). This amount was well below the allowable level resulting from the take analyses included in the EA (82 FR 52936–52937, November 15, 2017). In December 2019, in response to requests for increased take to alleviate growing conflicts, the Service issued a notice (84 FR 69762–69762, December 19, 2019) that it would implement a different proposed alternative analyzed in the 2017 EA (Potential Take Limit Alternative) that had a higher annual take threshold, increasing the take of cormorants authorized by permits to 74,396.

Management of cormorants in the western United States (Western population, *P. albociliatus*) is also through site-specific, case-by-case permits. The Service authorizes take of Western population cormorants primarily to reduce predation-related losses by cormorants of federally threatened or endangered juvenile salmon (*Oncorhyncus* spp.) and steelhead (*O. mykiss*) migrating to the Pacific Ocean. Additional authorizations for take occur at Federal, State, and Tribal hatcheries rearing federally threatened or endangered fish species, to protect aquaculture facilities, and for removing nests related to infrastructure maintenance. The U.S. Army Corps of Engineers' *Double-crested Cormorant Management Plan to Reduce Predation of Juvenile Salmonids in the Columbia River Estuary—Final Environmental Impact Statement* (FEIS; United States Army Corps of Engineers (USACE) 2015) guides management activities related to the take of cormorants in the Western cormorant population. The National Oceanographic and Atmospheric Administration's National Marine Fisheries Service (NOAA Fisheries) had previously determined that a reduced cormorant population of 5,380 to 5,939 breeding pairs on East Sand Island in the Columbia River Estuary would restore juvenile steelhead survival to the environmental baseline levels (NOAA Fisheries 2014), and the Service authorized lethal take at levels that attempted to achieve that colony abundance. Specifically, the Service authorized approximately 2,300 cormorants to be lethally taken each year under depredation permits, scientific collecting permits, and special purpose permits.

The Service expects the number of conflicts to increase, and we expect that demand for authorizations to take cormorants will continue to increase as a means to reduce those conflicts in the future. For example, between 2007 and 2018, the number of permit requests to take depredating cormorants (exclusive of requests to act under the depredation orders) increased from slightly less than 200 to almost 300 (USFWS, unpublished data). As requests to take cormorants increase, the use of multiple individual depredation permits to address conflicts within State and Tribal jurisdictions will become increasingly time-consuming and burdensome. Therefore, creating a new State and Tribal cormorant permit would enable the Service to more efficiently respond to the needs of States and Tribes seeking relief from conflicts associated with

cormorants. The new permit also provides States and Tribes with the ability to address conflicts between cormorants and wild and publicly stocked fish managed by State fish and wildlife agencies or federally recognized Tribes, which was not previously available to them under the scope of individual depredation permits per 50 CFR 21.41.

Estimating Allowable Take

To alleviate conflicts with cormorants, we used a method called Potential Take Level (PTL) analyses (Wade 1998, Runge et al. 2004) to determine the number of cormorants that may be taken while maintaining the species (and breeding populations) at sustainable levels. This process has been used to determine allowable take levels for cormorants in a previous EA (USFWS 2017) and for other species, including several bird species (*e.g.,* USFWS 2009, Runge et al. 2009, Johnson et al. 2012, Zimmerman *et al.* 2019). Methods used to determine population sizes and allowable take levels in this rule are detailed in the USFWS Final Environmental Impact Statement: Management of Conflicts Associated with Double-crested Cormorants (USFWS 2020). The median amount of allowable take resulting from the analysis was 166,800 cormorants annually. However, we recommend being more conservative and allowing take only up to the lower 20 percent of the distribution of the PTL annually (121,504 cormorants). Population-specific recommended levels of take are: Atlantic, 37,019; Interior, 78,632; Western, 9,077; and Southern (Florida), 1,314. At those levels of take, the continental population of double-crested cormorants is expected to average about 830,285 cormorants. However, due to concerns expressed by a number of commenters in the Pacific Flyway that take reaching the allowable level could negatively impact the Western Population, the Service initially will allow a maximum of 4,539 birds to be taken annually from that population.

This final rule brings all populations of double-crested cormorants under a common assessment framework to determine allowable levels of take. However, levels of take for each population could differ based on their current abundances, population biology, and population-specific management objectives.

Special Double-Crested Cormorant Permit

The Service establishes a new permit option under 50 CFR part 21 (Special Double-Crested Cormorant Permit) that is available to State and Tribal fish and wildlife agencies in the 48 contiguous United States to manage conflicts specifically associated with double-crested cormorants. The special permit is available only to a State or Tribal fish and wildlife management agency responsible for migratory bird management. Under this permit, the Service authorizes State and Tribal fish and wildlife agencies to conduct lethal take of double-crested cormorants that is normally prohibited and is intended to relieve or prevent impacts from cormorants on lands or in waters managed by those agencies within their respective jurisdictions or where States or Tribes manage wild or stocked fish that are accessible by the public or all Tribal members. The Service will issue this permit only when it is expected to reduce conflicts involving depredation at State- and Tribal-owned or operated aquaculture facilities (including hatcheries), impacts to health and human safety, impacts to threatened and endangered species (as listed under the ESA or identified in State- or Tribal-specific legislation as threatened or endangered) or those listed as Species of Greatest Conservation Need in State Wildlife Action Plans, damage to State- or Tribal-owned property and assets, and depredations of wild and publicly stocked fish managed by State fish and wildlife agencies or federally recognized Tribes and accessible to the public or all Tribal members. Those States and Tribes not wishing to obtain this new permit may apply for a depredation permit (50 CFR 21.41) to address site-specific conflicts with cormorants. However, these individual depredation permits do not authorize take of cormorants to reduce or prevent conflicts with wild and publicly stocked fisheries (except for threatened or endangered species).

The Service retains overall authority for the take of double-crested cormorants to ensure that levels of take are consistent with management objectives. States and Tribes must use nonlethal methods, and independently determine that those methods are insufficient to resolve conflicts before lethally taking double-crested cormorants. Lethal management should be considered as part of an integrated approach to managing cormorant conflicts and used only when other methods are insufficient to resolve conflicts. No permit is required merely to scare or herd migratory birds other than threatened or endangered species or bald or golden eagles (*see* 50 CFR 21.41). The Service will periodically determine the population-specific numbers of double-crested cormorants that may be taken lethally during a specified number of years in efforts to reduce conflicts while sustaining cormorant abundances, and will track authorized take through permits issued to States and Tribes to ensure take does not exceed those levels specified in the PTL. The annual allocation of take to States and Tribes will be based on recent demand by those entities and adjusted as needed (while remaining at or below population-specific allowable take levels) to respond to spatial and temporal changes in population status and the need to reduce conflicts in specific regions. The Service will prepare reports every 5 years, and additionally as necessary, to provide the public with information regarding the take of cormorants and the extent to which this permit, along with other management tools (*e.g.,* depredation permits per 50 CFR 21.41 and scientific collection permits per 50 CFR 21.23), is achieving management objectives.

The special double-crested cormorant permit is subject to the following conditions/restrictions:

1. States and Tribes must use nonlethal methods, and independently determine that those methods are insufficient in controlling the depredation conflict, before lethally taking double-crested cormorants.

2. Lethal take of adults during the breeding season must occur prior to hatching of eggs to avoid the loss of adults that likely would result in orphaning chicks and their ultimate death due to starvation. Adult birds may not be taken at any nest with young in it unless the purpose of the take of adults is intended to address a human health and safety issue. States and Tribes and their subpermittees must make efforts to avoid disturbance to co-nesting species. Existing research findings and publications detailing appropriate nonlethal methods and/or models for reducing conflicts should be used to justify activities.

3. A permit under this section does not authorize the taking of any other migratory bird, including other species of cormorants; the disturbance of bald or golden eagles; or the take of any species listed under the ESA as threatened or endangered. If these impacts to other migratory bird species or to threatened and endangered species are likely to occur, the permittee must obtain permits specifically authorizing those activities (*i.e.,* additional migratory bird, Bald and Golden Eagle Protection Act, and/or threatened and endangered species permits).

4. Actions under the permit may be conducted during any time of the year on lands or in waters managed by State or Tribal fish and wildlife agencies within their jurisdictions, or where States or Tribes manage wild or stocked fish that are accessible by the public or all Tribal members. Actions may occur only when cormorants are committing or are about to commit depredations at Tribal- and State-owned or operated aquaculture facilities (including hatcheries); to alleviate impacts to health and human safety; reduce impacts to threatened and endangered species (as listed under the ESA or identified in State- or Tribal-specific legislation as threatened or endangered) or those listed as Species of Greatest Conservation Need in State Wildlife Action Plans; and to prevent damage to State- or Tribal-owned property and assets. Take activities to prevent depredation on aquatic Species of Greatest Conservation Need may occur only in natural or public waters. Permittees need to include a description of long-term plans to eliminate or significantly reduce continued need to take double-crested cormorants as part of their application. Permits will be issued annually. Permittees are required to submit an annual report by January 31 for activities conducted during the preceding calendar year. The report must detail the amount of lethal take that occurred under their permit and for what purpose the take was conducted.

5. Anyone undertaking lethal control with a firearm must use nontoxic shot or nontoxic bullets (50 CFR 20.21). However, this prohibition would not apply if an air rifle or an air pistol is used.

6. Individuals conducting lethal control may not use decoys, calls, or other devices or bait to lure birds within gun range.

7. Methods of take are at the discretion of the permittee responsible for the action, but must be accomplished by means of humane lethal take or active nest take. Lethal take may occur by firearm in accordance with paragraph (5) above or lethal or live traps. Active nest take may occur by egg oiling or destruction of nest material and contents (including viable eggs and chicks). Birds may be euthanized by cervical dislocation, CO_2 asphyxiation, or other methods recommended by the American Veterinary Medical Association. Only 100 percent corn oil, a substance exempted from regulation by the Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act, may be used to oil eggs. Other damage control methods of take consistent with accepted wildlife damage management programs may be authorized.

8. States and Tribes applying for the first time must consult with the USDA Wildlife Services for an assessment of the appropriate level of take and provide recommendations of short-term measures to provide relief from depredation and long-term measures to help eliminate or significantly reduce conflicts. Wildlife Services provides a ''Form 37 Permit Review''. This form is required for first-time applicants only. Permittees need not submit a Form 37 for renewal applications unless requested by the regional Migratory Bird Permit Office. Permittees are expected to continue working with Wildlife Services for review of management plans and remaining current on best practices.

9. States and Tribes and their employees and subpermittees may possess, transport, and otherwise dispose of double-crested cormorants taken. Double-crested cormorants killed and nests/eggs destroyed under the authority of this permit must be properly disposed of by donation to an entity authorized by permit or regulation to receive migratory birds, or be destroyed completely in accordance with Federal, State, and/or local laws and ordinances. This may include donation to public museums or public scientific and educational institutions for exhibition, scientific, or educational purposes, or burial or incineration. This permit does not allow for birds or their parts or nests/eggs to be sold, offered for sale, bartered, or shipped for the purpose of sale or barter. Birds may not be retained for personal use.

10. This permit does not apply to any efforts to prevent depredation or harm to privately owned animals (*e.g.,* hobby animals, pets, or similar categories of animals) that are raised free-range or otherwise released to the wild. Private landowners may apply for a depredation permit (50 CFR 21.41) to alleviate damage to some types of property (*i.e.,* buildings and infrastructure; vehicles and equipment; some types of vegetation; and display animals, such as those in zoo exhibits).

11. States and Tribes may designate subpermittees who must operate under the conditions of the permit. Subpermittees can be employees of State and Tribal fish and wildlife agencies, USDA Wildlife Services employees, and employees of other Federal, State, or Tribal agencies or private companies specializing in wildlife damage abatement and under direct control of the permittee.

12. Any employee or subpermittee authorized by the State or Tribe to carry out actions under the special permit must retain in their possession a copy of the State's or Tribe's permit while carrying out any action.

13. Any State or Tribal agency, when exercising the privileges of this permit, must keep records of all activities, including those of subpermittees, carried out under the authority of the special permit. Prior to any permit renewal, the Service will require an annual report detailing the activities conducted under the permit and the numbers of cormorants, nests, and eggs lethally taken, treated, or destroyed.

14. Nothing in the permit should be construed to authorize the take of cormorants, their eggs, or nests contrary to any State or Tribal law or regulation or on any Federal land without written authorization by the appropriate management authority. Further, none of the privileges granted under the permit shall be exercised without any State or Tribal permit that may be required for such activities.

15. The scope of this permit applies to lands or in waters managed by State and Tribal fish and wildlife agencies and within those agencies' jurisdictions. If a State or Tribe must enter private property to access State and Tribal lands or waters where take is approved in their permit, the State or Tribe must obtain authorization from the private property owner, and require that the private property owner or occupant provide free and unrestricted access. The private property owner or occupant should also allow access at all reasonable times, including during actual operations, to any Service special agent or refuge officer, State or Tribal wildlife or deputy wildlife agent, warden, protector, or other wildlife law enforcement officer on the premises where they are, or were, conducting activities. Furthermore, any State or Tribal employee or approved subpermittee conducting such activities must promptly furnish information concerning such activities to any such wildlife officer.

16. The Service reserves the authority to immediately suspend or revoke any permit if the Service finds that the terms and conditions set forth in the permit have not been adhered to, as specified in 50 CFR 13.27 and 13.28.

Since November 2017, permits have been available only to address conflicts with aquaculture, human health and safety, threatened and endangered species, and personal property; take of cormorants to protect wild and publicly managed fisheries has not been authorized unless warranted to protected threatened or endangered species. The conflicts with these

managed fisheries are increasingly causing concerns with State and Tribal fish and wildlife agencies, particularly those involved with providing recreational fishing opportunities. As cormorant abundance increases, and even at current levels, the issuance of individual depredation permits to address conflicts is becoming increasingly time-consuming and lengthy in some cases. The Service expects this special double-crested cormorant permit, which increases the flexibility of States and Tribes to address issues and also expands the scope of conflicts that can be addressed to wild and publicly managed fish, will result in increased efforts to reduce those conflicts, including lethal take of birds, nests, and eggs. Localized abundances of cormorants may decline as a result of these efforts, but regional and continental populations are not likely to be negatively impacted.

The Service also expects that, by allowing States and Tribes to address conflicts through a special permit, more aggressive management activities will result at sites experiencing high levels of conflicts associated with cormorants, and within the scope of this rule. By authorizing conflict-management activities at the State or Tribal level, instead of at the Department of the Interior Regional level, management activities will be more responsive and timely than is currently the case. Quicker resolution of conflicts ultimately may result in fewer complaints regarding cormorants. In expanding authority given to the States and Tribes via this permit, workload burdens may shift with more being borne by the States and Tribes and less by the Service. However, because States and Tribes are not required to obtain this permit, this rule does not impose an unfunded mandate on State, local, or Tribal governments. Further, since this permit is available only to States and Tribes, it does not impose an unfunded mandate on the private sector. Those States and Tribes interested in obtaining the new permit would likely have staff and resources in place with dedicated duties falling within the scope of conflicts associated with cormorants. Additional explanations can be found in the Required Determinations section of this rule.

Importantly, reducing the abundance of double-crested cormorants is not the goal of the Service or this new management action. Reducing their overall abundance does not guarantee that conflicts in specific areas will decrease. If cormorants are attracted to an area due to food resources, nesting habitats, or other factors, those places will remain attractive regardless of the size of the cormorant population and may still experience damage to the resources. Rather, the goal of the Service is to reduce the number of conflicts with cormorants by combining lethal and nonlethal methods and allowing the lethal take of cormorants only when supported by information that such take would reduce conflicts. As a consequence, abundance of cormorants in some areas may be reduced, but regional and continental populations will be managed at sustainable levels, albeit at somewhat reduced abundances. The Service also wants to ensure accountability not only in determining allowable take, but also in reporting of actual take by permittees. We will annually review reports submitted by permit holders and will periodically assess the overall impact of this permit program to ensure compatibility with long-term conservation of double-crested cormorants. This approach will result in the transparency and accountability necessary to make informed decisions about and promote adherence to authorized levels of take.

Public Comments

On January 22, 2020 (85 FR 3601–3603), the Service published an advance notice of proposed rulemaking (ANPR) and announced our intent to prepare a NEPA document indicating that the Service intended to establish new regulations regarding the management of double-crested cormorants. The comment period for the ANPR continued through March 9, 2020. The ANPR listed possible alternatives, which include the no action alternative in addition to the following:

(1) Establish a new permit for State and Tribal fish and wildlife agencies for authorizing certain cormorant management and control activities;

(2) Establish an aquaculture depredation order; and

(3) Both (1) and (2) in combination.

We also announced that several public scoping meetings would be held, and that specific dates and times for the public meetings would be available on the internet at *https://www.fws.gov/birds/management/managed-species/double-crested-cormorants.php.* A total of four public scoping webinars were convened, two on February 11, 2020, and two on February 12, 2020. Additionally, we conducted two webinars provided only to Tribal members on February 19 and 27, 2020. We provided all attendees of all webinars with information on the following topics regarding cormorants, their management, and the regulations process: (1) Biology and population changes; (2) background of the issues and previous management approaches; (3) current management of conflicts; (4) proposed approaches and alternatives; and (5) the planning process for the NEPA analysis. We also informed attendees that they could provide comments on the proposed actions and the scope of the NEPA review via a website (*http://www.regulations.gov,* Docket No. FWS–HQ–MB–2019–0103) or by U.S. mail or hand-delivery to Public Comments Processing, Attn: FWS–HQ–MB–2019–0103; U.S. Fish and Wildlife Service Headquarters, MS: PRB (JAO/3W), 5275 Leesburg Pike, Falls Church, VA 22041–3803.

On June 5, 2020, the Service published a notice of proposed rulemaking (proposed rule; 85 FR 34578), and the Environmental Protection Agency published notice of a draft environmental impact statement (DEIS) (85 FR 34625). The comment period for each continued for 45 days, ending on July 20, 2020. The Department of the Interior's policy is, whenever possible, to afford the public an opportunity to participate in the rulemaking process. We received more than 1,400 comments in response to the ANPR and 1,047 in response to the proposed rule and DEIS.[1] You may review the comments received at the Federal eRulemaking Portal: *http://www.regulations.gov* in Docket No. FWS–HQ–MB–2019–0103. We considered comments on the ANPR in developing the proposed rule, and comments on the DEIS and proposed rule when developing this final rule. A summary of the comments is included in the 2020 FEIS associated with this rulemaking action, and we incorporate those responses to comments by reference to this rule. We also include additional responses to comments below that highlight important issues raised by the public. Comments and our responses pertaining to information collection are also set forth below in this document in Required Determinations, under *Paperwork Reduction Act,* as a majority of those comments pertained to information collection issues.

Use of Nonlethal Control: Commenters submitted several questions regarding the required use and efficacy of nonlethal methods used to address conflicts associated with cormorants. Comments appear to focus on two primary concerns: (1) How the Service will enforce or require that permittees implement nonlethal

[1] *Regulations.gov* shows 1,052 total comments, which comprise 1,047 public submissions, 2 primary documents (proposed rules), and 3 supporting documents (DEIS, 2003 FEIS, and U.S. Army Corps of Engineers documents)

methods first before carrying out authorized take, and (2) how the permittee will determine when nonlethal methods of management are ''enough'' or insufficient. Commenters also requested clarity on the type of nonlethal control methods the Service expects permittees to use. Specifically, some commenters requested that the Service require that permittees (individual or a new special permit for States and Tribes) ''make progress'' toward nonlethal solutions to conflicts as a condition of any permit. They further commented that they felt the DEIS did not provide information on how nonlethal methods are used in a comprehensive approach. Members of the general public commented that there is a general bias against nonlethal measures even when nonlethal measures are proven to work. Commenters assert that the Service failed to demonstrate how States and Tribes would satisfy the requirement that people first use nonlethal methods to address conflicts. In addition, commenters also recommended that the Service ensure that States and Tribes applying for the special permit have conclusive data on a site-by-site basis indicating the effectiveness of cormorant management before take begins.

Further, several State agencies expressed concern that a requirement for attempting nonlethal control before lethal control will delay effective management, and that such a requirement would be so complex that it will add unnecessary documentation and time before lethal controls may be used. Similarly, some State agencies mentioned that ''redundant'' documentation required under the proposed new permit process could delay control and impede success. One State agency commented seeking clarification on implementation of nonlethal methods as well, stating that such a request is not feasible since the geographic distribution of State and Tribal fish hatcheries is too broad and each hatchery is taken on a case-by-case basis. Another State agency commented that nonlethal control methods are often impractical or ineffective, as cormorants become habituated to persistent, affordable methods (*e.g.,* noise-making deterrents, lasers, harassment from shore by hatchery personnel). Commenters further stated that the size of some hatcheries makes other methods difficult or too expensive to implement. Another commenter suggested that the Service identify a process for the required evaluation of efficacy of nonlethal methods. A State agency recommended that the Service develop guidelines for determining when there is sufficient proof that nonlethal mechanisms are ineffective at resolving conflicts. Another State agency commented that the Service needs to clarify its expectations on use of nonlethal methods to meet the needs of managers, stating that there are certain cases where take is essentially unavoidable, or where there is significant evidence that would indicate, prima facie, the need for take. Yet another State agency also requested that the Service provide States seeking permits with a guide or Best Management Practices on nonlethal methods of resource protection. Lastly, a State agency recommended that the Service develop and provide States with sampling protocols to assist with collecting and analyzing fish population data where cormorant control activities occur.

Some commenters recommended no management of the conflict, or managing the conflict with nonlethal management methods only. And some commenters recommended the ''no action'' alternative, which would continue to address conflicts associated with cormorants within a specific scope with the issuance of individual permits. Reasons for support of the no action alternative generally indicate that this option would focus lethal control explicitly on birds that are committing or about to commit depredation or harm/damage, identifies and defines a limited and specific set of types of conflicts, requires permittees to demonstrate they have exhausted reasonable nonlethal methods of management, and requires the Service approval lethal control on a case-by-case basis.

Agency Response to use of Nonlethal Control: The Service agrees that harassment of cormorants may be effective in some areas, but ineffective in others. The conditions that dictate this outcome are often site-specific and variable throughout any given year. For example, some commenters note that many catfish farms must employ full-time employees to harass and take cormorants when authorized, but management of the conflict in general is considered an added business expense. Another commenter asserted that nonlethal measures may work for a limited time period, but some birds may become habituated. It is in these situations where the Service anticipates lethal removal of cormorants would be warranted. In addition, as the Service noted in the DEIS and the FEIS, the use of nonlethal methods alone is not an effective management tool to respond to conflicts associated with cormorants, which is why the Service rejected that possible alternative in its analysis.

The Service encourages and expects continued use of nonlethal measures in conjunction with lethal measures where permittees find this approach most effective. Often, a combination of measures is the most effective way to address conflicts associated with cormorants. The Service needs to rely on permittees to make site-specific assessments and employ cormorant conflict management in a manner that makes the most sense, so long as those permittees follow the conditions of the permit. For added clarity in response to these comments, the following is a condition that would be part of any permit issued by the Service under the preferred alternative in this FEIS: States and Tribes and their subpermittees must use nonlethal methods, and independently determine that those methods are insufficient in controlling the depredation conflict, before lethally taking double-crested cormorants. Permittees may also consult with USDA Wildlife Services for additional assistance to determine when nonlethal methods are insufficient.

With regard to methods of nonlethal management methods expected, the new special permit application now includes language intended to be clear and concise. The revised language reads, ''(2) For each location(s), describe the nonlethal methods that you have used previously and/or plan on implementing, including (a) active hazing (*e.g.,* horns, pyrotechnics, propane cannons, etc.), (b) passive deterrents (*e.g.,* netting, exclusion devices, nest deterrents, etc.), (c) habitat management (*e.g.,* vegetative barriers, grass management, prey management, etc.), and (d) changes in management practices (*e.g.,* water level management, fish release timing, etc.).''

With regard to the question in the FWS Form 3–200–90, Permit Application, and the language requesting, ''A statement indicating what information will be collected to assess whether the management and take of double-crested cormorants is alleviating the damage or other conflict,'' the Service revised this language as well. The revised language is intended to be less ambiguous and better solicit an answer that allows a Service permit staff employee/specialist to make a determination on efficacy. The revised language reads, ''Describe your long-term plans to eliminate or significantly reduce the continued take of double-crested cormorants or destruction of eggs/nests.''

With respect to the comment suggesting no management, or only using nonlethal controls, nonlethal management would essentially mean that the Federal Government would not issue any permits or other authorizations (*i.e.,* depredation permits, depredation orders, control orders, or conservation orders) that would allow the take of cormorants to alleviate depredations or other conflicts. This is an alternative the Service considered but eliminated from further analysis as it would not meet the purpose and need to address cormorant conflicts.

With respect to the ''no action alternative,'' while individual permits do offer control on a site-specific case-by-case basis, they do not meet the purpose and need for action as cited in the DEIS. Specifically, the no action alternative does not fully address the need for Tribes in the western region of the United States (excluding Alaska), to address cormorant impacts on fisheries—especially on hatchery-raised salmonids. Similarly, the Service is rejecting the no action alternative because it could potentially have a negative effect on wild and publicly stocked fish, as it would not allow for take of cormorants found to be heavily depredating a fishery. Under the no action alternative, the Service expects continued or enhanced conflict between cormorants and some economically important fisheries across the nation, as well as at some hatchery release sites.

Permit Conditions: Several commenters expressed concern that year-round lethal take will lead to high chick mortality through starvation, predation facilitated by human disturbance, a removal of parent(s), and/or exposure. One commenter requested the Service require a control moratorium during the nesting season when chicks are present. Several commenters voiced a preference for the Service to require only nontoxic shot and not allow the use of any lead ammunition. Some commenters also requested the Service specify permit conditions to protect nontarget and federally listed species. Separately, some commenters voiced a preference for the use of decoys when implementing cormorant management actions.

Agency Response to Permit Conditions: The Service views lethal control methods as a last resort for addressing conflicts between avian species and human interests. Lethal take of adults during the breeding season should occur prior to hatching of eggs to avoid the loss of adults that likely would result in orphaning chicks and their ultimate death due to starvation. Adult birds may not be taken at any nest with young in it unless the take of adults addresses a human health and safety issue. In addition, States and Tribes and their subpermittees must make efforts to avoid disturbance to co-nesting species.

This rule limits the use of lead ammunition when persons use firearms to take cormorants. As a standard condition for all permits under this rule, permit holders must use nontoxic shot when using shotguns or other firearms to take cormorants, except when using an air rifle or air pistol due to the limited availability of nontoxic bullets for them.

The Service considered the impacts of issuing depredation permits on nontarget migratory birds, including threatened and endangered species. The Service anticipates the unintentional take of nontarget species will occur infrequently and involve very few individuals of a particular species. An Intra-Service ESA Section 7 consultation Biological Evaluation (ESA BE) was completed to assess if any proposed, threatened, or endangered species or associated critical habitat would be affected by cormorant control. The Service added specific permit conditions for piping plover (*Charadrius melodus*), interior least tern (*Sterna antillarum*), and wood stork (*Mycteria americana*): (1) A buffer zone for wood storks for all activities; (2) a buffer zone for these three birds when discharging firearms; and (3) a buffer zone for these three birds for egg oiling, CO_2 asphyxiation, egg destruction, or nest destruction.

The Service acknowledges that decoys can be effective in luring birds into sites to make them easier to kill, particularly those that are gregarious by nature. In most cases, the kill of birds is higher when using decoys than when they are not used (*e.g.,* use of decoys in hunting situations). However, in cases concerning depredation issues, animals that may not otherwise depredate a particular area may do so when decoyed into that area. Decoying birds may create, extend, or exacerbate conflicts (*e.g.,* exacerbating a disease outbreak by attracting additional birds) where an issue may not exist or could be lessened if the birds had not been decoyed into the area; and could limit the ability of entities to obtain relief from cormorant conflicts due to the limited numbers of birds that could be taken to ensure sustainability of cormorant populations. For these and other reasons, decoys may not be used in the Service's depredation permit (50 CFR 21.41).

Western Subpopulation of Cormorants: Several entities commented with concerns regarding the PTL and potential impacts to the western subpopulation of cormorants. Similarly, some commenters also submitted additional data considerations and analyses. Commenters provided many specific empirical details for the Service to consider, but, in general, considerations included the following issues: (1) The confidence interval for this western subpopulation is too large; (2) the take limit for the western subpopulation is much larger than historical take in the West; and (3) there was an error in the equation used to estimate a pre-breeding multiplier.

Agency Response to Western Subpopulation of Cormorants: Based on information received during the public comment period, the PTL for the western subpopulation may not have captured complex and changing population dynamics precipitated by cormorant management in the Columbia River Estuary. To reduce the risk of over-exploiting the western subpopulation, the Service reduced the level of authorized annual take to half the PTL in the DEIS, or 4,539 individuals. This is a maximum allowable annual take level, not a prescribed level. Based on the average past take of cormorants, expected take is unlikely to exceed 2,000 annually. The status of the population can be reassessed at 5-year intervals, and additionally as necessary, and there is a sound monitoring program in place for the western subpopulation, which can estimate how the western subpopulation responds to take subsequent to the habitat management in the Columbia River Estuary.

With respect to the comments on the error in the pre-breeding multiplier, two errors were found in the formula. First, an equation had the denominator and numerator reversed. This was a typo in that the equation was used in its proper form to estimate a pre-breeding multiplier. The reversal did not result in any errors in estimating PTL. Second, an equation to extrapolate cormorant nest counts was missing a term needed to correctly estimate the proportion of nonbreeding birds. The equation as written estimates the number of nonbreeders as a percentage of breeders, whereas it should have estimated the number of nonbreeders as a percentage of the total population. This error was propagated in estimating PTL. Correcting this error caused estimates of PTL to increase 2–3% for each subpopulation.

Required Determinations

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) will review all significant rules. In accordance with the criteria in Executive Order 12866, this action is not a significant regulatory action subject to OMB review.

This rule will not have an annual economic effect of $100 million or adversely affect any economic sector, productivity, competition, jobs, the environment, or other units of government. This action will not create inconsistencies with other agencies' actions or otherwise interfere with an action taken or planned by another agency. Our economic analysis determined that this rule is expected to result in positive economic benefits to both the commercial aquaculture industry as well as the recreational sport fishing industry.

E.O. 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the Nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The Executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Codifying a new permit for the management of double-crested cormorants provides an additional tool for States and Tribes to appropriately manage conflicts on lands or in waters managed by their respective fish and wildlife agencies within their jurisdictions, while maintaining overall authority for the take of birds within the Service. Further, current regulations allow the take of cormorants only for the purposes of reducing conflicts with and damage to aquaculture, human health and safety, threatened and endangered species (as listed under the ESA) and State-listed species of management concern, and personal property. Many of the conflicts with cormorants involve depredations of sport fish by cormorants, for which there is no relief under current Federal regulations unless warranted to reduce impacts to threatened and endangered fish species listed under the ESA. This new permit would allow the take of cormorants to reduce depredation of wild and publicly stocked fish managed by State fish and wildlife agencies or Tribes, thus enhancing the scope of conflict resolution to more comprehensively address areas of concern. However, the total number of cormorants from each population that can be taken annually will be determined by the Service to ensure that cormorant populations are sustainable.

The Service does not have empirical information to quantify the changes in costs as a result of this new permit, because we do not know how many States and Tribes would avail themselves of this permit and the extent to which conflicts would be addressed using it. However, we expect that the overall cost and regulatory burden to individuals, businesses, and State, Tribal, and Federal government agencies associated with this new permit will be lower than exists under current regulations. The reduction would be the result of fewer requests by States and Tribes for individual depredation permits previously needed compared to single State or Tribal permits that could be used; hence, total costs associated with permit applications and biological assessments of those applications likely will be lower.

Executive Order 13771

This rule is not an E.O. 13771 (''Reducing Regulation and Controlling Regulatory Costs'') (82 FR 9339, February 3, 2017) regulatory action because it is not significant under E.O. 12866.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; 5 U.S.C. 801 *et seq.*), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

According to the Small Business Administration, small entities include small organizations such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include finfish farming and fish hatcheries (NAICS 112511) and other types of commercial aquaculture farms (NAICS Code 112519). The small business size standard defined for these businesses (as defined by the U.S. Small Business Administration) is businesses with revenues under $0.75 million.

The Service has difficulties estimating impacts to recreational fisheries because few studies have investigated direct economic impacts of cormorant management on recreational fisheries. Although a few studies have estimated impacts to local economies, loss of fishing day activities in those local areas may be offset through engaging in angling opportunities elsewhere. While it is feasible that this rule could have localized effects on recreational fisheries, data do not exist to predict where those effects could occur. Further research might determine whether any impacts that may be seen at local scales can be extended to larger scales. However, the Service concludes that this rule will result in an overall net benefit to facilities as it will provide another option to control double-crested cormorants that are negatively impacting their operations.

This new permit affects only State and Tribal governments and does not impact small businesses. The new special cormorant permit would be optional and available to State and Tribal fish and wildlife agencies in the 48 contiguous States to manage conflicts specifically associated with cormorants. This permit would provide State and Tribal fish and wildlife agencies flexibility within predefined guidelines to address conflicts caused by cormorants within their jurisdictions.

Commercial entities, such as privately managed aquaculture facilities, would continue to have the opportunity to apply for individual depredation permits to address site-specific conflicts. A higher threshold for annual take associated with this regulation will yield benefits to the aquaculture industry and others in need of individual depredation permits. These benefits result from indirect effects on cormorant populations from a higher threshold of authorized take, and the

resulting lower cormorant populations that are projected. The new permit coupled with the continued use of individual depredation permits for commercial aquaculture producers would provide the flexibility to manage cormorants sustainably and authorize take in an equitable fashion across multiple conflicts.

Thus, we are certifying that this rule will not have a significant economic impact on a substantial number of small business entities. Therefore, a regulatory flexibility analysis is not required.

Unfunded Mandates Reform Act

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we have determined the following:

(a) This rule will not ''significantly or uniquely'' affect small government activities, because the Federal Government would not require States or Tribes to obtain this permit. By authorizing conflict-management activities at the State or Tribal level, instead of at the Department of the Interior Regional level, management activities will be more responsive and timely than is currently the case. Quicker resolution of conflicts ultimately may result in fewer complaints regarding cormorants. In expanding authority given to the States and Tribes via this permit, workload burdens may shift with more being borne by the States and Tribes and less by the Service. However, a small government agency plan is not required.

(b) We have determined and certify, in compliance with the requirements of the Unfunded Mandates Reform Act, 2 U.S.C. 1502 *et seq.,* that this rulemaking will not impose a cost of $100 million or more in any given year on local or State government or private entities. The rule does not have a significant or unique effect on State, local, or Tribal governments or the private sector, and the permit is optional to States and Tribes. Those States and Tribes interested in obtaining the new permit would likely have staff and resources in place with dedicated duties falling within the scope of conflicts associated with cormorants. Therefore, this rule is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act.

Takings

In accordance with E.O. 12630, this rule does not contain a provision for taking of private property, and would not have significant takings implications. A takings implication assessment is not required.

Federalism

This rule would not interfere with the States' or Tribes' abilities to manage themselves or their funds. The new special cormorant permit would be optional and available to State and Tribal fish and wildlife agencies in the 48 contiguous States to manage conflicts specifically associated with cormorants. This permit would provide State and Tribal fish and wildlife agencies flexibility within predefined guidelines to address conflicts caused by cormorants within their jurisdictions. Therefore, this rule would not have sufficient federalism effects to warrant preparation of a federalism summary impact statement under E.O. 13132.

Civil Justice Reform

In accordance with E.O. 12988, we have reviewed this rule and determined that it will not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

Paperwork Reduction Act

This final rule contains a collection of information that we have submitted to OMB for review and approval under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number. OMB has reviewed the information collection requirements in this rule and assigned OMB Control Number 1018–0175. The new reporting and/or recordkeeping requirements identified below require approval by OMB:

(1) *FWS Form 3–200–90, Permit Application—Special Double-Crested Cormorant Permit (50 CFR part 21) (and associated amendments):* This new permit would be available only to State or Tribal fish and wildlife agencies responsible for migratory bird management on lands and in waters managed by those agencies within their jurisdictions. Under this permit, the Service would authorize State and Tribal fish and wildlife agencies to conduct lethal take to reduce conflicts involving depredation at State- and Tribal-owned or operated aquaculture facilities (including hatcheries); impacts to health and human safety; impacts to threatened and endangered species (as listed under the ESA and listed species identified in State- or Tribal-specific legislation as threatened or endangered) or those listed as Species of Greatest Conservation Need in State Wildlife Action Plans; damage to State- or Tribal-owned property and assets; and depredations of wild and publicly stocked fish managed by State fish and wildlife agencies or federally recognized Tribes and accessible to the public or all Tribal members. Take activities to prevent depredation on aquatic Species of Greatest Conservation Need may occur only in natural or public waters.

Any State or Tribal fish and wildlife agency wishing to obtain a permit must submit an application (FWS Form 3–200–90) to the appropriate Regional Director containing the general information and certification required by 50 CFR 13.12(a) plus the following information:

a. A brief description of your State's or Tribe's double-crested cormorant conflicts, including physical location(s) and type of conflict specified above in this paragraph (1);

b. A detailed description of the nonlethal methods (*i.e.,* active hazing, passive hazing, habitat management, and changes in management practices) you have and/or will implement and how activities will address one or more of the issues specified above in this paragraph (1);

c. The requested annual take of double-crested cormorants by life-stage, including eggs and nests;

d. A description of long-term plans to eliminate or significantly reduce continued need to take double-crested cormorants;

e. A statement indicating that the State or Tribe will inform and brief all employees and subpermittees of the requirements of these regulations and permit conditions;

f. A list of all subpermittees who may conduct activities under the Special Double-Crested Cormorant Permit, including their names, addresses, and telephone numbers; and

g. The name and telephone number of the individual in your agency who will oversee the double-crested cormorant management activities authorized under the permit.

States and Tribes applying for the first time must consult with the U.S. Department of Agriculture's Wildlife Services for an assessment of the appropriate level of take and provide recommendations of short-term measures to provide relief from depredation and long-term measures to help eliminate or significantly reduce conflicts. Wildlife Services provides a ''Form 37 Permit Review,'' which is required to be completed and included with the application for first-time applicants only.

(2) *FWS Form 3–202–56, Annual Report:* The State or Tribe must submit an annual report (FWS Form 3–202–56) detailing activities, including the dates,

numbers, and locations and life stages of birds, eggs, and nests taken and nonlethal techniques utilized, by January 31 for activities conducted during the preceding calendar year. The Service will require an annual report by the State or Tribe prior to any permit renewal.

(3) *Recordkeeping Requirements:* Any State or Tribal agency, when exercising the privileges of this permit, must keep records of all activities, including those of subpermittees, carried out under the authority of the special permit.

(4) *Designation of Subpermittees:* States and Tribes may designate subpermittees who must operate under the conditions of the permit. Subpermittees can be employees of State and Tribal fish and wildlife agencies, USDA Wildlife Services employees, and employees of other Federal, State, or Tribal agencies or private companies licensed to conduct wildlife damage abatement.

(5) *Landowner Notifications:* If a State or Tribe must enter private property to access State and Tribal lands or waters where take is approved in their permit, the State or Tribe must obtain authorization from the private property owner.

Title of Collection: Federal Fish and Wildlife Permit Applications and Reports—Special Double-Crested Cormorants; 50 CFR part 21.

OMB Control Number: 1018–0175.

Form Numbers: FWS Forms 3–200–90 and 3–202–56.

Type of Review: New.

Respondents/Affected Public: State and/or Tribal governments.

Total Estimated Number of Annual Respondents: 711.

Total Estimated Number of Annual Responses: 711.

Estimated Completion Time per Response: Varies from 10 minutes to 16 hours, depending on activity.

Total Estimated Number of Annual Burden Hours: 4,598.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion for applications, recordkeeping, and designations of subpermittees; and annually for annual reports.

Total Estimated Annual Nonhour Burden Cost: None.

A proposed rule, soliciting comments on this collection of information for 30 days, was published on June 5, 2020 (85 FR 34578). While we received no comments pertaining to information collection in response to the proposed rule, we also solicited comments regarding the DEIS titled ''Management of Conflicts Associated with Double-crested Cormorants'' (EIS number 20200116) that was published June 5, 2020. Of the 1,047 public comments submitted in response to the proposed rule and DEIS, we received 49 comments from the following entities in response to the DEIS that address the information collection requirements:

Agency	Date submitted
Arkansas Farm Bureau Federation	July 20, 2020.
Arkansas Game and Fish Commission	July 16, 2020.
Association of Fish and Wildlife Agencies	July 17, 2020.
Attorneys for Animals, Inc	July 21, 2020.
Audubon	July 20, 2020.
Audubon Society of Portland	July 21, 2020.
Arizona Game and Fish Department	July 20, 2020.
Catfish Farmers of America	June 30, 2020.
Center for Biological Diversity	July 20, 2020.
Central Flyway Council	July 20, 2020.
Columbia River Inter-Tribal Fish Commission	July 21, 2020.
Congressional Sportsmen's Foundation	July 20, 2020.
Congressman Jack Bergman	July 21, 2020.
Finger Lakes Conservation Council	July 13, 2020.
Georgia Department of Natural Resources, Wildlife Resources Division	July 20, 2020.
Idaho Department of Fish and Game	July 20, 2020.
Kalmiopsis Audubon Society	July 20, 2020.
Leech Lake Band of Ojibwe Division of Resources Management	July 13, 2020.
Louisiana Department of Wildlife and Fisheries	July 16, 2020.
Michigan United Conservation Clubs	July 16, 2020.
Mid-Columbia Public Utility District	July 20, 2020.
Mississippi Commissioner of Agriculture and Commerce	July 20, 2020.
Mississippi Farm Bureau Federation	July 20, 2020.
Mississippi Flyway Council	July 20, 2020.
Missouri Department of Conservation	July 17, 2020.
National Aquaculture Association	July 20, 2020.
New York State Department of Environmental Conservation	July 20, 2020.
New York State Fish and Wildlife Management Board	July 21, 2020.
New York State Conservation Council, Inc	July 20, 2020.
North Dakota Game and Fish Department	July 17, 2020.
Northwest Guides and Anglers Association	July 20, 2020.
Ohio Department of Natural Resources Division of Wildlife	July 20, 2020.
Oklahoma Department of Wildlife Conservation	July 20, 2020.
Oregon Department of Fish and Wildlife	July 20, 2020.
Pacific Flyway Council	July 20, 2020.
Pacific Public Employees for Environmental Responsibility	July 15, 2020.
Pro Lake Management, LLC	July 21, 2020.
Quality Lake, Inc	July 21, 2020.
Roby, Daniel	July 21, 2020.
South Carolina Department of Natural Resources	July 20, 2020.
Texas Parks and Wildlife Department	July 20, 2020.
University of Minnesota-Twin Cities Department of Fisheries, Wildlife and Conservation Biology	July 21, 2020.
U.S. Environmental Protection Agency, Region 9	July 16, 2020.
Virginia Department of Wildlife Resources	July 21, 2020.
Washington Department of Fish and Wildlife	July 20, 2020.

Agency	Date submitted
Waterbird Society	July 20, 2020.
Wisconsin Department of Natural Resources	July 20, 2020.
World Aquaculture Society	July 20, 2020.
Wyoming Game and Fish	July 20, 2020.

As mentioned previously, we incorporate by reference comments and our responses in the 2020 FEIS associated with this rulemaking action, and address below those comments directly relevant to this rule. We arranged the comments addressing the information collections by overarching themes and provide a synopsis of the comments related to each theme, along with the Service's response to each theme, as indicated below:

Funding/Resource Concerns

Several State agencies and organizations commented on the need for funding and technical support to implement a new State-wide special permit as described in the preferred alternative. Commenters expressed concern that a new permit process would be overly burdensome to implement, which could delay cormorant control efforts and impede management success. One State agency asked how much potential new monitoring or reporting a State would have to agree to, and the amount of time and resources that would need to be invested. They expressed concern that funding of population monitoring (and monitoring of take) would be sourced from State budgets if population monitoring is stepped down to the Flyways. Another State agency stated that in order to ensure that monitoring efforts are conducted consistently, the Service should conduct population monitoring or must allocate funding to the States for monitoring. A separate State agency expressed concerns about the burden that the proposed permit will place on States to develop and maintain programs to manage allowable take (*i.e.,* population monitoring, permitting, and reporting). Similarly, another State agency cautioned that State resources are limited, while a separate State agency inquired whether States will receive financial assistance to implement the new permit. Lastly, the Mississippi and Pacific Flyway Councils also commented that Federal financial support may be needed to manage reporting and monitoring and the ability to administer a cormorant depredation program.

Agency Response to Funding/Resource Concerns: This new permit does not require a State or Tribe to process or issue any depredation permits to entities within their jurisdiction. As stated in the proposed rule and DEIS, States and Tribes would not be required to request a permit, and those entities within States or Tribes not seeking a new permit would continue to be able to apply for individual depredation permits (except those that address wild and publicly stocked fisheries). The Service's purpose and need for this action, however, is to provide the flexibility for a State or Tribe to address spatial and temporal complexity of conflicts. This is because each State and Tribe has different goals and objectives for wildlife management, and, therefore, allowances for flexibility when prioritizing allocation of authorized take must be granted. In all cases under a new permit, States and Tribes would be required to respond to questions as part of a permit application, and document all take that occurs under their permit(s), and provide the Service with a report by January 31 for activities conducted during the preceding calendar year. But the cost and means to implement permit requirements will vary based on the goals of any particular State or Tribe seeking relief from conflicts associated with cormorants. The Service cannot obligate funds to implement a new special permit at this time, nor could the Service accurately project any necessary additional funding for each State or Tribe due to the flexibility provided to them. As with the management of other migratory bird species, the Service expects costs of management to be shared among the Service, States, and Tribes.

Monitoring Plans

Several States, organizations, and individuals commented on the need for more clarity and details from the Service with regard to the development of a cormorant population monitoring program, and how adaptive management will be incorporated. Entities requested that the Service provide an outline of a cormorant population monitoring regime as a foundation for current consideration by stakeholders and as the basis for stakeholder meetings with the Service following the publication of the record of decision. These commenters also asked how much potential new monitoring or reporting a State would have to agree to, and the amount of time and resources that would need to be invested. Some State agencies and Flyway Councils provided specific recommendations for population monitoring. One State agency, for example, requested that the Service provide standardized population monitoring and reporting protocols needed to evaluate impacts of authorized take on cormorant populations, as well as criteria to be used to assess the costs and benefits of take on wild fish stocks, aquaculture facilities, human health and safety, property, and species of conservation concern. Several commenters expressed concern over any requirement that permittees gather data to assess the efficacy of take. Similarly, commenters seek to clarify on who would be required to collect any such data.

Agency Response to Monitoring Plans Concerns: The Service will work with the four Flyway Councils and partnering Federal agencies to develop agreed-upon, standardized monitoring protocols. The purpose of the monitoring protocols will be to provide scientifically defensible estimates and/or indices of double-crested cormorant population abundance, biologically allowable take, and observed take. The protocols will detail agency-specific responsibilities and estimated annual costs associated with monitoring. The Service will also produce a report every 5 years, and additionally as needed, that provides analyses from population-monitoring efforts and other status information. This report would be provided to the public to promote transparency of decision-making and evaluation of the effectiveness of this conflict-management tool. This report would include, but not be limited to: (1) Updated cormorant population status and trends; (2) reported lethal take of cormorants nationally and by cormorant population; (3) updated PTL analyses based on new or more current population information; (4) the state of the conflicts described in the scope of the rule and assessment of a need for continued management, as reported by requests for depredation permits (both individually and programmatically by participating States and Tribes); and (5) a conflict-management decision and justification for either continued

management or a proposed new management approach, if appropriate and needed. In providing clarity to potential permittees about the necessary information applicants need to provide in the application, the Service clarifies that the application does not include language that permittees gather data to assess the efficacy of take. Rather, it includes language asking the applicant to provide a description of long-term plans to eliminate or significantly reduce continued need to take cormorants. The Service encourages State and Tribal fish and wildlife agencies to coordinate with subpermittees to assess take measures that address long-term prevention of depredation where possible, and to conduct monitoring in conjunction with the Service as it develops its population monitoring plan.

Development of Guidelines

A number of State agencies recommended that the Service develop guidelines for determining when there is sufficient proof that nonlethal mechanisms are ineffective at resolving conflicts. One State agency requested that the Service provide States seeking permits with a guide or Best Management Practices on nonlethal methods of resource protection. Another State agency recommended that the Service develop and provide States with sampling protocols to assist with collecting and analyzing fish population data where cormorant control activities occur.

Agency Response to Development of Guidelines Concerns: The Service received many comments either in favor of or opposed to using nonlethal methods in all situations. Commenters cited that nonlethal methods are not effective in all cases; some may be cost-prohibitive, and some may not respond well in situations where birds may become habituated to nonlethal management. The Service agrees that harassment of cormorants may be effective in some areas, but ineffective in others. The conditions that dictate this outcome are often site-specific and variable throughout any given year. Some commenters noted that nonlethal measures may work for a limited time period, but some birds may become habituated. The Service stated in the DEIS and the FEIS that the use of nonlethal methods alone is not an effective management tool to respond to conflicts associated with cormorants, which is why the Service rejected that possible alternative in its analysis.

The Service encourages and expects continued use of nonlethal measures in conjunction with lethal measures where permittees find this approach most effective. Often, a combination of measures is the most effective way to address conflicts associated with cormorants. The Service needs to rely on permittees to make site-specific assessments and employ cormorant conflict management in a manner that makes the most sense, so long as those permittees follow the conditions of the permit. For added clarity in response to these comments, the following is a condition that would be part of any permit issued by the Service under the preferred alternative in this FEIS: States and Tribes must use nonlethal methods, and independently determine that those methods are insufficient in controlling the depredation conflict, before lethally taking double-crested cormorants. Permittees may also consult with USDA Wildlife Services for additional assistance to determine when nonlethal methods are insufficient.

Flyway Councils and Adaptive Management

Comments from the Flyway Councils indicated an interest in being involved in the development of the Service's monitoring plans. The Mississippi Flyway Council noted that they felt the 5-year monitoring plan seemed reasonable, and suggested the Service consider the participation of Flyway Councils to develop coordinated monitoring. The Central Flyway Council indicated support for developing monitoring plans, and recommended that the four Flyways contribute recommendations on reasonable take allocations. A State agency recommended the Service use the Flyway system to assist in the allocation of permitted lethal removal of cormorants, due to the pressing need to resolve cormorant conflicts across broad geographic regions.

Another State agency requested that the Service convene meetings with the Flyways and other relevant stakeholders to develop a specific cormorant population monitoring plan. The need to ensure adequate monitoring and reporting to manage take while considering the limited State resources was cited by some State agencies as well. One State agency also noted a concern for how Flyways would fund and provide resources for additional monitoring and reporting of cormorant populations and lethal take, as much of their funding comes from State budgets.

Another State agency commented suggesting that the involvement of the Flyway Council could be beneficial in the development of monitoring plans, but felt that monitoring plan development should be the extent of their involvement, since their nongame technical section has little relevant experience with the management of overabundant species. Both the Mississippi Flyway Council and a State agency in that flyway encouraged the Service to align their regulatory cycle with the Flyway Council's summer meeting to provide sufficient time for States to properly and carefully consider the Service's regulatory proposals.

The Mississippi Flyway Council recognized, supports, and appreciates that, under Alternative A, some States and Tribes in the Flyway not wishing to establish a new permit system, as well as commercial aquaculture facilities experiencing cormorant issues, have the option to apply for depredation permits under 50 CFR 21.41. Lastly, the Central Flyway Council recommended the Flyway process be used to notify the Service of which States within each Flyway will be participating in the new permit.

Two stakeholders submitted comments regarding adaptive management. One stated that the Service did not address adaptive management in the information collection. Another stated that the concept of adaptive management only appeared once in the DEIS, in reference to the perceived benefits of Alternative A allowing flexibility in a State's or a Tribe's cormorant control strategies to achieve desired fisheries benefits.

Agency Response to Flyway Council and Adaptive Management Concerns: Regarding population monitoring and adaptive management, the Service will work with the four Flyway Councils and partnering Federal agencies to develop agreed-upon, standardized monitoring protocols. The Service will make every effort to align coordination with the Flyway Councils around their meetings throughout the calendar year. The purpose of the monitoring protocols will be to provide scientifically defensible estimates and/or indices of double-crested cormorant population abundance, biologically allowable take, and observed take. The protocols will detail agency-specific responsibilities and estimated annual costs associated with monitoring. The Service will also produce a report every 5 years, and additionally as needed, that provides analyses from population-monitoring efforts and other status information. This report will be provided to the public to promote transparency of decision-making and evaluate the effectiveness of this conflict-management tool. This report will include, but not be limited to: (1) Updated cormorant population status and trends; (2) reported lethal take of

cormorants nationally and by cormorant population; (3) updated PTL analyses based on new or more current population information; (4) the state of the conflicts described in the scope of the rule and an assessment of the need for continued management, as reported by requests for depredation permits (both individually and programmatically by participating States and Tribes); and (5) a conflict-management decision and justification for either continued management or a proposed new management approach, if appropriate and needed.

Depredation/Control Orders

Several entities and State agencies commented in support of an aquaculture depredation order in conjunction with a new special State and Tribal permit addressing conflicts associated with cormorants. Some State agencies also voiced support for a new aquaculture depredation order or a new general depredation order without commenting specifically on a new State or Tribal special permit. One State agency referenced the DEIS by concluding that the environmental impacts between Alternatives A and C would be similar, and stated that Alternative C would provide greater efficacy and less administrative burden for their agency. Another commenter submitted a similar comment and voiced support for a nationwide depredation order. Other entities also commented in support of an aquaculture depredation order in general, stating that individual permits are not effective and the proposed rule does not provide a lethal take management option for commercial aquaculture facilities such as catfish farms. A State agency also commented in support of Alternative C, citing specific support for a new special State and Tribal permit and the ability for States to manage their own water resources. A nongovernmental organization commented in support of a nationwide depredation order, stating that individual depredation permits are ineffective due to the unpredictable migratory patterns of cormorants making it difficult to effectively assess where individual permits are needed.

Commenters in support of a new aquaculture depredation order suggested that this alternative would reduce the administrative and regulatory burden on the Service and the aquaculture industry, and emphasized that individual take permit applications are a significant burden for small businesses. These commenters asserted that low take limits for individual permits are sometimes arbitrarily set by regional agency offices, making these permits inefficient, and that small businesses would be required to continue to apply for individual take permits. One aquaculture farmer spoke about complications with having to apply and pay for two separate permits at two separate regional offices due to having farms in bordering States. A State agency commented in disagreement with the assertion that the requirement to track take of cormorants under Alternative A is less burdensome than for other alternatives and that reporting requirements under most alternatives could be structured to equally assess take levels.

A Tribal Commission commented in support of Alternative D, a general depredation order. They also suggested that the Service include Federal lands in this alternative in order to allow State and Tribal wildlife managers the necessary flexibility to manage cormorants effectively and efficiently for the resources that need protection. This Commission further states Alternative D is ideal to maximize flexibility in protecting out-migrating juvenile salmon and steelhead as it includes all lands where cormorants impact fisheries resources throughout the Columbia River basin.

Lastly, an industry association commented in support of the vacated depredation order, and not the depredation orders analyzed in the DEIS.

Agency Response to Depredation Order Comments: As explained in the DEIS, the Service would apply an annual maximum allowable take threshold across all the needs identified by stakeholders. The Service determined this threshold by using a Potential Take Limit (PTL) model, which uses underlying cormorant population metrics (productive rates, survival rates, etc.) to calculate an annual allowable take level. This is the same type of model used to sustainably manage some migratory game bird species (band-tailed pigeons) and take levels for species such as black vultures. By establishing an annual sustainable take threshold, and ensuring systems are in place to keep take below that threshold, the Service will implement the robust tool needed to assess the effects of take on cormorant populations to address potential legal challenges.

Under the vacated aquaculture depredation order, aquaculture facilities were required to annually report lethal cormorant control activities. This system of limited accountability and self-reporting with a year time-lag was not adequate to consistently track authorized take on a national scale. In addition to timing, the lack of reliable annual take from information under the previous depredation orders complicated our ability to assess the impacts of the orders on cormorant populations.

The Service must be capable of tracking take by all authorization mechanisms available throughout the year. Presently, however, the Service does not have the necessary process or resources to adequately monitor take under any new depredation order. This is because, unlike the use of a permit system, the Service cannot track take under a depredation order until the take has already occurred, creating a greater probability that the take will exceed the maximum limit before it is reported. To adequately track take under any new depredation order, whether that order be the vacated orders, or those analyzed in the DEIS, the Service needs to develop a mechanism that allows take to be tracked in real time, such as the Canada Goose Registration database (50 CFR 21.50). Such a tool would reduce the likelihood of exceeding the annual take threshold or reaching the annual take threshold prior to the end of the year. Additionally, a registration/tracking tool would only be effective if those using the depredation order were willing to register and report take numbers on a regular and frequent basis. Since a tracking system is not currently in place, this alternative is not ripe for decision. The Service must therefore continue to rely on individual permits for private and commercial entities.

The Service will continue to issue individual depredation permits and is not proposing to implement any new cormorant depredation orders anywhere in the United States at this time. Based on information received during the public comment period, the PTL model for the western subpopulation may not have captured complex and changing population dynamics precipitated by cormorant management in the Columbia River Estuary. To reduce the risk of over-exploiting the western subpopulation, the Service will initially limit that annual take to half the PTL in the DEIS, or 4,539 individuals. This is a maximum allowable annual take level, not a prescribed level. Based on past take of cormorants, expected take is unlikely to exceed 2,000 annually.

In regard to comments questioning which entities may remain eligible to apply for and receive individual depredation permits, the Service acknowledges this complexity and refers commenters to Table 1 in the FEIS, ''Differences In Regulatory Frameworks That Would Address Conflicts Across All Alternatives,''

which outlines how each alternative in the NEPA analysis would employ different proposed regulatory frameworks to address conflicts relating to cormorants. The preferred alternative would establish a new, optional permit that would be available to State and Tribal fish and wildlife agencies in the 48 contiguous States to manage conflicts specifically associated with cormorants. This alternative would provide State wildlife management agencies and Tribes flexibility within predefined guidelines to address conflicts caused by cormorants within their jurisdictions. As stated in the rule and NEPA analyses, States and Tribes would not be required to request a permit, and those entities within States or Tribes not seeking a new permit would continue to be able to apply for individual depredation permits (individual depredation permits would not authorize the take of cormorants to protect wild or stocked fish except when circumstances require the protection of federally listed species). Commercial aquaculture facilities would continue to have the ability to apply for individual depredation permits (50 CFR 21.41) from the Service. Regarding the individual's comment about having to apply and pay for two separate permits at two separate regional offices due to having farms in bordering States, the Service emphasizes that multiregional depredation permits will remain available for these circumstances. For example, the regional office to which a commercial aquaculture producer would apply can issue a permit for more than one State and across regional boundaries. This would require a coordination step between those two regional permit offices, which is a standard operating practice for the Service when an applicant seeks to take migratory birds from States that occur in different administrative regions.

Permit Application/Permit System

Allocation and Scope of Authorized Take: Several commenters submitted questions pertaining to how the Service would manage overall allocation of authorized take of cormorants. Generally, commenters asked how the Service would: (1) Allocate take among all existing authorizations for take, including a new State and Tribal permit; (2) account for regional take under the national permit system; and (3) determine an upper limit of take for each State. For example, two State agencies commented on the need to understand how the Service would allocate take among all authorization mechanisms. Another State agency also commented on the need for clarity on how annual take, both at the State and regional level, would be shared among the States and Tribes so that they can make informed determinations in successive years. Another State agency stated that the method by which take will be allocated across the western population is unclear from the DEIS and needs to be clarified. The Central Flyway Council requests the Service engage the four administrative flyways so they can provide recommendations to the Service on reasonable take allocation among States and flyways. One individual commented with concern that States may take the majority of the allocated take within a cormorant subpopulation's allowable take threshold within the PTL. This commenter further states that there is no structure to ensure that take for resources will be balanced (prioritization) or that a diversity of stakeholder interests will be considered.

Several State agencies and commenters voiced a need for clarity on the scope of authorized take within a new cormorant depredation permit for States and Tribes outlined in the proposed rule. Specifically, commenters requested clarity on the scope of circumstances for when take would be authorized, the geographic and temporal scope, and whether the new special permit would apply to private property owners and Species of Greatest Conservation Need (SGCN) as identified in State Wildlife Action Plans. Commenters stated that this clarity is needed to understand where and when States and Tribes can implement take of cormorants. For example, two State agencies recommended rewording ''wild and publicly stocked fish stocked by State agencies or Tribes'' to ''wild and stocked fish managed by State agencies or Tribes.'' Another separate State agency stated that a State agency may need to apply control of cormorants on public waters, which can occur in cases where a State does not own the land, and recommends the final rule language be revised from, ''Lands under the jurisdiction of the State,'' to ''Lands and/or public waters under the jurisdiction of the State.'' Similarly, another State agency sought clarification on the language used in the proposed rule, and referenced ''state or tribal lands'' and ''respective jurisdiction.''

One private entity commented that the proposed rule should not limit State cormorant control efforts to only those water bodies where impact studies have been performed, and should be revised to provide relief for water bodies with ''publicly stocked fish'' to include ''publicly accessible fisheries'' to include protection for wild fish. A State agency similarly requested that the Service provide States with standardized guidance on determining when take is warranted to support fish resources, and to reduce conflicts associated with risks to human health and safety, property, and species of conservation concern. A separate State agency commented about the scope of the conflicts, and asked if a State permit is the only way a State can address cormorant conflicts. That agency further asked about possible ramifications of opting out of the permit system, and if there will still be a mechanism by which a State can address wild fishery conflicts with cormorants.

Agency Response to Allocation and Scope of Authorized Take Comments: States and Tribes would not be required to request a permit, and those entities within States or Tribes not seeking a new permit would continue to be able to apply for individual depredation permits (except those that address wild and publicly stocked fisheries). The Service cannot yet provide the specificity requested on how the allocation of individual permits for aquaculture facilities and property owners would occur because the Service does not yet know how many States or Tribes would request the proposed new permit. However, the Service understands that States and Tribes need clarity on the Service's expectations for an acceptable level of requested take in an application for a new permit. Permittees would be restricted to maximum levels of take authorized, designed not to exceed the PTL within the subpopulation where the State or Tribe is located. This level of authorized take would depend on: (1) Which States and Tribes seek a new special permit within the same subpopulation analyzed within the PTL; (2) an assessment by Service permit staff of the available level of take each year within the specific subpopulation where the State or Tribe is located; and (3) an assessment by Service permit staff of the historical information of authorized take of cormorants due to depredation in the past. However, allocation of authorized take may be modified as conditions change once take is allowed. The Service encourages interested States and Tribes to communicate with the Service during the application process to best determine prioritization and allocation of authorized take of cormorants.

The Service appreciates the comments that the scope of where take activities could occur may be too limiting relative to the areas that States and Tribes manage for fisheries. The Service therefore revised the language in the

final rule to better encompass the lands and waters managed by State and Tribal fish and wildlife management agencies stating that, under this (special double-crested cormorant) permit, the Service authorizes State and Tribal fish and wildlife agencies to conduct lethal take of double-crested cormorants that is normally prohibited and is intended to relieve or prevent impacts from cormorants on lands or in waters managed by those agencies within their respective jurisdictions. The scope of management and take activities conducted under the permit is intended to reduce or prevent conflicts associated with cormorants for the following concerns:

1. Depredation of fish at State- and Tribal-owned or operated aquaculture facilities, including hatcheries;
2. Realized and potential impacts to human health and safety (*e.g.,* collisions of airplanes with birds, fecal contamination of urban wetlands);
3. Impacts to threatened and endangered species (as listed under the ESA and listed species identified in State- or Tribal-specific legislation as threatened or endangered) or those listed as Species of Greatest Conservation Need in State Wildlife Action Plans, where take activities to prevent depredation on aquatic Species of Greatest Conservation Need may occur only in natural or public waters;
4. Damage to State- or Tribal-owned property and assets; and
5. Depredation of wild and publicly stocked fish managed by State fish and wildlife agencies or federally recognized Tribes and accessible to the public or all Tribal members.

Permit Application/Permit System

Geographic and Temporal Scope: Some commenters inquired about the geographic scope of a new State or Tribal permit, stating that implementation of lethal control of cormorants to reduce impacts on aquaculture, wild and stocked fisheries, human health and safety, property, and species of conservation concern should be authorized at a biologically sustainable level for the Alaska, Pacific Coast, Interior, Atlantic, and Southern breeding cormorant populations. These entities commented that the scope of the new special cormorant permit would allow States and Tribes to be able to take cormorants at any location and at any time.

Agency Response to Geographic and Temporal Scope Comments: The new permit would be available to all States and federally recognized Tribes in the contiguous 48 States. The geographic scope of the new State or Tribal permit is authorized at biologically sustainable levels for each subpopulation. To ensure biological sustainability, the Service used the most recent cormorant population data available to develop the PTL model. The PTL is a biologically based model and evaluates allowable take of cormorants in the contiguous 48 States. The Service regularly uses PTL models to determine sustainable levels of take and has concluded that if this level of take were to be authorized, it would be biologically sustainable based on knowledge of cormorant population dynamics. The PTL sets the upper limit for allowable take; it is not a take prescription. The PTL limits apply to take for entire subpopulations (*i.e.,* Florida, Western, and Atlantic plus Central). The number of birds authorized for take for each subpopulation will depend on (a) the number of States that request a State permit, and (b) the number of birds each State/Tribe requests to take in order to minimize their particular conflict. Regarding the comment about the geographic scope and the inclusion of Alaska, the Service notes that the Alaska population is not included.

On the comment of taking cormorants at any location and at any time, actions under the permit may be conducted during any time of the year, unless specified otherwise in the permit's terms and conditions. Specific conditions include those pertaining to lethal take during the breeding season. Lethal take of adults during the breeding season must occur prior to hatching of eggs to avoid the loss of adults that likely would result in orphaning chicks and their ultimate death due to starvation. Adult birds may not be taken at any nest with young in it unless the take of adults addresses a human health and safety issue.

Permit Application/Permit System

Private Property Owners: Several commenters also requested the Service include provisions that allow for the lethal take of cormorants on private property, particularly to protect fish that are stocked by the landowner for their personal use. One State agency recommended that the Service include private recreational pond owners in the scope of the new permit. Some commenters voiced concerns that, if such provisions are not allowed, landowners will take matters into their own hands to protect their fish and that the presence of and depredation by cormorants on stocked fish in private ponds would negatively impact recruitment of new anglers.

Agency Response to Private Property Owners: The Service, in some instances, does allow the take of migratory birds to protect private property. Private landowners may apply for a depredation permit (50 CFR 21.41) to alleviate damage to some types of property (*i.e.,* buildings and infrastructure, vehicles and equipment, some types of vegetation). However, by policy, the Service's Migratory Bird Program does not issue permits to prevent depredation or harm to privately owned animals (*e.g.,* hobby animals, pets, or similar categories of animals) that are raised free-range or otherwise released to the wild. Numerous nonlethal means, such as harassment, use of effigies, habitat modification, and others, are available to landowners who maintain animals in natural-like environments. Regarding the comment suggesting that some landowners may unlawfully take cormorants if they do not receive authorization to do so from the Service, we recognize that this activity may occur, but we can neither prevent unlawful activity nor predict where and when unlawful activity would occur in such cases. However, landowners taking such actions would face the possibility of being cited for violations of the MBTA, as well as fines for such violations.

Permit Application/Permit System

Species of Greatest Conservation Need (SGCN): Several State agencies also commented on the need to include conflicts related to SGCN as identified in State Wildlife Action Plans. Because not all States have State-designated lists of threatened and endangered species within their State, some State agencies recommended that the language of the rule be changed to ''state or tribal species of greatest conservation need,'' in reference to lists created for State Wildlife Grants. Similarly, another State agency recommended greater flexibility for State fish and wildlife agencies to authorize take to protect SGCN species. Another agency stressed in the comments responding to the DEIS and the ANPR that, when determining priority and allocation of allowable take of cormorants, the protection of special-status resources should have first priority. The Central Flyway Council stated that the final rule should include conflicts related to SGCN as identified in State Wildlife Action Plans in the scope of the new special permit.

Agency Response to SGCN Comments: With regard to Species of Greatest Conservation Need as identified in State Wildlife Action Plans, the Service agrees. One of the stated needs for action is to address impacts from cormorants on special status species. Impacts may involve competition for

nest sites, competition for food, reducing available nesting space and nesting material for co-nesting species, habitat degradation, and nest abandonment resulting from habitat degradation. Therefore, the Service included new language within the scope of the preferred alternative, which now states, ''listed species identified in State- or Tribal-specific legislation as threatened or endangered) or those listed as Species of Greatest Conservation Need in State Wildlife Action Plans, where take activities to prevent depredation on aquatic Species of Greatest Conservation Need may occur only in natural or public waters.''

Reporting Requirements

Several stakeholders inquired as to the specific requests for information required in a new special permit. Commenters also expressed concern regarding the Service's commitment to producing a report every 5 years. One nongovernmental organization asserted that the Service's reporting plan is inadequate as it will produce a report providing analysis of population monitoring efforts only every 5 years, and instead recommends it be done annually. Regarding reporting by permittees, both the Central Flyway Council and a State agency recommended authorization of a 5-year State and Tribal permit with annual reporting requirements, to provide the Service with timely data regarding take while reducing the Service's staff time needed to process annual permit renewals. The Central Flyway Council recommended annual reporting of control activities conducted under each permit, similar to what was required in the past, and a periodic cormorant population assessment at a decadal interval while encouraging the Service to explore the efficacy of existing monitoring programs. Another State agency suggested commercial aquaculture facilities and private landowners be required to report annually, at a minimum, and noted that issuing annual permits provides accurate and timely reporting to maintain compliance with permit provisions. Separately, another State agency recommended that the Service provide detailed criteria regarding the annual reporting requirements.

The Central Flyway Council opined that increased reporting requirements and intensive monitoring of cormorant populations would be difficult for many State wildlife agencies, given limited personnel and budget constraints. One State agency in that flyway requested clarification on how much potential new monitoring or reporting a State would have to agree to, and the amount of time and resources that would need to be invested.

Both the Pacific Flyway Council and a State agency in that flyway stressed the importance that any expectation of monitoring and reporting needed to implement the proposed new permit system must be backed with a robust program of Federal funding to support the duration of the monitoring activities. The Pacific Flyway Council also noted a concern that the costs of permit management, reporting, and monitoring will detract from other species conservation work, which is already difficult due to limited funding. A separate State agency commented with concern for the burden that the proposed permit will place on States to develop and maintain programs to manage allowable take (*i.e.,* population monitoring, permitting, and reporting). One private entity questioned whether the requirement to provide information to evaluate control efforts could become so complex and cumbersome that it curtails action, citing the information collected for a considerable amount of time by State agency wildlife professionals.

A State agency requested clarification of the Service's expectations with regards to permitting, monitoring, and reporting requirements on waters managed by private landowners. Another State agency noted that it does not desire the authority to issue take permits to other entities within their State to address aquaculture conflicts, property damage, nuisance, or human safety issues. Another State agency noted that the renewal of subpermittee authority would be conditional on timely and accurate reporting, and recommended that steps be taken to ensure data collection is timely, accurate, and complete by all persons authorized to take cormorants (offering a comparison to the Resident Canada Goose Nest and Egg Depredation Order under 50 CFR 21.50 (OMB Control No. 1018–0146)).

Separately, one State agency requested that the Service provide standardized population monitoring and reporting protocols needed to evaluate impacts of authorized take on cormorant populations, as well as criteria to be used to assess the cost and benefit of take on wild fish stocks, aquaculture facilities, human health and safety, property, and species of conservation concern. Another State noted their assumption that, under a special permit, the prioritization of issued take ultimately would be the responsibility of the respective State fish and wildlife agencies or Tribes to manage accordingly, including reporting. Yet another State opined that the reporting requirements for the proposed permit system are unclear.

Agency Response to Reporting Requirements Concerns: The Service will require, as part of receiving a permit, an annual report that must be submitted by January 31st each year. The annual report requires the permittee to include location of take (GPS coordinates in decimal degrees), purpose of take (aquaculture, health, threatened or endangered species, property, stocked fish), nonlethal methods implemented, month taken, quantity taken (birds killed, nests oiled/addled, and nests destroyed), and disposition of carcass (*e.g.,* buried, incinerated, donated).

Given the controversial nature of this issue and the novel approach toward reducing conflicts, the Service concludes annual permits and annual reporting by permittees are appropriate at this time. As we gain experience with this program, the Service could consider permits of longer duration, but additional NEPA analyses may be required for any additional rulemaking procedures or amendments.

Take of cormorants will be compiled annually and information can be made available if needed prior to completion of the 5-year reports. However, as with any bird population monitoring efforts, variation throughout the year, due largely to sampling error, can be quite high. The Service concludes that assessing population status over a 5-year period will avoid inappropriate decisions based on observed, but not necessarily real, annual changes in abundance, and still be sufficient to ensure sustainable populations of cormorants.

The new special permit would not apply to private landowners. Private property owners may apply for a depredation permit (50 CFR 21.41) to the Service to alleviate damage to some types of property (*i.e.,* buildings and infrastructure, vehicles and equipment, and some types of vegetation).

Designation of Subpermittees

Several commenters requested clarity about who a State or Tribe may delegate authority to as a subpermittee under a new permit to conduct take of cormorants. One State recommended that the Service allow willing States and Tribes to issue permits to subpermittees, with the subpermittee's renewal authority conditional on timely and accurate reporting. Another State agency requested clarity on the level of authority given by a State or Tribe to carry out lethal take, asking if this

would be limited to only State agency personnel, or other private and public entities or persons as authorized by States. For example, one State commented that the language related to subpermittees should read, ''Subpermittees may be, but are not limited to, employees of state and tribal wildlife agencies, Wildlife Services employees, and employees of federal and state agencies or private companies specializing in wildlife damage abatement.'' Some commenters opined that the Service should define the level of training and control needed to ensure people operate in a humane, accountable, and lawful manner.

Agency Response to Designation of Subpermittees Concerns: The Service agrees with the need to provide further clarification of the role that subpermittees may play, and to identify who can operate as a subpermittee pursuant to a permit issued under this rule. The final rule states that subpermittees ''can be employees of State and Tribal wildlife agencies, USDA Wildlife Services employees, and employees of Federal and State agencies or private companies specializing in wildlife damage abatement and under direct control of the permittee.'' The Service is limiting subpermittees to these entities because in some areas other cormorant species and look-alike species (*e.g.,* anhingas) can overlap in specific ranges and habitats with double-crested cormorants. Professional biologists and trained experts are more likely to be able to differentiate between these species and reduce the possibility of taking nontarget species.

There are many levels of training that vary widely across the country that may be appropriate. The Service will not identify specific training requirements necessary to become a subpermittee. Rather, we expect that the categories of individuals listed above will have the skills, or could readily acquire the skills, to accurately identify double-crested cormorants and differentiate other look-alike species to avoid taking them. Further, by virtue of their positions, we expect that all such employees will operate in a humane, accountable, and lawful manner. The authority to take double-crested cormorants conferred by the permit is given to the State or Tribal fish and wildlife agency, and those agencies may designate permittees that the Service approves on the application for the permit. To provide added clarity, the Service included as part of the application for a new permit that permittees must agree that, ''(e) Anyone taking birds under this permit must be skilled in double-crested cormorant identification. Nontarget take of any other avian species must be reported to your permit office with your annual report including species, number, and description of events.'' The application for this permit can be found in Appendix H of the FEIS, and we cross-reference the FEIS for additional comments and responses on this issue not directly related to this rulemaking. Further, any birds incidentally taken would be reported by States and Tribes, and the Service would use this data to better track accidental take of these species when take of cormorants occurs, and recommend appropriate actions such as additional training of personnel, or avoiding areas where there is a high concentration of non-target species in the area.

General Comments

Some entities commented that the Service would need to ensure that current depredation permits for take of cormorants continue to be issued under 50 CFR 21.41, as population levels allow. These commenters stated that depredation permits are essential to manage the effects of increased double-crested cormorant populations on migrating salmon and steelhead smolts. One State agency requested clarity on which entities remain eligible to receive individual depredation permits for those States that do choose to obtain a special statewide depredation permit, noting that they do not desire the authority to issue take permits to other entities within their State to address aquaculture conflicts, property damage, nuisance, or human safety issues. This particular State agency requested the preferred alternative include a specific statement affirming the continued availability of individual depredation permits for entities within States that choose to obtain a special depredation permit. Another State agency requested clarification on how the Service will account for the illegal take of cormorants. This State agency also inquired as to whether they should apply for and receive 150 permits. They ask if it is possible for the Service to consider a higher level of take (150 permits) under Alternative E for hatcheries to correspond to the higher level of authorized take, or the maximum allowable take, in Alternatives A–D. This State asserts that they operate four State-owned hatcheries, where fingerlings are raised for stocking public water bodies for the enjoyment and recreational use of fisheries resources by the public. The current number of depredation permits allocated to this State appears to be helpful in reducing fingerling depredation and pond liner damage, but not adequate to prevent still significant losses to production and facilities. Therefore, this particular State requested 150 cormorant depredation permits, regardless of the management alternative selected, to better manage cormorant populations at its State hatchery facilities.

Some commenters stated that the Service failed to address the cumulative impacts of climate change and other cormorant take, and should therefore evaluate the cumulative impact of other cormorant take, such as the planned hunting seasons in Ontario, Canada.

Agency Response to General Comments Concerns: Individual permits would still be available to address some depredation activities. However, conflicts associated with cormorants and wild or publicly stocked fish would only be addressed through the special cormorant permit, which would only be available to fish and wildlife agencies of States and federally recognized Tribes in the contiguous 48 States. Entities other than private landowners who want to reduce depredations of fish in their private ponds may be eligible to apply for permits other than the special cormorant permit.

The PTL estimate considers all forms of take and is conservative in that the lower 60 percent confidence interval of the PTL was used. However, in the NEPA analyses where comparisons are made to historical take data, historical take only included legal take. The Service was not able to include data relating to any potential illegal take of cormorants in the PTL. This is because the Service does not have the ability to adequately track where and when individuals might illegally take cormorants. If in the future the Service is sufficiently able to track and monitor illegal take across the broad geographic scale represented in the PTL, then this data can be counted against PTL. If illegal take is substantial, however, then this factor should also become an enforcement issue in the management of cormorants.

The Service encourages the State and Tribal agencies to seek a new permit under this final rule to accomplish its goals, as that permit would be less costly, but also sufficient for a State or Tribe to meet its needs. Permits under this rule will provide the flexibility to State and Tribal fish and wildlife agencies to address conflicts related to the following issues: Wild and publicly stocked fish managed by State fish and wildlife agencies or federally recognized Tribes; Tribal- and State-owned or operated aquaculture facilities (including hatcheries); human health

and safety; State- or Tribal-owned property and assets; and threatened and endangered species or those listed as Species of Greatest Conservation Need in State Wildlife Action Plans. If a State or Tribe determines a permit under this rule would meet their needs, upon receiving the permit, that State or Tribe would have the discretion to determine whether, when, where, and for which of the above purposes they conduct lethal take within limits and allocations set by the Service.

The Service used population data from Canada in the subpopulation estimates, and will work closely with Ontario on population monitoring and obtain take data and incorporate it into our assessments. Our DEIS discussed climate change, and we noted that there remains some uncertainty regarding effects of climate change, but the Service can estimate that there will likely be less water available in the Great Basin, and cormorant colonies may shift locations. Cormorants may be able to stay and forage longer in northern portions of the Interior and Atlantic subpopulations, and it is possible that breeding seasons may lengthen. The Service makes decisions given this uncertainty by using the data and modeling available and adapting through time as change occurs. The planned 5-year assessment will address this issue.

Impact on Small Businesses

The U.S. Small Business Administration (SBA) commented in support of an aquaculture depredation order in combination with a new special permit for States and Tribes. SBA stated that, prior to the previous aquaculture depredation order being vacated, commercial aquaculture producers were able to manage cormorant populations while not exceeding the allowable take limits established by the Service. SBA further stated that this rulemaking has the potential to increase costs to small private aquaculture facilities that are not otherwise able to employ effective methods of controlling cormorant damage and that have seen and may well continue to see an increase in cormorant feeding. SBA further stated that individual depredation permit applications are a significant burden for small businesses, citing lower take limits for cormorants and complications among Service regions in issuing permits. SBA stated that an aquaculture depredation order would eliminate these burdensome and time-consuming application requirements. SBA also cautioned that the Service should not require documentation of revenue increases as part of any new aquaculture depredation order, as this would result in additional administrative costs associated with recordkeeping. SBA recommended that the Service consider other sources of data, and methods of data collection other than reporting increased revenue data, to measure the success of conflict management programs. SBA urged the Service to consult with industry directly to devise a cost-effective and more accurate method of data collection.

Agency Response to Impact on Small Businesses Concerns: This collection associated with the new permit affects only State and Tribal governments, and does not impact small businesses. Commercial entities, such as privately managed aquaculture facilities, would continue to have the opportunity to apply for individual depredation permits to address site-specific conflicts. Information collection requirements associated with individual depredation permits are outside the scope of this rulemaking.

In response to comments about a new aquaculture depredation order, we reference our response above. The Service must be capable of tracking take by all authorization mechanisms available throughout the year. Presently, however, the Service does not have the necessary process or resources to adequately monitor take under any new depredation order. However, the Service established a new, higher threshold for annual maximum allowable take using the most recent biological information. While the Service is best equipped to accurately monitor the authorized and actual take of cormorants throughout the year under preferred Alternative A (the new State and Tribal permit in this final rule), a higher threshold for annual take will still yield benefits to the aquaculture industry and others in need of individual depredation permits. These benefits result from indirect effects on cormorant populations from a higher threshold of authorized take, and the resulting lower cormorant populations projected in the EIS. The new special cormorant permit would be optional and available to State and Tribal fish and wildlife agencies in the 48 contiguous States to manage conflicts specifically associated with cormorants. This permit would provide State wildlife management agencies and Tribes flexibility within predefined guidelines to address conflicts caused by cormorants within their jurisdictions. The new permit coupled with the continued use of individual depredation permits for commercial aquaculture producers would provide the accountability and flexibility to manage cormorants while ensuring populations are managed sustainably and take is authorized in an equitable fashion across multiple conflicts.

Comments Requested

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on any aspect of this information collection, including:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this 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) How the agency might 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 response.

Written comments and recommendations for the information collection should be sent within 30 days of publication of this document to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Please provide a copy of your comments to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, MS: PRB (JAO/3W), Falls Church, VA 22041–3803 (mail); or *Info_Coll@fws.gov* (email). Please reference OMB Control Number 1018–0175 in the subject line of your comments.

National Environmental Policy Act

We evaluated this regulation in accordance with the criteria of NEPA, the Department of the Interior regulations on implementation of NEPA (43 CFR 46.10–46.450), and the Department of the Interior Manual (516 DM 8). On June 5, 2020, the Service published a DEIS, and the comment period ended on July 20, 2020. You may review the comments received at the Federal eRulemaking Portal: *http://www.regulations.gov* in Docket No. FWS–HQ–MB–2019–0103. We considered comments on the DEIS when developing this final rule, and a summary of the comments is included in the FEIS associated with this

rulemaking action. The Service initiated development of the FEIS prior to the establishment of updated Council on Environmental Quality regulations on September 14, 2020, and, therefore, the FEIS is written to comply with the previous regulations. You may review the DEIS, FEIS, and the comments received at the Federal eRulemaking Portal: *http://www.regulations.gov* in Docket No. FWS–HQ–MB–2019–0103. We will issue a record of decision no sooner than 30 days after the Environmental Protection Agency publishes notice of the FEIS in the **Federal Register**.

Compliance With Endangered Species Act Requirements

Section 7 of the ESA (16 U.S.C. 1531–44) requires that ''The Secretary [of the Interior] shall review other programs administered by him and utilize such programs in furtherance of the purposes of this Act'' (16 U.S.C. 1536(a)(1)). It further states that ''[e]ach Federal agency shall, in consultation with and with the assistance of the Secretary, insure that any action authorized, funded, or carried out by such agency . . . is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of [critical] habitat.'' We have complied with provisions of the ESA as necessary to ensure that this new regulation is not likely to jeopardize the continued existence of any species designated as endangered or threatened or destroy or adversely modify its critical habitat.

Government-to-Government Relationship With Tribes

In accordance with Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments,'' and the Department of the Interior's manual at 512 DM 2, we have considered the possible effects of this rule on federally recognized Indian Tribes. The Department of the Interior strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation when appropriate and recognition of their right to self-governance and Tribal sovereignty. We readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. We evaluated this rule under the criteria in Executive Order 13175 and under the Department's Tribal consultation policy and have determined that this rule may have a substantial direct effect on federally recognized Indian Tribes.

In February we held four public scoping webinars and then two webinars only for Tribal members (February 19 and 27, 2020). We provided the attendees of all the webinars with information on the following topics regarding cormorants, their management, and the regulations process: (1) Biology and population changes; (2) background of the issues and previous management approaches; (3) current management of conflicts; (4) proposed approaches and alternatives; and (5) the planning process for the NEPA analysis. We also informed attendees that they could provide comments on the proposed actions and the scope of the NEPA review via a website or by U.S. mail or hand-delivery. Two Tribal entities provided comments, and they have been addressed in this final rule. No formal requests for government-to-government consultations were submitted in response to this rulemaking.

Energy Supply, Distribution, or Use (E.O. 13211)

E.O. 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. This rule is not a significant regulatory action under E.O. 13211 and would not significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action. No Statement of Energy Effects is required.

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List of Subjects in 50 CFR Part 21

Exports, Hunting, Imports, Reporting and recordkeeping requirements, Transportation, Wildlife.

Regulation Promulgation

For the reasons described in the preamble, we hereby amend part 21 of subchapter B, chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 21—MIGRATORY BIRD PERMITS

■ 1. The authority citation for part 21 continues to read as follows:

Authority: 16 U.S.C. 703–712.

■ 2. Add § 21.28 to read as follows:

§ 21.28 Special double-crested cormorant permit.

(a) *What is the special double-crested cormorant permit, and what is its purpose?* The special double-crested cormorant permit is a permit issued by the Service to State or Tribal fish and wildlife agencies that authorizes specific take activities that are normally prohibited and are intended to relieve or prevent impacts from cormorants on lands or in waters managed by those agencies and within those agencies' jurisdiction. We will issue such a permit only when we determine that an application submitted by a State or Tribal fish and wildlife agency meets the requirements set forth in paragraph (c) of this section. The take activities conducted under the permit are intended to reduce or prevent conflicts associated with cormorants for the following concerns:

(1) Depredation of fish at State- and Tribal-owned or operated aquaculture facilities, including hatcheries;

(2) Realized and potential impacts to human health and safety (*e.g.,* collisions of airplanes with birds, fecal contamination of urban wetlands);

(3) Impacts to threatened and endangered species (species listed under the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and species identified in State- or Tribal-specific legislation as threatened or endangered) or those listed as Species of Greatest Conservation Need in State Wildlife Action Plans, where take activities to prevent depredation on aquatic Species of Greatest Conservation Need may occur only in natural or public waters;

(4) Damage to State- or Tribal-owned property and assets; and

(5) Depredation of wild and publicly stocked fish managed by State fish and wildlife agencies or federally recognized Tribes and accessible to the public or all Tribal members.

(b) *Who may receive a permit?* Only State and Tribal fish and wildlife agencies are eligible to receive a permit to undertake management and take activities. Additionally, only employees or subpermittees of a permitted State or Tribal fish and wildlife agency designated on the permit application may undertake activities for double-crested cormorants in accordance with the conditions specified in the permit, conditions specified in 50 CFR part 13, other requirements set forth in this section, and conditions specified in paragraph (d) of this section.

(c) *How does a State or Tribe apply for a permit?* Any State or federally recognized Tribal fish and wildlife agency wishing to obtain a permit must submit an application (FWS Form 3–200–90) to the appropriate Regional Director (see § 13.11(b) of this subchapter) containing the general information and certification required by § 13.12(a) of this subchapter plus the following information:

(1) A description of your State's or Tribe's double-crested cormorant conflicts, including physical location(s) and type of conflict specified in paragraph (a) of this section;

(2) A detailed description of the nonlethal methods (*i.e.,* active hazing, passive hazing, habitat management, and changes in management practices) you have and/or will implement and how take activities will address one or more of the issues specified in paragraph (a) of this section;

(3) The requested annual take of double-crested cormorants by life-stage, including eggs and nests;

(4) A description of long-term plans to eliminate or significantly reduce continued need to take double-crested cormorants;

(5) A statement indicating that the State or Tribe will inform and brief all employees and subpermittees of the requirements of these regulations and permit conditions;

(6) A list of all subpermittees who may conduct activities under the special double-crested cormorant permit, including their names, addresses, and telephone numbers; and

(7) The name and telephone number of the individual in your agency who will oversee the double-crested cormorant management activities authorized under the permit.

(d) *What are the conditions of the permit?* The special double-crested cormorant permits are subject to the conditions specified in the permit, the general conditions in 50 CFR part 13, and other requirements set forth elsewhere in this section, and, unless otherwise specifically authorized on the permit, the following conditions:

(1) *What are the limitations on management and take activities?* Take of double-crested cormorants under this section may not exceed the number authorized by the permit. In addition, permittees must adhere to these provisions:

(i) States and Tribes must implement nonlethal methods, and independently determine that those methods are insufficient at resolving depredation conflicts, before taking double-crested cormorants.

(ii) A permit under this section does not authorize the take of any other migratory bird, including other species of cormorants; the take of bald or golden eagles; or the take of any species federally listed as threatened or endangered. If take of those species is likely to occur, the permittee must obtain permits specifically authorizing that take (*i.e.,* permits under the Migratory Bird Treaty Act, Bald and Golden Eagle Protection Act, or the Endangered Species Act of 1973, as amended).

(iii) Methods of take for double-crested cormorants are at the State's or Tribe's discretion. Take of double-crested cormorants may occur by means of humane lethal take or active nest take. Lethal take of adults during the breeding season should occur prior to hatching of eggs. Adult birds may not be taken at any nest with young in it unless the take of adults addresses a human health and safety issue. States and Tribes and their subpermittees must make efforts to avoid disturbance to co-nesting species. Lethal take may occur by firearm in accordance with paragraph (d)(1)(iv) of this section or lethal or live traps. Active nest take may occur by egg oiling or destruction of nest material and contents (including viable eggs and chicks). Birds may be euthanized by cervical dislocation, CO_2 asphyxiation, or other methods recommended by the American Veterinary Medical Association. Only 100 percent corn oil, a substance exempted from regulation by the Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act, may be used to oil eggs. Other damage control methods of take consistent with accepted wildlife damage management programs may be authorized.

(iv) Take using firearms (other than an air rifle or air pistol) must use nontoxic shot or nontoxic bullets (see § 20.21 of this subchapter).

(v) Individuals conducting lethal take activities may not use decoys, calls, or other devices or bait to lure birds within gun range.

(vi) States and Tribes applying for the first time must consult with the U.S. Department of Agriculture's Wildlife Services for an assessment of the appropriate level of take and provide recommendations of short-term measures to provide relief from depredation and long-term measures to help eliminate or significantly reduce conflicts. First-time applicants must include a completed ''Form 37 Permit Review'' from Wildlife Services.

Permittees need not submit a Form 37 for renewal applications unless requested by the regional Migratory Bird Permit Office. Permittees should continue working with Wildlife Services for review of conflict management approaches and anticipated level of take, and to remain current on effective strategies for nonlethal removal.

(2) *When may a State or Tribe conduct management and control activities?* Actions may occur only when cormorants are committing or are about to commit depredations. State and Tribal employees and approved subpermittees may conduct management activities, including lethal take, at any time of year.

(3) *How must States and Tribes dispose of or utilize cormorants taken under this permit?* Unless otherwise authorized on your permit, double-crested cormorants taken under this permit may be temporarily possessed and transported for the purposes of disposal under the regulations in this section. Double-crested cormorants must be disposed of by donation to an entity authorized by permit or regulation to receive migratory birds, such as a public museum or public institution for scientific or educational purposes, or be destroyed completely by burial or incineration in accordance with Federal, State, and/or local laws and ordinances. States, Tribes, their employees, and subpermittees may not sell, offer for sale, barter, or ship for the purpose of sale or barter any double-crested cormorants taken under this section or their parts or eggs. Birds may not be retained for personal use.

(4) *How does the permit relate to existing State and Tribal law and Federal land?* Permits under this section do not authorize the take of double-crested cormorants contrary to any State or Tribal laws or regulations or on any Federal land without specific written authorization by the responsible management agency. Prior to taking double-crested cormorants pursuant to a permit under this section, the permittee must obtain any permits required by State, Tribal, or other Federal law or regulation.

(5) *How will the Service ensure that persons conducting control activities have the authority to do so?* Any State or Tribal employee or approved subpermittee authorized to carry out management and take activities must have a copy of the permit and, if appropriate, the subpermittee's designation in their possession when carrying out any activities. The scope of this permit applies to lands or in waters managed by State and Tribal fish and wildlife agencies and within those agencies' jurisdictions. If a State or Tribe must enter private property to access State and Tribal lands or waters where take is approved in their permit, the State or Tribe must obtain authorization from the private property owner, and require that the private property owner or occupant provide free and unrestricted access. The private property owner or occupant should also allow access at all reasonable times, including during actual operations, to any Service special agent or refuge officer, State or Tribal wildlife or deputy wildlife agent, warden, protector, or other wildlife law enforcement officer on the premises where they are, or were, conducting activities. Furthermore, any State or Tribal employee or approved subpermittee conducting such activities must promptly furnish information concerning such activities to any such wildlife officer.

(6) *What are the reporting requirements of the permit?* Any State or Tribal agency, when exercising the privileges of this permit, must keep records of all activities, including those of subpermittees, carried out under the authority of the special permit, including the number of double-crested cormorants taken and their disposition. Any other species of bird taken incidentally to double-crested cormorant management activities under this permit, along with the numbers of birds taken of those species, also must be reported. The State or Tribe must submit an annual report (FWS Form 3–202–56) detailing activities and purpose for take, including the date birds were taken, numbers, and locations and life stage of birds, eggs, and nests taken and nonlethal techniques utilized, by January 31 for activities conducted during the preceding calendar year. The State or Tribe must submit the annual report to the appropriate Migratory Bird Permit Office (*see* § 2.2 of this subchapter).

(7) *What are the limitations of this permit?* The following limitations apply:

(i) Nothing in this section applies to any Federal land within a State's or Tribe's boundaries without written permission of the Federal agency with jurisdiction.

(ii) We will issue permits only to State and Tribal fish and wildlife agencies in the conterminous (*i.e.,* contiguous 48) United States.

(iii) States and Tribes may designate subpermittees who must operate under the conditions of the permit. Subpermittees can be employees of State and Tribal fish and wildlife agencies, U.S. Department of Agriculture's Wildlife Services employees, employees of other Federal, State, or Tribal agencies, or private companies licensed to conduct wildlife damage abatement and under direct control of the permittee.

(iv) A special double-crested cormorant permit issued or renewed under the regulations in this section expires on the date designated on the face of the permit unless it is amended or revoked, or at such time we determine that conflicts with cormorants within the bounds of the specific population of double-crested cormorants have been reduced to the point where lethal take is no longer necessary. In all cases, the term of the permit may not exceed 1 year from the date of issuance or renewal.

(v) We reserve the right to suspend or revoke any permit, as specified in §§ 13.27 and 13.28 of this subchapter.

(e) *What are the OMB information collection requirements of the permit program?* OMB has approved the information collection requirements of the permit and assigned OMB Control Number 1018–0175. Federal agencies 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. Direct comments regarding the burden estimate or any other aspect of the information collection to the Service's Information Collection Clearance Officer at the address provided at 50 CFR 2.1(b).

George Wallace,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2020–28742 Filed 12–28–20; 8:45 am]

BILLING CODE 4333–15–P

Proposed Rules

Federal Register
Vol. 85, No. 249
Tuesday, December 29, 2020

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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–1030; Project Identifier AD–2020–01079–T]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain The Boeing Company Model 777–300ER series airplanes. This proposed AD was prompted by a report that a production design change to certain insulation blankets inadvertently opened up leakage paths for halon and smoke to escape from the aft cargo compartment in the event of a fire. This proposed AD would require installation of an insulation blanket assembly on top of existing insulation blankets, in certain areas of the forward endwall in the aft cargo compartment. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by February 12, 2021.

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

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* 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 to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1030.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1030; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Susan L. Monroe, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3570; email: *susan.l.monroe@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to participate in this rulemaking by submitting written comments, data, or views about this proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one copy of the comments. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2020–1030; Project Identifier AD–2020–01079–T'' at the beginning of your comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments received by the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this NPRM because of those comments.

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 NPRM 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 NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Susan L. Monroe, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3570; email: *susan.l.monroe@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Discussion

The FAA has received a report indicating that a production design change to certain insulation blankets inadvertently opened up leakage paths for halon and smoke to escape from the aft cargo compartment. This condition, if not addressed, could, in the event of a fire, result in loss of fire suppressant in the cargo compartment, and could lead to an uncontained fire and subsequent loss of the airplane.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Special Attention Requirements Bulletin 777–25–0753 RB, dated July 31, 2020. This service information describes procedures for installing an insulation blanket assembly on top of existing insulation blankets, on the left and right side corner of the forward endwall in the aft cargo compartment. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

The FAA is proposing this AD because the agency evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishment of the actions identified in Boeing Special Attention Requirements Bulletin 777–25–0753 RB, dated July 31, 2020, described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

For information on the procedures and compliance times, see this service information at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1030.

Explanation of Requirements Bulletin

The FAA worked in conjunction with industry, under the Airworthiness Directive Implementation Aviation Rulemaking Committee (AD ARC), to enhance the AD system. One enhancement is a process for annotating which steps in the service information are ''required for compliance'' (RC) with an AD. Boeing has implemented this RC concept into Boeing service bulletins.

In an effort to further improve the quality of ADs and AD-related Boeing service information, a joint process improvement initiative was worked between the FAA and Boeing. The initiative resulted in the development of a new process in which the service information more clearly identifies the actions needed to address the unsafe condition in the ''Accomplishment Instructions.'' The new process results in a Boeing Requirements Bulletin, which contains only the actions needed to address the unsafe condition (*i.e.,* only the RC actions).

Costs of Compliance

The FAA estimates that this proposed AD affects 22 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Insulation blanket installation	1 work-hour × $85 per hour = $85	$240	$325	$7,150

According to the manufacturer, some or all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected individuals. As a result, the FAA has included all known costs in the cost estimate.

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect 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.

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2020–1030; Project Identifier AD–2020–01079–T.

(a) Comments Due Date

The FAA must receive comments by February 12, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 777–300ER series airplanes, certificated in any category, as identified in Boeing Special Attention Requirements Bulletin 777–25–0753 RB, dated July 31, 2020.

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/Furnishings.

(e) Unsafe Condition

This AD was prompted by a report that a production design change to certain insulation blankets inadvertently opened up

leakage paths for halon and smoke to escape from the aft cargo compartment in the event of a fire. The FAA is issuing this AD to address increased leakage paths, which, in the event of a fire, could result in loss of fire suppressant in the cargo compartment, and could lead to an uncontained fire and subsequent loss of the airplane.

(f) Compliance

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

(g) Required Actions

Except as specified by paragraph (h) of this AD: At the applicable times specified in the ''Compliance'' paragraph of Boeing Special Attention Requirements Bulletin 777–25–0753 RB, dated July 31, 2020, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Special Attention Requirements Bulletin 777–25–0753 RB, dated July 31, 2020.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by this AD can be found in Boeing Special Attention Service Bulletin 777–25–0753, dated July 31, 2020, which is referred to in Boeing Special Attention Requirements Bulletin 777–25–0753 RB, dated July 31, 2020.

(h) Exceptions to Service Information Specifications

Where Boeing Special Attention Requirements Bulletin 777–25–0753 RB, dated July 31, 2020, uses the phrase ''the original issue date of the Requirements Bulletin 777–25–0753 RB,'' this AD requires using ''the effective date of this AD.''

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(j) Related Information

(1) For more information about this AD, contact Susan L. Monroe, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3570; email: *susan.l.monroe@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued on November 13, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–28824 Filed 12–28–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–1028; Project Identifier AD–2020–00978–T]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all The Boeing Company Model 717–200 airplanes. This proposed AD was prompted by a report of discrepant spoiler assemblies, which have the wrong splice bar installed and lack reinforcing doublers. This proposed AD would require a one-time inspection of the left- and right-wing inboard and outboard spoiler assemblies for the correct splice bar and doublers configuration, and repair if necessary. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by February 12, 2021.

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

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* 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 to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1028.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1028; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Mohit Garg, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5264; fax: 562–627–5210; email: *mohit.garg@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to participate in this rulemaking by submitting written comments, data, or views about this proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one copy of the comments. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2020–1028; Project Identifier AD–2020–00978–T at the beginning of your comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments received by the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this NPRM because of those comments.

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 NPRM 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 NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to the person identified in the **FOR FURTHER INFORMATION CONTACT** section. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Discussion

The FAA has received a report of discrepant spoiler assemblies, which have the wrong splice bar installed and lack reinforcing doublers. These two features were introduced to meet fail-safe requirements. The splice bar, unique to the Boeing Model 717 airplane, features the capability to minimize uncommanded spoiler float in the event of a spoiler drive connection failure. The Boeing Model 717 airplane design utilizes a back-up to the hold-down actuator. The drive link in the spoiler operating mechanism features hooks that are designed to engage the splice bar when the spoiler unintentionally rises. In normal operation, the hooks of the drive link never contact the splice bar. Although the incorrect spoilers with no reinforcing doublers and an incorrect splice bar do not affect the strength requirements of the spoiler under normal conditions, an incorrect splice bar is not structurally adequate to support the spoiler drive link hook fail-safe load condition. This condition, if not addressed, could lead to failure of the splice bar to keep the spoiler drive link engaged, and could result in spoiler float and consequent reduced controllability of the airplane.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Alert Requirements Bulletin 717–57A0027 RB, dated June 26, 2020. This service information describes procedures for a one-time general visual inspection of the left- and right-wing inboard and outboard spoiler assemblies for the correct splice bar and doublers configuration, and repair. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

The FAA is proposing this AD because the agency evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishment of the actions identified in Boeing Alert Requirements Bulletin 717–57A0027 RB, dated June 26, 2020, described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

For information on the procedures and compliance times, see this service information at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1028.

Explanation of Requirements Bulletin

The FAA worked in conjunction with industry, under the Airworthiness Directive Implementation Aviation Rulemaking Committee (AD ARC), to enhance the AD system. One enhancement is a process for annotating which steps in the service information are ''required for compliance'' (RC) with an AD. Boeing has implemented this RC concept into Boeing service bulletins.

In an effort to further improve the quality of ADs and AD-related Boeing service information, a joint process improvement initiative was worked between the FAA and Boeing. The initiative resulted in the development of a new process in which the service information more clearly identifies the actions needed to address the unsafe condition in the ''Accomplishment Instructions.'' The new process results in a Boeing Requirements Bulletin, which contains only the actions needed to address the unsafe condition (*i.e.,* only the RC actions).

Costs of Compliance

The FAA estimates that this proposed AD affects 114 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	4 work-hours × $85 per hour = $340	$0	$340	$38,760

The FAA estimates the following costs to do any necessary on-condition actions that would be required. The FAA has no way of determining the number of aircraft that might need these on-condition actions:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
Up to 2 work-hour × $85 per hour = $170 per spoiler assembly	$5,432 per spoiler assembly	Up to $5,602 per spoiler assembly.

Authority for This Rulemaking

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

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

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect 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.

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2020–1028; Project Identifier AD–2020–00978–T.

(a) Comments Due Date

The FAA must receive comments by February 12, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model 717–200 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 57, Wings.

(e) Unsafe Condition

This AD was prompted by a report of discrepant spoiler assemblies, which have the wrong splice bar installed and lack reinforcing doublers. The FAA is issuing this AD to address splice bars which are not structurally adequate, which can lead to failure of the splice bar to keep the spoiler drive link engaged, and could result in spoiler float and consequent reduced controllability of the airplane.

(f) Compliance

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

(g) Required Actions

Except as specified by paragraph (h) of this AD: At the applicable times specified in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 717–57A0027 RB, dated June 26, 2020, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 717–57A0027 RB, dated June 26, 2020.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin 717–57A0027, dated June 26, 2020, which is referred to in Boeing Alert Requirements Bulletin 717–57A0027 RB, dated June 26, 2020.

(h) Exceptions to Service Information Specifications

(1) Where Boeing Alert Requirements Bulletin 717–57A0027 RB, dated June 26, 2020, uses the phrase ''the original issue date of Requirements Bulletin 717–57A0027 RB,'' this AD requires using ''the effective date of this AD.''

(2) Where Boeing Alert Requirements Bulletin 717–57A0027 RB, dated June 26, 2020, specifies contacting Boeing for repair instructions: This AD requires doing the repair before further flight using a method approved in accordance with the procedures specified in paragraph (k) of this AD.

(i) Credit for Previous Actions

This paragraph provides credit for the actions specified in paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Multi Operator Message MOM–MOM–19–0572–01B, dated October 16, 2019.

(j) Parts Installation Limitation

As of the effective date of this AD, no person may install, on any airplane, any affected spoiler assembly (a spoiler assembly that does not have a splice bar having part number 3914588–501 and two doublers having part/number 5940974–31), unless it has been inspected and all applicable corrective actions have been done as specified in paragraph (g) of this AD.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (l)(1) of this AD. Information may be emailed to: *9-ANM-LAACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(l) Related Information

(1) For more information about this AD, contact Mohit Garg, Aerospace Engineer, Airframe Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5264; fax: 562–627–5210; email: *mohit.garg@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued on November 13, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–28825 Filed 12–28–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–1147; Airspace Docket No. 20–ASO–30]

RIN 2120–AA66

Proposed Amendment of Area Navigation (RNAV) Route Q–29; Northeastern United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Area Navigation (RNAV) route Q–29 in the northeastern United States in support of the Northeast Corridor Atlantic Coast Route Project (NEC ACR) for improve efficiency of the National Airspace System (NAS) while reducing the dependency on ground based navigational systems.

DATES: Comments must be received on or before February 12, 2021.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1(800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2020–1147; Airspace Docket No. 20–ASO–30 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC, 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email: *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Sean Hook, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would expand the availability of RNAV routes in the NAS, increase airspace capacity, and reduce complexity in high air traffic volume areas.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2020–1147 and Airspace Docket No. 20–ASO–30) and be submitted in triplicate to the Docket Management Facility (*see* **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2020–1147 and Airspace Docket No. 20–ASO–30.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (*see* **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Ave., College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020 and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

The Northeast Corridor Atlantic Coast Route (NEC ACR) project developed

Performance Based Navigation (PBN) routes involving the Washington, Boston, New York, and Jacksonville Air Route Traffic Control Centers (ARTCC). The proposed route would enable aircraft to travel from most locations along the east coast of the United States mainland between Maine and Charleston, SC. The proposed NEC ACR route would also tie-in to the existing high altitude RNAV route structure enabling more efficient direct routings between the U.S. east coast and Caribbean area locations.

Additionally, the proposed Q-route would support the strategy to transition the NAS from a ground-based navigation aid, and radar-based system, to a satellite-based PBN system.

The Proposal

The FAA is proposing an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to amend Q–29, in the northeastern United States to support the Northeast Corridor Atlantic Coast Route Project.

Q–29: Q–29 currently extends between the HARES, LA, WP and the DUVOK, Canada, WP. The FAA is proposing to remove the Memphis VORTAC and replace it with the MEMFS, TN, WP moving the DUNMO, ME, WP 1.26 NM east to the United States/Canada border and removing the DUVOK, Canada, WP. As proposed Q–29 would extend between the HARES, LA, WP and the DUNMO, ME, WP.

United States area navigation routes are published in paragraph 2006 of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The area navigation routes listed in this document would be subsequently published in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020 and effective September 15, 2020, is amended as follows:

Paragraph 2066 United States Area Navigation Routes.

* * * * *

Q–29 HARES, LA to DUNOM, ME [New]

HARES, LA	WP	(Lat. 33°00′00.00″ N, long. 091°44′00.00″ W)
BAKRE, MS	WP	(Lat. 33°53′45.85″ N, long. 090°58′04.75″ W)
MEMFS, TN	WP	(Lat. 35°00′54.62″ N, long. 089°58′58.87″ W)
OMDUE, TN	WP	(Lat. 36°07′47.32″ N, long. 088°58′11.49″ W)
SIDAE, KY	WP	(Lat. 37°20′00.00″ N, long. 087°50′00.00″ W)
CREEP, OH	FIX	(Lat. 39°55′15.28″ N, long. 084°18′31.41″ W)
KLYNE, OH	WP	(Lat. 40°41′54.46″ N, long. 083°18′44.19″ W)
DUTSH, OH	WP	(Lat. 41°08′26.35″ N, long. 082°33′12.68″ W)
WWSHR, OH	WP	(Lat. 41°20′34.09″ N, long. 082°03′05.76″ W)
DORET, OH	FIX	(Lat. 41°48′05.90″ N, long. 080°35′04.64″ W)
JAMESTOWN, NY (JHW)	VOR/DME	(Lat. 42°11′18.99″ N, long. 079°07′16.70″ W)
HANKK, NY	FIX	(Lat. 42°53′41.82″ N, long. 077°09′15.21″ W)
GONZZ, NY	WP	(Lat. 43°05′22.00″ N, long. 076°41′12.00″ W)
KRAZZ, NY	WP	(Lat. 43°25′00.00″ N, long. 074°18′00.00″ W)
NIPPY, NY	FIX	(Lat. 43°41′23.08″ N, long. 073°58′06.74″ W)
CABCI, VT	WP	(Lat. 44°49′19.94″ N, long. 071°42′55.14″ W)
EBONY, ME	FIX	(Lat. 44°54′08.68″ N, long. 067°09′23.65″ W)
DUNOM, ME	WP	(Lat. 44°54′09.29″ N, long. 066°58′13.68″ W)

* * * * *

Issued in Washington, DC, on December 22, 2020.

George Gonzalez,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2020–28743 Filed 12–28–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–1098; Airspace Docket No. 20–ANM–25]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Meeker, CO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify the Class E airspace extending upward from 700 feet above the surface at Meeker Coulter Field Airport. The airspace area is larger than required and should be reduced to properly contain instrument flight rules (IFR) aircraft departing and arriving at the airport. Additionally, this action proposes an administrative update to the airport's name. This action would ensure the safety and management of IFR operations at the airport.

DATES: Comments must be received on or before February 12, 2021.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1–800–647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2020–1098; Airspace Docket No. 20–ANM–25, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Matthew Van Der Wal, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–3695.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would amend the Class E airspace at Meeker Coulter Field Airport, Meeker, CO, to support IFR operations at the airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Persons wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2020–1098; Airspace Docket No. 20–ANM–25''. The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations Part 71 by modifying the Class E airspace extending upward from 700 feet above the surface at Meeker Coulter Field Airport, Meeker, CO. This airspace is designed to contain IFR departures to 1,200 feet above the surface and IFR arrivals descending below 1,500 feet above the surface. The airspace area is larger than required to properly contain IFR aircraft departing and arriving at the airport. To properly contain IFR aircraft, a 3.5-mile radius of the airport should be established to contain aircraft performing a circling maneuver. An area should be added southeast of the airport to contain IFR aircraft arriving via the RNAV (GPS) Runway 3 approach. An area west of the airport should also be added to contain IFR aircraft performing the procedure turn maneuver for the VOR–A approach. The airspace area

would be described as follows: That airspace extending upward from 700 feet above the surface within a 3.5-mile radius of the airport, and within 1 mile each side of the 220° bearing from the airport, extending from the 3.5-mile radius to 9 mile southwest of the airport, and within 4 miles north and 8 miles south of the 292° bearing from the airport, extending from the 3.5-mile radius of the airport and extending from 2.1 miles west of the airport to 18.1 miles west of Meeker Coulter Field Airport.

Additionally, this action proposes an administrative update to the airport's name. To match the FAA database, the airport name should be updated to Meeker Coulter Field Airport.

Class E5 airspace designations are published in paragraph 6005 of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial, and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ANM CO E5 Meeker, CO [Amended]

Meeker Coulter Field Airport, CO
(Lat. 40°02′56″ N, long. 107°53′09″ W)

That airspace extending upward from 700 feet above the surface within a 3.5-mile radius of the airport, and within 1 mile each side of the 220° bearing from the airport, extending from the 3.5-mile radius to 9 mile southwest of the airport, and within 4 miles north and 8 miles south of the 292° bearing from the airport, extending from the 3.5-mile radius of the airport and extending from 2.1 miles west of the airport to 18.1 miles west of Meeker Coulter Field Airport.

Issued in Seattle, Washington, on December 21, 2020.

Brian D. Ochs,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2020–28643 Filed 12–28–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–1124; Airspace Docket No. 20–AWP–48]

RIN 2120–AA66

Proposed Revocation of Class E Airspace; Kayenta, AZ

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to revoke the Class E airspace established for Bedard Field Airport, Kayenta, AZ. The special instrument procedures that were developed for the private airport are being canceled. The Class E airspace is no longer required.

DATES: Comments must be received on or before February 12, 2021.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1–800–647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2020–1124; Airspace Docket No. 20–AWP–48, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Matthew Van Der Wal, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–3695.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would revoke the Class E airspace at Bedard Field Airport, Kayenta, AZ.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Persons wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2020–1124; Airspace Docket No. 20–AWP–48''. The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations Part 71 by revoking the Class E airspace established for Bedard Field Airport, Kayenta, AZ. The special instrument procedures that were developed for the private airport are being canceled. The Class E airspace is no longer required to contain instrument procedures at the airport.

Class E5 airspace designations are published in paragraph 6005 of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial, and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AWP AZ E5 Kayenta, AZ [Revoked]

Bedard Field, AZ
(Lat. 36°28′18″ N, long. 110°25′05″ W)

Issued in Seattle, Washington, on December 21, 2020.

Brian D. Ochs,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2020–28644 Filed 12–28–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–1096; Airspace Docket No. 20–ANM–41]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Buena Vista, CO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify the Class E airspace extending upward from 700 feet above the surface at Central Colorado Regional Airport. Modification of this airspace area is necessary to properly contain

instrument flight rules (IFR) aircraft departing and arriving at the airport. Additionally, this action proposes to remove the Class E airspace extending upward from 1,200 feet above the surface. This airspace is wholly contained within the Denver en route airspace area and duplication is not necessary. Lastly, the action proposes an administrative update to the airport's name. This action would ensure the safety and management of IFR operations at the airport.

DATES: Comments must be received on or before February 12, 2021.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1–800–647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2020–1096; Airspace Docket No. 20–ANM–41, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Matthew Van Der Wal, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–3695.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would amend the Class E airspace at Central Colorado Regional Airport, Buena Vista, CO, to support IFR operations at the airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Persons wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2020–1096; Airspace Docket No. 20–ANM–41''. The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations Part 71 by modifying the Class E airspace extending upward from 700 feet above the surface at Central Colorado Regional Airport, Buena Vista, CO. This airspace is designed to contain IFR departures to 1,200 feet above the surface and IFR arrivals descending below 1,500 feet above the surface. The circular radius of the airport is larger than required, and the airspace does not properly contain IFR departures and aircraft performing an Area Navigation Runway 33 approach. The proposed action would reduce the circular radius from 4.7 miles to 3.5 miles and add an area south of the airport. The airspace area would be described as follows: That airspace extending upward from 700 feet above the surface within a 3.5-mile radius of the airport, and within 1.8 miles each side of the 160° bearing from the airport, extending from the 3.5-mile radius to 8.7 miles south of Central Colorado Regional Airport.

Additionally, this action proposes to remove the Class E airspace extending upward from 1,200 feet above the surface. This airspace area is wholly contained in the Denver en route airspace area and duplication is not necessary.

Lastly, the action proposes an administrative update to the airport's name. To match the FAA database, the airport name should be updated to Central Colorado Regional Airport.

Class E5 airspace designations are published in paragraph 6005 of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial, and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ANM CO E5 Buena Vista, CO [Amended]

Central Colorado Regional Airport, CO

(Lat. 38°48′51″ N, long. 106°07′14″ W)

That airspace extending upward from 700 feet above the surface within a 3.5-mile radius of the airport, and within 1.8 miles each side of the 160° bearing from the airport, extending from the 3.5-mile radius to 8.7 miles south of Central Colorado Regional Airport.

Issued in Seattle, Washington, on December 21, 2020.

Brian D. Ochs,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2020–28645 Filed 12–28–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–1097; Airspace Docket No. 20–ANM–24]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Kremmling, CO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify the Class E airspace extending upward from 700 feet above the surface at Mc Elroy Airfield Airport. Modification of this airspace area is necessary to properly contain instrument flight rules (IFR) aircraft departing and arriving at the airport. Additionally, this action proposes administrative updates to the airport's name and geographic coordinates. This action would ensure the safety and management of IFR operations at the airport.

DATES: Comments must be received on or before February 12, 2021.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1–800–647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2020–1097; Airspace Docket No. 20–ANM–24, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Matthew Van Der Wal, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–3695.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would amend the Class E airspace at Mc Elroy Airfield Airport, Kremmling, CO, to support IFR operations at the airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Persons wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2020–1097; Airspace Docket No. 20–ANM–24''. The postcard

will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations Part 71 by modifying the Class E airspace extending upward from 700 feet above the surface at Mc Elroy Airfield Airport, Kremmling, CO. This airspace is designed to contain IFR departures to 1,200 feet above the surface and IFR arrivals descending below 1,500 feet above the surface. The circular radius of the airport is larger than required and should be reduced from a 10.1-mile radius to a 4.6-mile radius of the airport. An area should also be added east of the airport to contain IFR aircraft departing toward/over rising terrain and IFR aircraft arriving via the RNAV Runway 27 approach. A second area should be added southwest of the airport to contain IFR aircraft arriving via the VOR/DME–A and the RNAV (GPS)–B approaches. A third area should be added west of the airport to contain IFR aircraft departing toward/over rising terrain. The airspace area would be described as follows: That airspace extending upward from 700 feet above the surface within a 4.6-mile radius of the airport, and within 2 miles each side of the 103° bearing from the airport, extending from the 4.6-mile radius to 16 miles east of the airport, and within 3.4 miles north and 4.2 miles south of the 239° bearing from the airport, extending from the 4.6-mile radius to 12.5 miles southwest of the airport, and within 1.8 miles each side of the 283° bearing from the airport, extending from the 4.6-mile radius to 19 miles west of Mc Elroy Airfield Airport.

This action also proposes administrative updates to the airport's name and geographic coordinates. To match the FAA database, the airport's name should be corrected by removing the city name ''Kremmling'' from the second line of the text header. To match the FAA database, the airport's geographic coordinates should be updated to lat. 40°03′12″ N, long. 106°22′08″ W.

Class E5 airspace designations are published in paragraph 6005 of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial, and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ANM CO E5 Kremmling, CO [Amended]

Mc Elroy Airfield Airport, CO

(Lat. 40°03′12″ N, long. 106°22′08″ W)

That airspace extending upward from 700 feet above the surface within a 4.6-mile radius of the airport, and within 2 miles each side of the 103° bearing from the airport, extending from the 4.6-mile radius to 16 miles east of the airport, and within 3.4 miles north and 4.2 miles south of the 239° bearing from the airport, extending from the 4.6-mile radius to 12.5 miles southwest of the airport, and within 1.8 miles each side of the 283° bearing from the airport, extending from the 4.6-mile radius to 19 miles west of Mc Elroy Airfield Airport.

Issued in Seattle, Washington, on December 21, 2020.

Brian D. Ochs,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2020–28639 Filed 12–28–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Parts 470, 635 and 655

[FHWA Docket No. FHWA–2020–0001]

RIN 2125–AF85

National Standards for Traffic Control Devices; the Manual on Uniform Traffic Control Devices for Streets and Highways; Revision

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Proposed rule; notice of proposed amendments; correction (NPA).

SUMMARY: The Manual on Uniform Traffic Control Devices for Streets and Highways (MUTCD) is incorporated in FHWA regulations and recognized as the national standard for traffic control devices used on all public roads. FHWA recently published its NPA and placed supplemental documents to the docket for the rulemaking. Two of the supplemental documents contained the same drafting error. By this notice FHWA is correcting that error and providing public notice of the revised documents.

DATES: December 29, 2020.

FOR FURTHER INFORMATION CONTACT: Mr. Kevin Sylvester, Office of Transportation Operations, (202) 366–2161, *Kevin.Sylvester@dot.gov,* or Mr. William Winne, Office of the Chief Counsel, (202) 366–1397, *William.Winne@dot.gov,* Federal Highway Administration, 1200 New Jersey Avenue SE, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

This document and all comments received may be viewed online through the Federal eRulemaking portal at *http://www.regulations.gov.* The website is available

24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded by accessing the Office of the Federal Register's home page at: *https://www.federalregister.gov.*

Background

FHWA published its NPA proposing changes to the MUTCD on December 14, 2020, at 85 FR 80898. FHWA published several supplemental documents to the docket for this rulemaking to aid the public review of the proposals described in the NPA. Two of those documents, ''MUTCD 11ed NPA Text-Mark-up.pdf'' and ''MUTCD 11ed NPA Text-Clean.pdf,'' contained a drafting error which suggests that FHWA is making a change to the text that was neither intended nor described in the NPA document. The phrase ''shall not'' was inadvertently included in a proposed editorial deletion in the Standard statement of proposed Section 9A.01. This error has been corrected and FHWA has placed the updated version of MUTCD Proposed Text.pdf to the docket.

Nicole R. Nason,

Administrator, Federal Highway Administration.

[FR Doc. 2020–28494 Filed 12–28–20; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 334

[Docket Number COE–2019–0010]

Washington Channel, Fort McNair, Washington, DC; Restricted Area

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: On October 13, 2020, the U.S. Army Corps of Engineers (the Corps) published a proposed rule to establish a permanent restricted area in the Washington Channel adjacent to Fort McNair in Washington, DC. The comment period ended on November 12, 2020, and we received requests to extend the comment period. As it closed prior to the publication of this document, we are reopening the comment period. Comments previously submitted do not need to be resubmitted, as they have already been incorporated into the administrative record and will be fully considered in the Corps' decision making process for this rulemaking action.

DATES: Written comments must be submitted on or before January 28, 2021.

ADDRESSES: You may submit comments, identified by docket number COE–2019–0010, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Email: david.b.olson@usace.army.mil. Include the docket number, COE–2019–0010, in the subject line of the message.

Mail: U.S. Army Corps of Engineers, Attn: CECW–CO–R (David B. Olson), 441 G Street NW, Washington, DC 20314–1000.

Hand Delivery/Courier: Due to security requirements, we cannot receive comments by hand delivery or courier.

Instructions: Instructions for submitting comments are provided in the proposed rule published on October 13, 2020 (85 FR 64434). Consideration will be given to all comments received by January 28, 2021.

FOR FURTHER INFORMATION CONTACT: Mr. David Olson, Headquarters, Operations and Regulatory Division, Washington, DC, at 202–761–4922.

SUPPLEMENTARY INFORMATION: In the October 13, 2020, issue of the **Federal Register** (85 FR 64434), the Corps published a proposed rule for establishing a permanent restricted area in the Washington Channel adjacent to Fort McNair. Fort McNair is the headquarters of the Army's Military District of Washington and home of the National Defense University as well as the official residence of the U.S. Army's Vice Chief of Staff. Fort McNair requested a restricted area to fulfill Joint Base Myer-Henderson Hall (JBM–HH) security needs including Marine Helicopter Squadron (HMX) missions and protection of VIP quarters at Fort McNair.

We have received requests for an extension of the comment period for the proposed rule. The Corps finds that a 30-day extension of the comment period for this proposed rule is warranted. Therefore, the comment period for this proposed rule is extended until January 28, 2021.

(Authority: 40 Stat. 266 (33 U.S.C. 1) and 40 Stat. 892 (33 U.S.C. 3))

Thomas P. Smith,

Chief, Operations and Regulatory Division, Directorate of Civil Works.

[FR Doc. 2020–26701 Filed 12–28–20; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Parts 393 and 399

[Docket No. FMCSA–2019–0211]

RIN 2126–AC31

Parts and Accessories Necessary for Safe Operation; Rear Impact Guards and Rear Impact Protection

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: FMCSA proposes to amend the Federal Motor Carrier Safety Regulations (FMCSRs) to include rear impact guards on the list of items that must be examined as part of the required annual inspection for each commercial motor vehicle (CMV). In addition, FMCSA proposes to amend the labeling requirements for rear impact guards, and to exclude road construction controlled (RCC) horizontal discharge trailers from the rear impact guard requirements, consistent with changes made by the National Highway Traffic Safety Administration (NHTSA) to the corresponding Federal Motor Vehicle Safety Standards (FMVSS). This notice of proposed rulemaking (NPRM) responds to rulemaking petitions, as well as a recommendation from the Government Accountability Office (GAO).

DATES: Comments on this notice must be received on or before March 1, 2021.

ADDRESSES: You may submit comments identified by Docket Number FMCSA-2019-0211 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov/docket?D=FMCSA-2019-0211.* 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 or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., 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.
- *Fax:* (202) 493–2251.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Mr. Luke Loy, Vehicle and Roadside Operations, Office of Carrier, Driver, and Vehicle Safety, MC–PSV, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, (202) 366–0676, *luke.loy@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

A. Submitting Comments

If you submit a comment, please include the docket number for this NPRM (FMCSA–2019-0211), indicate the specific section of this document to which 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 telephone 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 *https://www.regulations.gov/docket?D=FMCSA-2019-0211,* click on the ''Comment Now!'' 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, on paper 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 and may make changes based on your comments. FMCSA may issue a final rule at any time after the close of the comment period.

Confidential Business Information (CBI)

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to the interim rule contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to the interim rule, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission that constitutes CBI as ''PROPIN'' to indicate it contains proprietary information. FMCSA will treat such marked submissions as confidential under the Freedom of Information Act, and they will not be placed in the public docket of the interim rule. Submissions containing CBI should be sent to Mr. Brian Dahlin, Chief, Regulatory Analysis Division, Office of Policy, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington DC 20590–0001. Any comments FMCSA receives not specifically designated as CBI will be placed in the public docket for this rulemaking.

B. Viewing Comments and Documents

Supporting documents and any comments we receive on this docket may be viewed at *https://www.regulations.gov/docket?D=FMCSA-2019-0211.* If you do not have access to the internet, you may view the docket online by visiting the 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., e.t., 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 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. 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.*

D. Advance Notice of Proposed Rulemaking

Under the Fixing America's Surface Transportation Act, Public Law 114–94 (FAST Act), FMCSA is required to publish an advance notice of proposed rulemaking (ANPRM) or conduct a negotiated rulemaking ''if a proposed rule is likely to lead to the promulgation of a major rule.'' 49 U.S.C. 31136(g)(1). As this proposed rule is not likely to lead to the promulgation of a major rule, the Agency is not required to issue an

ANPRM or to proceed with a negotiated rulemaking.

II. Executive Summary

A. Purpose and Summary of Major Provisions

Section 393.86 of the FMCSRs, ''Rear impact guards and rear end protection,'' requires rear impact guards to be installed on most CMVs to reduce the incidence of passenger compartment intrusion during underride crashes in which a passenger vehicle strikes the rear of the CMV. Regulations requiring rear impact guards have been in the FMCSRs since 1952. The FMCSRs require that all CMVs be systematically inspected, repaired, and maintained to ensure that all required parts and accessories—including rear impact guards—are in safe and proper operating condition at all times (section 396.3(a)(1)). Operation of a CMV with a missing or noncompliant rear impact guard would be a violation of the FMCSRs, precluding the issuance of a Commercial Vehicle Safety Alliance (CVSA) inspection decal if the vehicle were to be inspected.

Among other things, the regulations require every CMV to be inspected at least once every 12 months. A motor carrier may not use a CMV unless each component identified in Appendix G of Subchapter B of Chapter III of title 49, Code of Federal Regulations, ''Minimum Periodic Inspection Standards,'' has passed the required annual inspection. While the FMCSRs have required rear impact guards for more than 65 years, they are not included on the list of components in Appendix G that must be inspected during the annual CMV inspection. This means that a vehicle can pass an annual inspection with a missing or damaged rear impact guard.

In response to petitions from the CVSA and Jerry and Marianne Karth (''the Karths'' [1]); a recommendation included in GAO Report GAO–19–264, ''Truck Underride Guards: Improved Data Collection, Inspections, and Research Needed;'' [2] and Congressional correspondence,[3] this rulemaking proposes to amend the FMCSRs to include rear impact guards on the list of items that must be examined as part of the required annual inspection for each CMV.

In addition, NHTSA published two final rules on November 19, 2004, relating to rear impact guards. First, NHTSA amended the labeling requirement in FMVSS No. 223, ''Rear impact guards,'' to permit the rear impact guard certification label to be mounted on either the forward- or rearward-facing surface of the horizontal member of the guard, provided the label does not interfere with the retroreflective sheeting required by the FMVSS (69 FR 67660).[4] Prior to the amendment, the certification label was required to be mounted on the forward-facing surface of the horizontal member, 12 inches inboard of the right end of the guard. Second, NHTSA amended the applicability section of FMVSS No. 224, ''Rear impact protection,'' to exclude RCC horizontal discharge semitrailers from the requirements of the standard (69 FR 67663).[5] NHTSA concluded that installation of rear impact guards on RCC horizontal discharge trailers would interfere with the intended function of the trailers and was therefore impracticable due to the unique design and purpose of those vehicles. However, neither of NHTSA's November 2004 amendments to the FMVSS has been incorporated into the corresponding rear impact requirements in section 393.86 of the FMCSRs. FMCSA is proposing to amend the FMCSRs to adopt the changes above to maintain consistency with FMVSS Nos. 223 and 224.

B. Costs and Benefits of Proposal

The Agency does not expect this rulemaking to result in incremental costs or benefits. Although rear impact guards are not currently among the items that must be examined during annual inspections, 49 CFR 393.86 requires that certain CMVs operated in interstate commerce be equipped with the devices and that they remain installed and in safe and proper operating conditions at all times. Therefore, for the purposes of assessing the potential economic impact of this rulemaking on motor carriers, the Agency assumes compliance as part of the baseline established by the existing FMCSRs in section 393.86. Neither the labeling requirements that would result from this proposed rule nor the exclusion of RCC horizontal discharge semitrailers from these requirements would result in incremental costs or benefits.

III. Legal Basis for the Rulemaking

This rulemaking is based on the authority of the Motor Carrier Act of 1935 (1935 Act) and the Motor Carrier Safety Act of 1984 (1984 Act).

The 1935 Act, as amended, provides that ''[t]he Secretary of Transportation may prescribe requirements for—(1) qualifications and maximum hours of service of employees of, and safety of operation and equipment of, a motor carrier; and (2) qualifications and maximum hours of service of employees of, and standards of equipment of, a private motor carrier, when needed to promote safety of operation'' (49 U.S.C. 31502(b)).

This NPRM would amend the FMCSRs to respond to petitions for rulemaking. The adoption and enforcement of such rules is specifically authorized by the 1935 Act. This proposed rulemaking rests squarely on that authority.

The 1984 Act provides concurrent authority to regulate drivers, motor carriers, and vehicle equipment. It requires the Secretary to ''prescribe regulations on commercial motor vehicle safety.'' The regulations shall prescribe minimum safety standards for CMVs. At a minimum, the regulations shall ensure that: (1) CMVs are maintained, equipped, loaded, and operated safely; (2) the responsibilities imposed on operators of CMVs do not impair their ability to operate the vehicles safely; (3) the physical condition of operators of CMVs is adequate to enable them to operate vehicles safely; (4) the operation of CMVs does not have a deleterious effect on the physical condition of the operators; and (5) drivers are not coerced by motor carriers, shippers, receivers, or transportation intermediaries to operate a vehicle in violation of a regulation promulgated under 49 U.S.C. 31136 (which is the basis for much of the FMCSRs) or 49 U.S.C. chapters 51 or 313 (49 U.S.C. 31136(a)).

This proposed rule concerns parts and accessories necessary for the safe operation of CMVs, and the inspection, repair, and maintenance of CMVs. It is based on section 31136(a)(1) because it deals with CMV maintenance of rear impact guards. The NPRM does not address the driver-centered requirements of sections 31136(a)(2)–(4). As the amendments proposed by this rule are primarily technical changes that clarify existing requirements and improve enforcement consistency,

[1] Copies of the petitions from CVSA and the Karths are available online at *https://www.regulations.gov/docket?D=FMCSA-2019-0211* and in Dockets Operations.

[2] A copy of the GAO Report is available online at *https://www.regulations.gov/docket?D=FMCSA-2019-0211* and in Dockets Operations.

[3] A copy of the letter is available online at *https://www.regulations.gov/docket?D=FMCSA-2019-0211* and in Dockets Operations.

[4] You may view the NHTSA rule online at *https://www.federalregister.gov/documents/2004/11/19/04-25704/federal-motor-vehicle-safety-standards-rear-impact-guard-labels.*

[5] You may view the NHTSA rule online at *https://www.federalregister.gov/documents/2004/11/19/04-25703/federal-motor-vehicle-safety-standards-rear-impact-guards-final-rule.*

FMCSA believes there will be stakeholder support for this initiative and that coercion to violate the proposed amendments, which is already prohibited by section 31136(a)(5), will not be an issue.

Before prescribing any such regulations, FMCSA must consider the ''costs and benefits'' of any proposal (49 U.S.C. 31136(c)(2)(A) and 31502(d)). As discussed in greater detail in the ''Regulatory Analyses'' section, FMCSA has determined that this proposed rule is not a significant regulatory action.

IV. Background

A. History of Rear Impact Guard Requirements

The first Federal requirements concerning heavy vehicle rear underride protection were issued in 1952 by the Bureau of Motor Carriers of the Interstate Commerce Commission (ICC). The regulation required all heavy trucks, trailers, and semitrailers manufactured after December 31, 1952, to be equipped with a rear-end protection device designed to help prevent underride. The rule required that the ground clearance of the underride guard be no more than 30 inches when the vehicle is empty. The rule also required that the underride guard be located no more than 24 inches forward of the rear of the vehicle, and that it extend laterally to within 18 inches of each side. The underride device was required to be ''substantially constructed and firmly attached'' (17 FR 4445, May 15, 1952). The ICC's authority over motor carrier safety was transferred to DOT by Section 6(e)(6)(C) of the Department of Transportation Act (Pub. L. 89–670, 80 Stat. 931, 939–940, Oct. 15, 1966). The authority was delegated by the Secretary to the Federal Highway Administration (FHWA).

On January 24, 1996, NHTSA published a final rule creating FMVSS Nos. 223 and 224 (61 FR 2004). The requirements apply to most trailers and semitrailers with a gross vehicle weight rating of 10,000 pounds or more, manufactured on or after January 26, 1998.

FMVSS No. 223 specifies performance requirements that rear impact guards must meet before they can be installed on new trailers or semitrailers. It specifies strength and energy absorption requirements, as well as test procedures that manufacturers and NHTSA will use to determine compliance with the standard. The standard also requires the guard manufacturer to permanently label the impact guard to certify that it meets the requirements and to provide instructions on the proper installation of the guard.

FMVSS No. 224 requires that most new trailers and semitrailers with a GVWR of 10,000 pounds or more be equipped with a rear impact guard meeting the requirements of FMVSS No. 223. The guards must extend laterally to within 4 inches of the sides of the trailer, have a ground clearance of no more than 22 inches, and be placed as close as possible to, but not more than 12 inches from, the rear of the vehicle. To ensure that the guard will perform properly, the standard also requires it to be mounted on the trailer or semitrailer in accordance with the installation instructions provided by the guard manufacturer.

On September 1, 1999, FHWA published a final rule amending the FMCSRs to require trailers and semitrailers manufactured on or after January 26, 1998, with a GVWR of 10,000 pounds or more, be equipped with rear impact guards that meet the requirements of FMVSS No. 223. The rear impact guards must be installed to ensure that the trailer or semitrailer meets the rear end protection requirements of FMVSS No. 224. This rule was intended to ensure that the rear impact protection requirements of the FMCSRs are consistent with the FMVSS (64 FR 47703).

As stated previously, NHTSA published two final rules on November 19, 2004, relating to rear impact guards. NHTSA amended the labeling requirement in FMVSS No. 223 to permit the rear impact guard certification label to be mounted on either the forward- or rearward-facing surface of the horizontal member of the guard (69 FR 67660), and amended the applicability section of FMVSS No. 224 to exclude RCC horizontal discharge semitrailers from the requirements of the standard (69 FR 67663). However, neither of NHTSA's November 2004 amendments to the FMVSS has been incorporated into the corresponding rear impact requirements in section 393.86 of the FMCSRs.

B. History of Appendix G Requirements

Section 210 of the 1984 Act required the Secretary of Transportation to establish standards for the annual or more frequent (*i.e.,* periodic) inspection of all CMVs engaged in interstate or foreign commerce (49 U.S.C. 31142(b)). In response, FHWA adopted new section 396.17 on December 7, 1988, which requires all CMVs to be inspected at least once every 12 months (53 FR 49380, as amended on Dec. 8, 1989 (54 FR 50722)). The rule was based largely on (1) the CVSA vehicle out-of-service criteria, and (2) the vehicle portion of the FHWA National Uniform Driver-Vehicle Inspection Procedure (NUD–VIP). The latter was used as the standard for successful completion of the annual inspection, and the details of the required inspection were spelled out in Appendix G to the FMCSRs, also promulgated by the final rule. FHWA noted that utilization of the FHWA NUD–VIP would (1) provide the necessary inspection-related pass/fail criteria for the periodic inspection at a more stringent level than the vehicle out-of-service criteria, and (2) provide the proper level of Federal oversight in establishing and revising the criteria.

V. Discussion of Proposed Rulemaking

A. Rear Impact Guards in Appendix G

Rear impact guards are not included on the list of items in Appendix G that must be examined during the annual inspection required by section 396.17. This means that a vehicle could pass the annual inspection with a missing or damaged rear impact guard. However, the operation of the vehicle with a missing or damaged rear impact guard would be a violation of the FMCSRs, and according to CVSA policy, a CVSA inspection decal would not be issued if the vehicle were inspected.

In its petition, CVSA requested that the Agency amend Appendix G to include specific language regarding the inspection of rear impact guards during annual inspections. The petition stated:

> A vehicle's rear impact guard/rear end protection is inspected roadside as part of the North American Standard Inspection Program. However, the majority of commercial motor vehicles do not come into contact with an inspector on an annual basis . . .
>
> According to data available through FMCSA's Analysis and Information Online web page, in fiscal year 2017 inspectors document[ed] more than 2,300 violations related to rear impact guards and rear end protection, more than half of which are for components that are missing, damaged or improperly constructed. Including rear impact guards and rear end protection in the periodic inspection requirements in Appendix G will call additional attention to this critical safety component and help ensure that each vehicle is checked at least once a year, improving compliance and helping to prevent fatalities and injuries when rear-end collisions occur. Furthermore, including rear impact guards and rear end protection in the periodic annual inspection standards will harmonize U.S. regulations with those in Canada and Mexico, which include rear impact guards and rear end protection as part of their annual inspection programs.

The Karths' petition requested that FMCSA ''Add underride guards to

Appendix G and 396.17 (Periodic Inspection),'' but did not provide any supporting information.[6]

In addition, several Senators asked GAO to review data on truck underride crashes and information on underride guards. Between January 2018 and March 2019, GAO conducted a performance audit that included a literature review and interviews with stakeholders familiar with underride crashes and guards.

GAO Report GAO–19–264, published in March 2019, examines (1) the data that DOT reports on underride crashes, and (2) the development and use of underride guard technologies in the United States. GAO analyzed DOT's underride crash data for 2008 through 2017; reviewed NHTSA's proposed regulations and research on new guard technologies (80 FR 78418, Dec. 16, 2015); and interviewed stakeholders including DOT officials, industry and safety groups, and State officials.

With respect to FMCSA, the GAO concluded that the lack of an annual inspection requirement for rear impact guards potentially affects the safety of the traveling public and FMCSA's ability to achieve its safety mission. GAO stated that ''without explicitly including the inspection of the rear guard in Appendix G, there is no assurance that rear guards in operation will be inspected at least annually to ensure they perform as designed to prevent or mitigate an underride crash.'' In its ''Recommendations for Executive Action,'' GAO stated:

> The Administrator of the Federal Motor Carrier Safety Administration should revise Appendix G of the agency's regulations to require that rear guards are inspected during commercial vehicle annual inspections. (Recommendation 3)

While the GAO review was being conducted, FMCSA received Congressional correspondence urging the Agency to ''add 'underride guards' to the list of annual inspection items required [for] trucks and trailers under current periodic inspection regulations.'' The Senators stated:

> Requiring an annual inspection of rear underride guards, in addition to the current list of items already checked during annual inspections, would ensure trucks and trailers are complying with regulations already on the books. Therefore, we ask that FMCSA consider initiating a rulemaking to amend federal Minimum Periodic Inspection Standards to include a subsection on ''underride guards.'' Should you decide to move forward with this rulemaking, we respectfully request that an inserted subsection be identical to the already mandated minimum standards of rear impact guards and rear end protection.

FMCSA agrees that the failure of a motor carrier to properly maintain an important safety feature such as a rear impact guard should result in the vehicle failing the required annual inspection. Given that rear impact guards have been included in part 393 for more than 65 years, and that part 396 requires all parts and accessories specified in part 393—to include rear impact guards—to be in safe and proper operating condition at all times, FMCSA assumes that the majority of motor carriers currently inspect rear impact guards annually despite the absence of an explicit requirement to do so in Appendix G. According to FMCSA's Motor Carrier Management Information System (MCMIS), out of approximately 5.8 million regulatory violations identified during inspections in 2017, only approximately 2,400—or about 0.041 percent—were rear impact guard violations.

For these reasons, and as discussed in the Regulatory Analyses section, the Agency believes that amending Appendix G to include a review of rear impact guards and maintain consistency with part 393, would result in only a de minimis economic impact. FMCSA proposes to amend Appendix G to require rear impact guards to be inspected as part of the annual inspection required under § 396.17.

B. Rear Impact Guard Labeling

NHTSA amended the labeling requirement in FMVSS No. 223 on November 19, 2004, to permit the rear impact guard certification label to be mounted on either the forward- or rearward-facing surface of the horizontal member of the guard, if the label does not interfere with the retroreflective sheeting required by the FMVSS. Prior to the amendment, the certification label was required to be mounted on the forward-facing surface of the horizontal member, 12 inches inboard of the right end of the guard. NHTSA decided to allow rear impact guard manufacturers flexibility in determining where to place the label on the horizontal member of the guard so that they can minimize exposure to operational and environmental damage, while at the same time ensuring that it is readily accessible for visual inspection. FMCSA proposes to amend the labeling requirements in section 393.86(a)(6) to be consistent with the changes made by NHTSA in 2004.

C. Applicability—RCC Horizontal Discharge Trailers

Also on November 19, 2004, NHTSA amended the applicability section of FMVSS No. 224 to exclude RCC horizontal discharge trailers from its requirements. RCC horizontal discharge trailers are used to deliver asphalt to road construction sites and gradually to discharge asphalt mix into paving machines. Typically, the paving machine attaches to the rear axle of the RCC horizontal discharge trailer via hydraulic arms, and the edge of the trailer's conveyor belt extends over the paving machine opening. A rear impact guard required by the FMVSS would prevent the RCC horizontal discharge trailer from effectively connecting with a paving machine. NHTSA concluded that installation of rear impact guards on RCC horizontal discharge trailers would interfere with the intended function of the trailers and therefore exempted them from the standard.

FMCSA proposes to amend (1) § 393.5 to add a definition of *road construction controlled horizontal discharge trailer* consistent with the NHTSA definition in FMVSS No. 224, and (2) § 393.86(a)(1) and § 393.86(b)(1) to make it clear that RCC horizontal discharge trailers are not required to have a rear impact guard installed, consistent with the amendments made by NHTSA in 2004.

Although neither of NHTSA's November 2004 amendments was incorporated into the rear impact requirements in § 393.86, FMCSA is not aware of any enforcement or compliance issues that have arisen with respect to these items in the ensuing 15 years. As such, FMCSA does not expect the proposed amendments to have any impact on motor carriers.

VI. International Impacts

The FMCSRs, and any exceptions to the FMCSRs, apply only within the United States (and, in some cases, U.S. territories). Motor carriers and drivers are subject to the laws and regulations of the countries in which they operate, unless an international agreement states otherwise. Drivers and carriers should be aware of the regulatory differences among nations.

[6] The Karths' petition also requested that FMCSA change the definition of Out of Service Criteria to read as follows: ''A vehicle(s) is placed out-of-service only when by reason of its mechanical condition or loading it is determined to be so imminently hazardous as to likely cause an accident or breakdown, or when such condition(s) would likely contribute to loss of control of the vehicle(s) by the driver, or to allow death and/or injuries from truck underride (passenger compartment intrusion) upon collision.'' [Emphasis in original.] FMCSA notes that the North American Standard Out-of-Service Criteria are developed and maintained by CVSA, and are not part of the FMCSR. As such, any amendments to the Out-of-Service criteria are outside the scope of this rulemaking.

VII. Section-by-Section Analysis

A. Part 393—Parts and Accessories Necessary for Safe Operation

Section 393.86(a)(1) (General requirements for trailers and semitrailers manufactured on or after January 26, 1998).

FMCSA proposes to amend this section by adding RCC horizontal discharge trailers to the list of vehicles that are not required to have a rear impact guard.

Section 393.86(a)(6) (Certification and labeling requirements for rear impact protection guards).

FMCSA proposes to amend this section to clarify that the label may be on the forward- or rear-facing surface of the horizontal member of the guard, provided it does not interfere with the retroreflective sheeting required by the FMVSS.

Section 393.86(b)(1) (Requirements for motor vehicles manufactured after December 31, 1952 (except trailers or semitrailers manufactured on or after January 26, 1998)).

FMCSA proposes to amend this section by adding RCC horizontal discharge trailers to the list of vehicles that are not required to have a rear impact guard.

B. Appendix G to Subchapter B of Chapter III (Minimum Periodic Inspection Standards)

FMCSA proposes to amend Appendix G by adding rear impact guards to the list of items required to be inspected pursuant to section 396.17.

VIII. Regulatory Analyses

A. Executive Order 12866 (Regulatory Planning and Review as Supplemented by Executive Order 13563 and DOT Regulations)

The Office of Information and Regulatory Affairs determined that this proposed rule is not a significant regulatory action under section 3(f) of E.O. 12866 (58 FR 51735, Oct. 4, 1993), Regulatory Planning and Review, as supplemented by E.O. 13563 (76 FR 3821, Jan. 21, 2011), Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. This rule is also not significant within the meaning of DOT regulations (49 CFR 5.13(a)). Accordingly, the Office of Management and Budget has not reviewed it under these Orders.

In response to rulemaking petitions and a recommendation from the GAO, FMCSA proposes to amend Appendix G to Subchapter B of Chapter III in title 49 CFR. This amendment would add rear impact guards to the list of items that must be examined as part of the required annual inspection for each CMV.

Section 393.86(a) currently requires most trailers and semitrailers manufactured on or after January 26, 1998, to be equipped with rear impact guards. This proposed rule would not require installation or maintenance of rear impact guards beyond the current requirements in § 393.86.

The Agency does not expect this proposed rule to result in incremental costs or benefits beyond the baseline established in the FMCSRs. As required by 49 CFR 396.17, motor carriers currently complete annual inspections of all items identified in Appendix G. FMCSA assumes that motor carriers review rear impact guards in their annual inspection programs to remain in compliance with the current requirements in 49 CFR 396.3(a)(1), which states that rear impact guards must be installed and in safe and proper operating conditions at all times. Additionally, CMVs are subject to inspections conducted in accordance with the CVSA's North American Standard Inspection Program that may occur throughout the year, which include the examination of rear impact guards. According to MCMIS, most motor carriers comply with 49 CFR 396.3(a)(1). Specifically, out of approximately 5.8 million regulatory violations identified during inspections in 2017, only approximately 2,400—or about 0.041 percent—were rear impact guard violations.

FMCSA also proposes two minor changes to maintain consistency between the FMCSRs and NHTSA's FMVSS Nos. 223 and 224. As described above, these changes would provide consistent labeling requirements and would exclude RCC horizontal discharge semitrailers from the requirements of this standard. FMCSA does not expect these administrative changes to result in incremental impacts.

B. Executive Order 13771 Reducing Regulation and Controlling Regulatory Costs

This proposed rule is expected to be neither an Executive Order 13771 regulatory action nor an Executive Order 13771 deregulatory action because there would be no cost impacts resulting from the rule.[7]

[7] Executive Office of the President, *Executive Order 13771 of January 30, 2017, Reducing Regulation and Controlling Regulatory Costs,* 82 FR 9339–9341, February 3, 2017.

C. Regulatory Flexibility Act (Small Entities)

The Regulatory Flexibility Act of 1980 (RFA) (5 U.S.C. 601 *et seq.*) requires Federal agencies to consider the effects of their regulatory actions on small businesses and other small entities and to minimize any significant economic impact. The term ''small entities'' encompasses small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields and governmental jurisdictions with populations of less than 50,000.[8] Accordingly, DOT policy requires an analysis of the impact of all regulations on small entities and mandates that agencies strive to lessen any adverse effects on these businesses. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

''Small entity'' is defined in 5 U.S.C. 601(3) as having the same meaning as ''small business concern'' under Section 3 of the Small Business Act (SBA). This includes any small business concern that is independently owned and operated, and is not dominant in its field of operation. Section 601(4), likewise, includes within the definition of ''small entities'' not-for-profit enterprises that are independently owned and operated, and are not dominant in their fields of operation. In addition, Section 601(5) defines ''small entities'' as governments of cities, counties, towns, townships, villages, school districts, or special districts with populations less than 50,000. The Small Business Administration develops the size standards used to classify entities as small, and establishes separate standards for each industry, as defined by the North American Industry Classification System (NAICS). The motor carriers that would be affected by this rule fall into many different industry codes with differing size standards. Because this rule would impact all motor carriers, including those considered to be small entities, FMCSA anticipates that this rule would impact a substantial number of small entities.

However, FMCSA has determined that this rule would not have a significant impact on the affected entities. This rule would require motor carriers to include rear impact guards on the list of items that must be examined as part of the required annual CMV

[8] Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), see National Archives at *http://www.archives.gov/federal-register/laws/regulaotry-flexibility/601.html.*

inspection completed. FMCSA believes that motor carriers have been inspecting the rear impact guards on their CMVs to remain in compliance with requirements that have been in the FMCSRs since 1952. As such, FMCSA does not expect this proposed rule to have incremental impacts on the affected entities. The Agency also does not expect the two minor changes proposed to maintain consistency between the FMCSRs and NHTSA's FMVSS Nos. 223 and 224 to result in incremental impacts. The Agency expects the impacts of this proposed rule would be de minimis, and therefore, does not expect the proposed rule to have a significant economic impact on a substantial number of small entities.

Consequently, I certify that the proposed action will not have a significant economic impact on a substantial number of small entities. FMCSA invites comment from members of the public who believe there will be a significant impact either on small businesses or on governmental jurisdictions with a population of less than 50,000.

D. Assistance for Small Entities

In accordance with section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996, FMCSA wants to assist small entities in understanding this proposed rule so that they can better evaluate its effects on themselves and participate in the rulemaking initiative. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

Small businesses may send comments on the actions of Federal employees who enforce or otherwise determine compliance with Federal regulations to the Small Business Administration's Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of FMCSA, call 1–888–REG–FAIR (1–888–734–3247). DOT has a policy regarding the rights of small entities to regulatory enforcement fairness and an explicit policy against retaliation for exercising these rights.

E. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $165 million (which is the value equivalent of $100,000,000 in 1995, adjusted for inflation to 2018 levels) or more in any one year. Though this proposed rule would not result in such an expenditure, the Agency does discuss the effects of this rule elsewhere in this preamble.

F. Paperwork Reduction Act

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

G. Executive Order 13132 (Federalism)

A rule has implications for federalism under Section 1(a) of Executive Order 13132 if it has ''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.'' FMCSA determined that this proposal would not have substantial direct costs on or for States, nor would it limit the policymaking discretion of States. Nothing in this document preempts any State law or regulation. Therefore, this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Impact Statement.

H. Executive Order 12988 (Civil Justice Reform)

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

I. Executive Order 13045 (Protection of Children)

Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), requires agencies issuing ''economically significant'' rules, if the regulation also concerns an environmental health or safety risk that an agency has reason to believe may disproportionately affect children, to include an evaluation of the regulation's environmental health and safety effects on children. The Agency determined this proposed rule is not economically significant. Therefore, no analysis of the impacts on children is required. In any event, the Agency does not anticipate that this regulatory action could in any respect present an environmental or safety risk that could disproportionately affect children.

J. Executive Order 12630 (Taking of Private Property)

FMCSA reviewed this proposed rule in accordance with Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights, and has determined it will not result in the effect a taking of private property or otherwise have taking implications.

K. Privacy

Section 522 of title I of division H of the Consolidated Appropriations Act, 2005, enacted December 8, 2004 (Pub. L. 108–447, 118 Stat. 2809, 3268, 5 U.S.C. 552a note), requires the Agency to conduct a privacy impact assessment (PIA) of a regulation that will affect the privacy of individuals. The Agency completed a Privacy Threshold Assessment (PTA) to assist in analyzing the new rulemaking to determine if it creates privacy risk for individuals that could require other entities to collect, use, store or share personally identifiable information (PII), or deploy technologies as a result of this rulemaking implementation. The PTA is also used to identify programs and systems that are privacy sensitive and help determine whether additional privacy compliance, such a PIA or System of Records Notice (SORN), is required for a particular rulemaking or system. Based on the preliminary adjudication of the PTA by the FMCSA Privacy Officer, this rule does not require the collection of PII and the Agency is not required to conduct a PIA. The PTA has been submitted to FMCSA's Privacy Officer for review and preliminary adjudication and to DOT's Privacy Officer for review and final adjudication. The DOT Privacy Office has determined that this rulemaking does not create privacy risk.

L. Executive Order 12372 (Intergovernmental Review)

The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this program.

M. Executive Order 13211 (Energy Supply, Distribution, or Use)

FMCSA has analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply,

Distribution, or Use. The Agency has determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

N. Executive Order 13175 (Indian Tribal Governments)

This rule does not have Tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

O. National Technology Transfer and Advancement Act (Technical Standards)

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through OMB, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) are standards that are developed or adopted by voluntary consensus standards bodies. This rule does not use technical standards. Therefore, FMCSA did not consider the use of voluntary consensus standards.

P. National Environmental Policy Act of 1969

FMCSA analyzed this NPRM for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and determined this action is categorically excluded from further analysis and documentation in an environmental assessment or environmental impact statement under FMCSA Order 5610.1 (69 FR 9680, March 1, 2004), Appendix 2, paragraph (aa). The Categorical Exclusion (CE) in paragraph (aa) covers regulations requiring motor carriers, their officers, drivers, agents, representatives, and employees directly in control of CMVs to inspect, repair, and provide maintenance for every CMV used on a public road. The proposed requirements in this rule are covered by this CE and the NPRM does not have any effect on the quality of the environment. The CE determination is available for inspection or copying in the *regulations.gov* website listed under **ADDRESSES**.

Q. Executive Order 13783 (Promoting Energy Independence and Economic Growth)

Executive Order 13783 directs executive departments and agencies to review existing regulations that potentially burden the development or use of domestically produced energy resources, and to appropriately suspend, revise, or rescind those that unduly burden the development of domestic energy resources. In accordance with Executive Order 13783, DOT prepared and submitted a report to the Director of OMB that provides specific recommendations that, to the extent permitted by law, could alleviate or eliminate aspects of agency action that burden domestic energy production. This proposed rule has not been identified by DOT under Executive Order 13783 as potentially alleviating unnecessary burdens on domestic energy production.

List of Subjects

49 CFR Part 393

Highway safety, Motor carriers, Motor vehicle safety, Reporting and recordkeeping requirements.

49 CFR Part 399

Motor carriers, Motor vehicle safety, Occupational safety and health.

In consideration of the foregoing, FMCSA proposes to amend 49 CFR parts 393 and 399 as follows:

PART 393—PARTS AND ACCESSORIES NECESSARY FOR SAFE OPERATION

■ 1. The authority citation for part 393 continues to read as follows:

Authority: 49 U.S.C. 31136, 31151, and 31502; sec. 1041(b) of Pub. L. 102–240, 105 Stat. 1914, 1993 (1991); sec. 5301 and 5524 of Pub. L. 114–94, 129 Stat. 1312, 1543, 1560; and 49 CFR 1.87.

■ 2. Amend § 393.5 by adding a definition for *Road construction controlled horizontal discharge trailer* in alphabetical order to read as follows:

§ 393.5 Definitions.

* * * * *

Road construction controlled horizontal discharge trailer means a trailer or semitrailer that is equipped with a mechanical drive and a conveyor to deliver asphalt and other road building materials, in a controlled horizontal manner, into a lay down machine or paving equipment for road construction and paving operations.

* * * * *

■ 3. In § 393.86 revise paragraphs (a)(1), (6) and (b)(1) to read as follows:

§ 393.86 Rear impact guards and rear end protection.

(a)(1) *General requirements for trailers and semitrailers manufactured on or after January 26, 1998.* Each trailer and semitrailer with a gross vehicle weight rating of 4,536 kg (10,000 pounds) or more, and manufactured on or after January 26, 1998, must be equipped with a rear impact guard that meets the requirements of Federal Motor Vehicle Safety Standard No. 223 (49 CFR 571.223) in effect at the time the vehicle was manufactured. When the rear impact guard is installed on the trailer or semitrailer, the vehicle must, at a minimum, meet the requirements of FMVSS No. 224 (49 CFR 571.224) in effect at the time the vehicle was manufactured. The requirements of paragraph (a) of this section do not apply to pole trailers (as defined in § 390.5 of this chapter); pulpwood trailers, low chassis vehicles, special purpose vehicles, wheels back vehicles (as defined in § 393.5), road construction controlled horizontal discharge trailers; and trailers towed in driveaway-towaway operations (as defined in § 390.5).

* * * * *

(6) *Certification and labeling requirements for rear impact protection guards.* Each rear impact guard used to satisfy the requirements of paragraph (a)(1) of this section must be permanently marked or labeled as required by FMVSS No. 223 (49 CFR 571.223, S5.3). The label shall be placed on the forward or rearward facing surface of the horizontal member of the guard, provided that the label does not interfere with the retroreflective sheeting required by S5.7.1.4.1(c) of FMVSS No. 108 (49 CFR 571.108), and is readily accessible for visual inspection. The certification label must contain the following information:

* * * * *

(b)(1) *Requirements for motor vehicles manufactured after December 31, 1952 (except trailers or semitrailers manufactured on or after January 26, 1998).* Each motor vehicle manufactured after December 31, 1952, (except truck

tractors, pole trailers, pulpwood trailers, road construction controlled horizontal discharge trailers, or vehicles in driveaway-towaway operations) in which the vertical distance between the rear bottom edge of the body (or the chassis assembly if the chassis is the rearmost part of the vehicle) and the ground is greater than 76.2 cm (30 inches) when the motor vehicle is empty, shall be equipped with a rear impact guard(s). The rear impact guard(s) must be installed and maintained in such a manner that:

* * * * *

PART 399—EMPLOYEE SAFETY AND HEALTH STANDARDS

■ 4. The authority citation for part 399 continues to read as follows:

Authority: 49 U.S.C. 31502 and 49 CFR 1.87.

■ 5. Amend Appendix G to Subchapter B of Chapter III by adding Section 15 as follows:

Appendix G to Subchapter B of Chapter III—Minimum Periodic Inspection Standards

* * * * *

15. Rear Impact Guard

a. Trailers and semitrailers with a GVWR of 4,536 kg (10,000 lbs) or more, manufactured on or after January 26, 1998 (see exceptions in § 393.86(a)(1)).

1. Missing guard.
2. Guard is not securely attached to trailer.
3. Guard does not extend to within 100 mm (4 inches) of each side extremity of the vehicle, and not beyond.
4. Guard is more than 560 mm (22 inches) above the ground.
5. Guard is more than 305 mm (12 inches) forward of the rear extremity of the vehicle.
6. Guard does not have a cross sectional vertical height of at least 100 mm (4 inches) across its entire width.

b. Commercial motor vehicles manufactured after December 31, 1952 (except trailers and semitrailers manufactured on or after January 26, 1998) (see exceptions in § 393.86(b)(1) and § 393.86(b)(3)).

1. Missing guard.
2. Guard is not securely attached to trailer by bolts, welding, or other comparable means.
3. Guard is more than 762 mm (30 inches) above the ground.
4. Guard does not extend to within 457 mm (18 inches) of each side extremity of the vehicle.
5. Guard is more than 610 mm (24 inches) forward of the rear extremity of the vehicle.

Issued under authority delegated in 49 CFR 1.87.

James W. Deck,

Deputy Administrator.

[FR Doc. 2020–27502 Filed 12–28–20; 8:45 am]

BILLING CODE 4910–EX–P

Notices

Federal Register
Vol. 85, No. 249
Tuesday, December 29, 2020

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

Office of the Chief Information Officer; Notice of Request for a Revision to and Extension of an Information Collection; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Office of the Chief Information Officer, USDA.

ACTION: Notice and request for comments.

SUMMARY: The Office of the Chief Information Officer, as part of its continuing effort to reduce paperwork and respondent burden, invites the public to comment on the ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery'' for approval under the Paperwork Reduction Act. This collection was developed as part of a Federal Government-wide effort to streamline the process for seeking feedback from the public on service delivery. This notice announces our intent to submit this collection to Office of Management and Budget (OMB) for approval and solicit comments on specific aspects for the proposed information collection.

DATES: Consideration will be given to all comments received by March 1, 2021.

ADDRESSES: Submit comments by one of the following methods:

- *Website: www.regulations.gov.*
- *Email: Ruth.Brown@ocio.usda.gov* and
- *Fax:* 202–692–0203.

Comments submitted in response to this notice may be made available to the public. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information (PII) or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: Ruth Brown, 202–720–8958, *Ruth.Brown@usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Control Number: 0503–0021.

Abstract: The proposed information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improve service delivery. By qualitative feedback, we mean information that provides useful insights on perceptions and opinions, but not statistical surveys that yield quantitative results that can be generalized to the population. This feedback will, (1) provide insights into customer or stakeholder perceptions, experiences and expectations, (2) provide an early warning of issues with service and, (3) focus attention on areas where communication, training or changes in operations might improve delivery of products or services. This collection will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target areas such as: Timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency's services will be unavailable.

The Agency will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future;
- Personally identifiable information (PII) is collected only to the extent necessary and is not retained;
- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency;
- Information gathered will not be used for substantially informing influential policy decisions; and
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data usage requires more rigorous designs that address the target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

As a general matter, information collections will not result in any new

system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

Current Actions: Revision/Extension of approval for a collection of information.

Type of Review: Revision.

Affected Public: Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.

Estimated Number of Respondents: 30,000.

Below we provide projected average estimates for the next 3-years:

Average Expected Annual Number of Activities: 20.

Average Number of Respondents per Activity: 1.

Annual Responses: 30,000.

Frequency of Response: Once per request.

Average Minutes per Response: 30.

Burden Hours: 16,750.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose, or provide information to or for a Federal agency. This includes the time needed to review instructions to (1) develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; (2) train personnel and be able to respond to a collection of information, to search data sources, (3) complete and review the collection of information; and to transmit or otherwise disclose the information.

All written comments will be available for public inspection at *Regulations.gov.*

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 Office of Management and Budget control number.

Gary Washington,

Chief Information Officer.

[FR Doc. 2020–28717 Filed 12–28–20; 8:45 am]

BILLING CODE 3410–KR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–840]

Certain Frozen Warmwater Shrimp From India: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2018–2019

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

SUMMARY: The Department of Commerce (Commerce) determines that producers and/or exporters of certain frozen warmwater shrimp (shrimp) from India made sales at less than normal value during the period of review (POR), February 1, 2018 through January 31, 2019.

DATES: Applicable December 29, 2020.

FOR FURTHER INFORMATION CONTACT: Brittany Bauer or Benjamin Luberda, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3860 or (202) 482–2185, respectively.

SUPPLEMENTARY INFORMATION:

Background

This administrative review covers 183 producers and/or exporters of the subject merchandise. Commerce selected two mandatory respondents for individual examination: Razban Seafoods Ltd. (Razban) and ZA Sea Foods Pvt. Ltd. (ZA Sea Foods). The producers/exporters not selected for individual examination are listed in the ''Final Results of the Review'' section of this notice.

On March 6, 2020, Commerce published the *Preliminary Results.*[1] On April 10, 2020, we received a case brief from ZA Sea Foods and seven other Indian shrimp producers. On April 17, 2020, we received rebuttal briefs from the petitioner and the American Shrimp Processors Association.[2]

On April 24, 2020, Commerce tolled all deadlines in administrative reviews by 50 days.[3] On July 21, 2020, Commerce tolled all deadlines in administrative reviews by an additional 60 days.[4] On October 7, 2020, Commerce extended the final results of this review by 60 days.[5] The deadline for the final results of this review is now December 21, 2020.

Commerce conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The merchandise subject to the order is certain frozen warmwater shrimp.[6] The product is currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) item numbers: 0306.17.00.03, 0306.17.00.06, 0306.17.00.09, 0306.17.00.12, 0306.17.00.15, 0306.17.00.18, 0306.17.00.21, 0306.17.00.24, 0306.17.00.27, 0306.17.00.40, 1605.21.10.30, and 1605.29.10.10. Although the HTSUS numbers are provided for convenience and customs purposes, the written product description remains dispositive.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs are listed in Appendix I to this notice and addressed in the IDM. Parties can find a complete discussion of these issues and the corresponding recommendations in this public memorandum, which is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users

[1] *See Certain Frozen Warmwater Shrimp from India: Preliminary Results of Antidumping Duty Administrative Review; 2018–2019,* 85 FR 13131 (March 6, 2020) (*Preliminary Results*).

[2] The petitioner is the Ad Hoc Shrimp Trade Action Committee.

[3] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews in Response to Operational Adjustments Due to COVID–19,'' dated April 24, 2020.

[4] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews,'' dated July 21, 2020.

[5] *See* Memorandum, ''Certain Frozen Warmwater Shrimp from India; 2018–2019 Administrative Review: Extension of Deadline for Final Results,'' dated October 7, 2020.

[6] For a complete description of the Scope of the Order, *see* Memorandum, ''Issues and Decision Memorandum for the Final Results of the 2018–2019 Antidumping Duty Administrative Review of Certain Frozen Warmwater Shrimp from India,'' dated concurrently with, and hereby adopted by, this notice (IDM).

at *http://access.trade.gov.* In addition, a complete version of the IDM can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties regarding our *Preliminary Results,* we made certain changes to the preliminary weighted-average margin calculations for ZA Sea Foods and for those companies not selected for individual review.[7]

Final Results of the Review

We are assigning the following dumping margins to the firms listed below for the POR, February 1, 2018 through January 31, 2019:

Producers/exporters	Weighted-average dumping margin (percent)
ZA Sea Foods Pvt. Ltd	3.06
Companies Receiving a Review-Specific Average Rate[8]	3.06

We intend to disclose the calculations performed within five days of the date of publication of this notice to parties in this proceeding, in accordance with 19 CFR 351.224(b).

Final Determination of No Shipments

In the *Preliminary Results,* Commerce determined that Razban made no shipments of the subject merchandise during the POR. As we have not received any information to contradict our preliminary finding, we continue to find that Razban did not have any shipments of subject merchandise during the POR and intend to issue appropriate instructions to U.S. Customs and Border Protection (CBP) based on the final results of this review.

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act, and 19 CFR 351.212(b)(1), Commerce has determined, and CBP shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review.

Pursuant to 19 CFR 351.212(b)(1), because ZA Sea Foods reported the entered value for all its U.S. sales, we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total entered value of the sales for which entered value was reported. Where the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

Further, because we continue to find in these final results that Razban had no shipments of subject merchandise during the POR, we will instruct CBP to liquidate any suspended entries that entered under its antidumping duty case number (*i.e.,* at the exporter's rate) at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.

For the companies that were not selected for individual examination, we used, as the assessment rate, the cash deposit rate assigned to ZA Sea Foods, in accordance with our practice.[9]

Commerce's ''reseller policy'' will apply to entries of subject merchandise during the POR produced by companies included in these final results of review for which the reviewed companies did not know that the merchandise they sold to the intermediary (*e.g.,* a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[10]

Commerce intends to issue assessment instructions to CBP 15 days after the date of publication of these final results of review.

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rates for the reviewed companies will be the rates shown above, except if the rate is less than 0.50 percent (*de minimis* within the meaning of 19 CFR 351.106(c)(1)), the cash deposit will be zero; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a previous review, or the original investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all-other manufacturers or exporters will continue to be 10.17 percent, the all-others rate established in the investigation.[11] These 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 the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under the 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 sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i) of the Act and 19 CFR 351.221(b)(5).

Dated: December 21, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the IDM

I. Summary

[7] *See* accompanying IDM.

[8] *See* Appendix II.

[9] *See, e.g., Certain Frozen Warmwater Shrimp from India: Final Results of Antidumping Duty Administrative Review; 2016–2017,* 83 FR 32835 (July 16, 2018).

[10] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[11] *See Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Certain Frozen Warmwater Shrimp from India,* 70 FR 5147, 5148 (February 1, 2005).

II. Background
III. Scope of the Order
IV. Discussion of the Issues
Comment 1: Differential Pricing Time Periods
Comment 2: Use of Third-Country Sales as a Comparison Market
Comment 3: Methodology for Constructed Value Profit and Selling Expenses
Comment 4: Names in Customs Instructions
V. Recommendation

Appendix II

Review-Specific Average Rate Applicable to the Following Companies: [12]

Producers/exporters	Weighted-average dumping margin (percent)
Abad Fisheries	3.06
Albys Agro Private Limited	3.06
Allana Frozen Foods Pvt. Ltd	3.06
Allanasons Ltd	3.06
Amarsagar Seafoods Private Limited	3.06
AMI Enterprises	3.06
Amulya Seafoods	3.06
Anatha Seafoods Private Limited	3.06
Angelique International Ltd	3.06
Ayshwarya Seafood Private Limited	3.06
B R Traders	3.06
Baby Marine Eastern Exports	3.06
Baby Marine Exports	3.06
Baby Marine International	3.06
Baby Marine Sarass	3.06
Baby Marine Ventures	3.06
Balasore Marine Exports Private Limited	3.06
Bell Exim Private Limited (Bells Foods (Marine Division))	3.06
Bhatsons Aquatic Products	3.06
Bhavani Seafoods	3.06
Bijaya Marine Products	3.06
Blue Fin Frozen Foods Pvt. Ltd	3.06
Blue Water Foods & Exports P. Ltd	3.06
B-One Business House Pvt. Ltd	3.06
Britto Seafood Exports Pvt Ltd	3.06
Canaan Marine Products	3.06
Capithan Exporting Co	3.06
Cargomar Private Limited	3.06
Chakri Fisheries Private Limited	3.06
Chemmeens (Regd)	3.06
Cherukattu Industries (Marine Div)	3.06
Cochin Frozen Food Exports Pvt. Ltd	3.06
Continental Fisheries India Private Limited	3.06
Coreline Exports	3.06
Corlim Marine Exports Pvt. Ltd	3.06
Crystal Sea Foods Private Limited	3.06
D2 D Logistics Private Limited	3.06
Damco India Private	3.06
Delsea Exports Pvt. Ltd	3.06
Devi Sea Foods Limited [13]	3.06
Entel Food Products Private Limited	3.06
Esmario Export Enterprises	3.06
Everblue Sea Foods Private Limited	3.06
Exporter Coreline Exports	3.06
Febin Marine Foods	3.06
Five Star Marine Exports Private Limited	3.06
Forstar Frozen Foods Pvt. Ltd	3.06
Fouress Food Products Private Limited	3.06
Frontline Exports Pvt. Ltd	3.06
G A Randerian Ltd	3.06
Gadre Marine Exports	3.06
Galaxy Maritech Exports P. Ltd	3.06
Geo Aquatic Products (P) Ltd	3.06
Goodwill Enterprises	3.06
Grandtrust Overseas (P) Ltd	3.06
Green House Agro Products	3.06
GVR Exports Pvt. Ltd	3.06
Hari Marine Private Limited	3.06
Haripriya Marine Export Pvt. Ltd	3.06
Harmony Spices Pvt. Ltd	3.06
HIC ABF Special Foods Pvt. Ltd	3.06
Hindustan Lever, Ltd	3.06
Hiravata Ice & Cold Storage	3.06

Producers/exporters	Weighted-average dumping margin (percent)
Hiravati Exports Pvt. Ltd	3.06
Hiravati International Pvt. Ltd. (located at APM-Mafco Yard, Sector-18, Vashi, Navi, Mumbai-400 705, India)	3.06
Hiravati International Pvt. Ltd. (located at Jawar Naka, Porbandar, Gujarat, 360 575, India)	3.06
Hiravati Marine Products Private Limited	3.06
HN Indigos Private Limited	3.06
Hyson Logistics and Marine Exports Private Limited	3.06
Indian Aquatic Products	3.06
Indo Aquatics	3.06
Indo Fisheries	3.06
Indo French Shellfish Company Private Limited	3.06
Innovative Foods Limited	3.06
International Freezefish Exports	3.06
Interseas	3.06
Jinny Marine Traders	3.06
Jiya Packagings	3.06
Kalyanee Marine	3.06
Kanch Ghar	3.06
Karunya Marine Exports Private Limited	3.06
Kaushalya Aqua Marine Product Exports Pvt. Ltd	3.06
Kay Exports	3.06
Kings Marine Products	3.06
Koluthara Exports Ltd	3.06
Landauer Ltd	3.06
Libran Cold Storages (P) Ltd	3.06
Magnum Export	3.06
Malabar Arabian Fisheries	3.06
Malnad Exports Pvt. Ltd	3.06
Mangala Sea Products	3.06
Marine Harvest India	3.06
Meenaxi Fisheries Pvt. Ltd	3.06
Megaa Moda Pvt. Ltd	3.06
Milsha Agro Exports Private Limited	3.06
Mourya Aquex Pvt. Ltd	3.06
MTR Foods	3.06
N.C. John & Sons (P) Ltd	3.06
Naik Frozen Foods	3.06
Naik Oceanic Exports Pvt. Ltd./Rafiq Naik Exports Pvt. Ltd.[14]	3.06
Naik Seafoods Ltd	3.06
Nekkanti Mega Food Park Private Limited	3.06
Nine Up Frozen Foods	3.06
Nutrient Marine Foods Limited	3.06
Oceanic Edibles International Limited	3.06
Paragon Sea Foods Pvt. Ltd	3.06
Paramount Seafoods	3.06
Parayil Food Products Pvt., Ltd	3.06
Pesca Marine Products Pvt., Ltd	3.06
Pijikay International Exports P Ltd	3.06
Pisces Seafoods International	3.06
Pravesh Seafood Private Limited	3.06
Premier Exports International	3.06
Premier Marine Foods	3.06
Premier Seafoods Exim (P) Ltd	3.06
R F Exports	3.06
R V R Marine Products Limited	3.06
Raa Systems Pvt. Ltd	3.06
Raju Exports	3.06
Raunaq Ice & Cold Storage	3.06
Raysons Aquatics Pvt. Ltd	3.06
RBT Exports	3.06
RDR Exports	3.06
RF Exports Private Limited	3.06
Riviera Exports Pvt. Ltd	3.06
Rohi Marine Private Ltd	3.06
Royal Imports and Exports	3.06
RSA Marines	3.06
S & S Seafoods	3.06
S Chanchala Combines	3.06
Safa Enterprises	3.06
Sagar Foods	3.06
Sagar Samrat Seafoods	3.06

Producers/exporters	Weighted-average dumping margin (percent)
Sagravihar Fisheries Pvt. Ltd	3.06
Salvam Exports (P) Ltd	3.06
Samaki Exports Private Limited	3.06
Sanchita Marine Products P Limited	3.06
Santhi Fisheries & Exports Ltd	3.06
Sarveshwari Exp	3.06
Sea Foods Private Limited	3.06
Sea Gold Overseas Pvt. Ltd	3.06
Selvam Exports Private Limited	3.06
Sharma Industries	3.06
Shimpo Exports Private Limited	3.06
Shimpo Seafoods Private Limited	3.06
Shiva Frozen Food Exp. Pvt. Ltd	3.06
Shroff Processed Food & Cold Storage P Ltd	3.06
Silver Seafood	3.06
Sita Marine Exports	3.06
Sowmya Agri Marine Exports	3.06
Sri Sakkthi Cold Storage	3.06
Sri Venkata Padmavathi Marine Foods Pvt. Ltd	3.06
Srikanth International [15]	3.06
SSF Ltd	3.06
Star Agro Marine Exports Private Limited	3.06
Star Organic Foods Incorporated	3.06
Star Organic Foods Private Limited	3.06
Stellar Marine Foods Private Limited	3.06
Sterling Foods	3.06
Sun Agro Exim	3.06
Sun-Bio Technology Ltd	3.06
Supran Exim Private Limited	3.06
Suvarna Rekha Exports Private Limited	3.06
Suvarna Rekha Marine P Ltd	3.06
TBR Exports Pvt Ltd	3.06
Teekay Marine P. Ltd	3.06
The Waterbase Limited	3.06
Triveni Fisheries P. Ltd	3.06
U & Company Marine Exports	3.06
Ulka Sea Foods Private Limited	3.06
Uniroyal Marine Exports Ltd	3.06
Unitriveni Overseas	3.06
V.S Exim Pvt Ltd	3.06
Vasai Frozen Food Co	3.06
Veejay Impex	3.06
Veronica Marine Exports Private Limited	3.06
Victoria Marine & Agro Exports Ltd	3.06
Vinner Marine	3.06
Vitality Aquaculture Pvt. Ltd	3.06
VRC Marine Foods LLP	3.06
Zeal Aqua Limited	3.06

[12] Because we only had one respondent with a calculated rate, this rate is used for the review-specific rate.

[13] Shrimp produced and exported by Devi Sea Foods Limited (Devi) was excluded from the order effective February 1, 2009. *See Certain Frozen Warmwater Shrimp from India: Final Results of the Antidumping Duty Administrative Review, Partial Rescission of Review, and Notice of Revocation of Order in Part,* 75 FR 41813, 41814 (July 19, 2010). Accordingly, we initiated this administrative review with respect to Devi only for shrimp produced in India where Devi acted as either the manufacturer or exporter (but not both).

[14] In past reviews, Commerce has treated these companies as a single entity. *See, e.g., Certain Frozen Warmwater Shrimp from India: Final Results of Antidumping Duty Administrative Review; 2016–2017,* 83 FR 32835 (July 16, 2018). Absent information to the contrary, we continue to treat these companies as a single entity for purposes of this administrative review.

[15] On August 27, 2010, Srikanth International was found to be the successor-in-interest to NGR Aqua International. *See Certain Warmwater Shrimp from India: Final Results of Antidumping Duty Changed Circumstances Review,* 75 FR 52718 (August 27, 2010). Therefore, we did not initiate a separate administrative review with respect to NGR Aqua International.

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–714–001]

Phosphate Fertilizers From the Kingdom of Morocco: Amended Preliminary Determination of Countervailing Duty Investigation

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

SUMMARY: The Department of Commerce (Commerce) is amending the preliminary affirmative countervailing duty determination on phosphate fertilizers from the Kingdom of Morocco (Morocco) to correct a significant ministerial error.

DATES: Applicable December 29, 2020.

FOR FURTHER INFORMATION CONTACT: Robert Palmer or Samuel Glickstein, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–9068 or (202) 482-5307, respectively.

SUPPLEMENTARY INFORMATION:

Background

In accordance with section 703(b) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.205(b), on November 30, 2020, Commerce published its preliminary affirmative countervailing duty determination on phosphate fertilizers from Morocco.[1] On November 30, 2020, we received timely ministerial error allegations from the petitioner[2] and OCP S.A. (OCP) that Commerce made significant ministerial errors in the Preliminary Determination with respect to OCP's subsidy rate.[3]

Period of Investigation

The period of investigation (POI) is January 1, 2019 through December 31, 2019.

Scope of the Investigation

The products covered by this investigation are phosphate fertilizers from Morocco. For a complete description of the scope of this investigation, *see* Appendix.

Analysis of Significant Ministerial Error Allegations

Commerce will analyze any comments received and, if appropriate, correct any significant ministerial error by amending the preliminary determination according to 19 CFR 351.224(e). A ministerial error is defined in 19 CFR 351.224(f) as ''an error in addition, subtraction, or other arithmetic function, clerical error resulting from inaccurate copying, duplication, or the like, and any other similar type of unintentional error which the Secretary considers ministerial.''[4] A significant ministerial error is defined as a ministerial error, the correction of which, singly or in combination with other errors, would result in: (1) A change of at least five absolute percentage points in, but not less than 25 percent of, the countervailing duty rate calculated in the original preliminary determination; or (2) a difference between a countervailing duty rate of zero (or *de minimis*) and a countervailing duty rate greater than *de minimis,* or vice versa.[5]

Amended Preliminary Determination

Pursuant to 19 CFR 351.224(e) and (g)(1), Commerce is amending the *Preliminary Determination* to reflect the correction of one ministerial error made in the calculation of the countervailable subsidy rate for OCP.[6] Specifically, when applying the benchmark interest rate to calculate OCP's benefit under the loan guarantee program, we inadvertently failed to convert the number into a useable percentage format. Commerce finds that this ministerial error is a significant ministerial error within the meaning of 19 CFR 351.224(g), because correction of this error decreases OCP's countervailing subsidy rate from 23.46 to 16.88 percent, which is a change that is at least five absolute percentage points in, but not less than 25 percent of, the subsidy rate calculated for OCP in the original *Preliminary Determination.* Furthermore, as OCP's subsidy rate is the only calculated subsidy rate in this investigation and as such is also the all-others subsidy rate,[7] Commerce is amending the preliminary all-others subsidy rate accordingly. For a complete discussion of the alleged ministerial errors, *see* the Preliminary Ministerial Error Memo.

AMENDED PRELIMINARY DETERMINATION

Company	Subsidy rate (percent)
OCP S.A.[8]	16.88
All-Others	16.88

Amended Cash Deposits and Suspension of Liquidation

The collection of cash deposits and suspension of liquidation will be revised according to the rates calculated in this amended preliminary determination. Because the amended rates for OCP and all others result in decreased cash deposits, they will be effective retroactively to November 30, 2020, the date of publication of the *Preliminary Determination.* Parties will be notified of this determination, in accordance with section 703(d) and (f) of the Act.

Disclosure

We intend to disclose the calculations performed to parties in this proceeding within five days after public

[1] *See Phosphate Fertilizers from the Kingdom of Morocco: Preliminary Affirmative Countervailing Duty Determination,* 85 FR 76522 November 30, 2020) (*Preliminary Determination*) and accompanying Preliminary Decision Memorandum.

[2] The petitioner in this investigation is The Mosaic Company.

[3] *See* Petitioner's letter, ''Ministerial Error Comments on the Preliminary Determination,'' dated November 30, 2020 (Petitioner's Clerical Error Comments); and OCP's letter, ''Ministerial Error Comments,'' dated November 30, 2020 (OCP's Ministerial Error Comments).

[4] *See* section 705(e) of the Act.

[5] *See* 19 CFR 351.224(g).

[6] *See* Memorandum, ''Countervailing Duty Investigation of Phosphate Fertilizers from the Kingdom of Morocco: Allegations of Significant Ministerial Errors in the Preliminary Determination,'' dated concurrently with this notice (Preliminary Ministerial Error Memo).

[7] *See Preliminary Determination* at 85 FR 76522, 76523.

[8] As discussed in the Preliminary Decision Memorandum, Commerce has found the following companies to be cross-owned with OCP S.A.: Jorf Fertilizers Company I, Jorf Fertilizers Company II, Jorf Fertilizers Company III, Jorf Fertilizers Company IV, Jorf Fertilizers Company V, and Maroc Phosphore.

[12] Because we only had one respondent with a calculated rate, this rate is used for the review-specific rate.

[13] Shrimp produced and exported by Devi Sea Foods Limited (Devi) was excluded from the order effective February 1, 2009. *See Certain Frozen Warmwater Shrimp from India: Final Results of the Antidumping Duty Administrative Review, Partial Rescission of Review, and Notice of Revocation of Order in Part,* 75 FR 41813, 41814 (July 19, 2010). Accordingly, we initiated this administrative review with respect to Devi only for shrimp produced in India where Devi acted as either the manufacturer or exporter (but not both).

[14] In past reviews, Commerce has treated these companies as a single entity. *See, e.g., Certain Frozen Warmwater Shrimp from India: Final Results of Antidumping Duty Administrative Review; 2016–2017,* 83 FR 32835 (July 16, 2018). Absent information to the contrary, we continue to treat these companies as a single entity for purposes of this administrative review.

[15] On August 27, 2010, Srikanth International was found to be the successor-in-interest to NGR Aqua International. *See Certain Warmwater Shrimp from India: Final Results of Antidumping Duty Changed Circumstances Review,* 75 FR 52718 (August 27, 2010). Therefore, we did not initiate a separate administrative review with respect to NGR Aqua International.

announcement of the amended preliminary determination, in accordance with 19 CFR 351.224.

International Trade Commission Notification

In accordance with section 703(f) of the Act, we will notify the International Trade Commission of our amended preliminary determination.

Notification to Interested Parties

This amended preliminary determination is issued and published pursuant to sections 703(f) and 777(i) of the Act and 19 CFR 351.224(e).

Dated: December 21, 2020.

Joseph A. Laroski Jr.,

Deputy Assistant Secretary for Policy and Negotiations.

Appendix

Scope of the Investigation

The merchandise covered by this investigation is phosphate fertilizers in all physical forms (*i.e.,* solid or liquid form), with or without coating or additives such as anti-caking agents. Phosphate fertilizers in solid form are covered whether granular, prilled (*i.e.,* pelletized), or in other solid form (*e.g.,* powdered).

The covered merchandise includes phosphate fertilizers in the following forms: Ammonium dihydrogenorthophosphate or monoammonium phosphate (MAP), chemical formula NH4H2PO4; diammonium hydrogenorthophosphate or diammonium phosphate (DAP), chemical formula (NH4)2HPO4; normal superphosphate (NSP), also known as ordinary superphosphate or single superphosphate, chemical formula Ca(H2PO4)2·CaSO4; concentrated superphosphate, also known as double, treble, or triple superphosphate (TSP), chemical formula Ca(H2PO4)2·H2O; and proprietary formulations of MAP, DAP, NSP, and TSP.

The covered merchandise also includes other fertilizer formulations incorporating phosphorous and non-phosphorous plant nutrient components, whether chemically-bonded, granulated (*e.g.,* when multiple components are incorporated into granules through, *e.g.,* a slurry process), or compounded (*e.g.,* when multiple components are compacted together under high pressure), including nitrogen, phosphate, sulfur (NPS) fertilizers, nitrogen, phosphorous, potassium (NPK) fertilizers, nitric phosphate (also known as nitrophosphate) fertilizers, ammoniated superphosphate fertilizers, and proprietary formulations thereof that may or may not include other nonphosphorous plant nutrient components. For phosphate fertilizers that contain non-phosphorous plant nutrient components, such as nitrogen, potassium, sulfur, zinc, or other non-phosphorous components, the entire article is covered, including the non-phosphorous content, provided that the phosphorous content (measured by available diphosphorous pentaoxide, chemical formula P2O5) is at least 5% by actual weight.

Phosphate fertilizers that are otherwise subject to this investigation are included when commingled (*i.e.,* mixed or blended) with phosphate fertilizers from sources not subject to this investigation. Phosphate fertilizers that are otherwise subject to this investigation are included when commingled with substances other than phosphate fertilizers subject to this investigation (*e.g.,* granules containing only non-phosphate fertilizers such as potash or urea). Only the subject component of such commingled products is covered by the scope of this investigation. The following products are specifically excluded from the scope of this investigation:

(1) ABC dry chemical powder preparations for fire extinguishers containing MAP or DAP in powdered form;

(2) industrial or technical grade MAP in white crystalline form with available P2O5 content of at least 60% by actual weight;

(3) industrial or technical grade diammonium phosphate in white crystalline form with available P2O5 content of at least 50% by actual weight;

(4) liquid ammonium polyphosphate fertilizers;

(5) dicalcium phosphate, chemical formula CaHPO4;

(6) monocalcium phosphate, chemical formula CaH4P2O8;

(7) trisodium phosphate, chemical formula Na3PO4;

(8) sodium tripolyphosphate, chemical formula Na5P3O10;

(9) prepared baking powders containing sodium bicarbonate and any form of phosphate;

(10) animal or vegetable fertilizers not containing phosphate fertilizers otherwise covered by the scope of this investigation;

(11) phosphoric acid, chemical formula H3PO4.

The Chemical Abstracts Service (CAS) numbers for covered phosphate fertilizers include, but are not limited to: 7722–76–1 (MAP); 7783–28–0 (DAP); and 65996–95–4 (TSP). The covered products may also be identified by Nitrogen-Phosphate-Potash composition, including but not limited to: NP 11–52–0 (MAP); NP 18–46–0 (DAP); and NP 0–46–0 (TSP).

The covered merchandise is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheadings 3103.11.0000; 3103.19.0000; 3105.20.0000; 3105.30.0000; 3105.40.0010; 3105.40.0050; 3105.51.0000; and 3105.59.0000. Phosphate fertilizers subject to this investigation may also enter under subheadings 3103.90.0010, 3105.10.0000, 3105.60.0000, 3105.90.0010, and 3105.90.0050. Although the HTSUS subheadings and CAS registry numbers are provided for convenience and customs purposes, the written description of the scope is dispositive.

[FR Doc. 2020–28760 Filed 12–28–20; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–895]

Low Melt Polyester Staple Fiber From the Republic of Korea: Final Results of Antidumping Duty Administrative Review; 2018–2019

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

SUMMARY: The Department of Commerce (Commerce) determines that the sole producer/exporter subject to this administrative review made sales of subject merchandise at less than normal value during the period of review (POR), February 1, 2018 through July 31, 2019.

DATES: Applicable December 29, 2020.

FOR FURTHER INFORMATION CONTACT: Alice Maldonado or Melissa Kinter, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4682 or (202) 482–1413, respectively.

SUPPLEMENTARY INFORMATION:

Background

The review covers one producer and exporter of the subject merchandise, Toray Advanced Materials Korea, Inc. (TAK).[1]

On June 23, 2020, Commerce published the *Preliminary Results.*[2] Although we invited parties to comment on the preliminary results of the review,[3] no interested party submitted comments. Accordingly, no decision memorandum accompanies this **Federal Register** notice.[4] On July 21, 2020, Commerce tolled all deadlines in administrative reviews by an additional 60 days.[5] The deadline for the final results of this review is now December 21, 2020.

Commerce conducted this administrative review in accordance

[1] On August 28, 2019, Commerce determined that TAK is the successor-in-interest to Toray Chemical Korea, Inc. *See Low Melt Polyester Staple Fiber from the Republic of Korea: Notice of Final Results of Antidumping Duty Changed Circumstances Review,* 84 FR 45129 (August 28, 2019).

[2] *See Low Melt Polyester Staple Fiber from the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review; 2018–2019,* 85 FR 37627 (June 23, 2020) (*Preliminary Results*).

[3] *Id.,* 85 FR at 37628.

[4] For further details of the issues addressed in this proceeding, *see Preliminary Results* and accompanying Preliminary Decision Memorandum.

[5] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews,'' dated July 21, 2020.

with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The merchandise subject to the order includes synthetic staple fibers, not carded or combed, specifically bi-component polyester fibers having a polyester fiber component that melts at a lower temperature than the other polyester fiber component (low melt PSF). The scope includes bi-component polyester staple fibers of any denier or cut length. The subject merchandise may be coated, usually with a finish or dye, or not coated.

Low melt PSF is classifiable under the Harmonized Tariff Schedule of the United States (HTSUS) subheading 5503.20.0015. Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

Final Results of the Review

We are assigning the following weighted-average dumping margin to TAK for the period February 1, 2018 through July 31, 2019, as follows:

Exporter/producer	Weighted-average dumping margin (percent)
Toray Advanced Materials Korea, Inc	2.60

Assessment Rates

Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries in accordance with section 751(a)(2)(C) of the Act and 19 CFR 351.212(b).

Pursuant to 19 CFR 351.212(b)(1), where the respondent reported the entered value of their U.S. sales, we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the examined sales to the total entered value of the sales for which entered value was reported. Where the respondent did not report entered value, we calculated the entered value in order to calculate the assessment rate. Where either the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. We intend to instruct CBP to take into account the ''provisional measures deposit cap,'' in accordance with 19 CFR 351.212(d).

The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.[6]

Commerce's ''automatic assessment'' will apply to entries of subject merchandise during the POR produced by TAK for which it did not know that the merchandise it sold to an intermediary (*e.g.,* a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[7] The all-others rate is 16.27 percent.[8]

Commerce intends to issue assessment instructions to CBP 15 days after the date of publication of these final results of review.

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for TAK will be the rate shown above; (2) for previously reviewed or investigated companies not participating in this review, the cash deposit rate will continue to be the company-specific rate published for the most recently-completed segment; (3) if the exporter is not a firm covered in this review, a previous review, or the original less-than-fair value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent segment for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 16.27 percent, the all-others rate made effective by the LTFV investigation.[9] These 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 the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition 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 return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i) of the Act.

Dated: December 21, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2020–28754 Filed 12–28–20; 8:45 am]

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[6] *See* section 751(a)(2)(C) of the Act.

[7] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[8] *See Low Melt Polyester Staple Fiber from the Republic of Korea and Taiwan: Antidumping Duty Orders,* 83 FR 40752, 40753 (August 16, 2018).

[9] *Id.*

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Sanctuary System Business Advisory Council: Public Meeting

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of open meeting.

SUMMARY: Notice is hereby given of a meeting of the Sanctuary System Business Advisory Council (council). The meeting is open to the public, an opportunity for ''oral and written'' comments will be provided.

DATES: The meeting will be held Thursday, January 14, 2021 from 12 to 3 p.m. ET, and an opportunity for public comment will be provided around 2:15 p.m. ET. Both these times and agenda topics are subject to change.

ADDRESSES: The meeting will be held virtually. To participate in the public meeting, online registration is requested in advance via the link below. After registering, you will receive a confirmation email containing information about joining the webinar. If you are unable to participate online, you can also connect to the public meeting using the phone number provided below.

Registration: https://attendee.gotowebinar.com/register/3251401429937219595.

Phone: +1 (914) 614–3221, Pin: 375–797–022.

To provide a public comment during the virtual meeting, please sign up in advance. Select ''yes'' during the online registration. The line-up of speakers will be based on your date and time of registration. By selecting ''yes'', you agree that these communications, including your name and comment, will be maintained by the Office of National Marine Sanctuaries as part of its administrative record and may be subject to release pursuant to the Freedom of Information Act.

FOR FURTHER INFORMATION CONTACT: Katie Denman, Office of National Marine Sanctuaries, 1305 East West Highway, N/NMS, Silver Spring, Maryland 20910 (Phone: 240–533–0702; Email: *Katie.Denman@noaa.gov*).

SUPPLEMENTARY INFORMATION: ONMS serves as the trustee for a network of underwater parks encompassing more than 620,000 square miles of marine and Great Lakes waters from Washington State to the Florida Keys, and from Lake Huron to American Samoa. The network includes a system of 14 national marine sanctuaries and Papahānaumokuākea and Rose Atoll marine national monuments. National marine sanctuaries protect our nation's most vital coastal and marine natural and cultural resources, and through active research, management, and public engagement, sustain healthy environments that are the foundation for thriving communities and stable economies.

One of the many ways ONMS ensures public participation in the designation and management of national marine sanctuaries is through the formation of advisory councils. The Sanctuary System Business Advisory Council (council) has been formed to provide advice and recommendations to the Director regarding the relationship of ONMS with the business community. Additional information on the council can be found at *http://sanctuaries.noaa.gov/management/ac/welcome.html*.

Matters to be discussed: The meeting will include updates from the Office of National Marine Sanctuaries, introductions from the newly appointed members, an overview of Business Advisory Council member roles and responsibilities including the formation of and goals for working groups to address issues related to sustainable recreation and tourism in national marine sanctuaries, and an opportunity for the public to provide written and oral comments. For a complete agenda, including times and topics, please visit *http://sanctuaries.noaa.gov/management/bac/meetings.html*.

Authority: 16 U.S.C. Sections 1431, *et seq.*

John Armor,

Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2020–28630 Filed 12–28–20; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Hydrographic Services Review Panel

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

ACTION: Notice of call for nominations for NOAA's Hydrographic Services Review Panel Federal advisory committee.

SUMMARY: The National Oceanic and Atmospheric Administration is seeking nominations for members to serve on the Hydrographic Services Review Panel with nominations due by April 26, 2021.

DATES: Nominations are sought to keep an active pool of candidates and should be submitted by April 26, 2021, and will be kept to be used for future vacancies. Five vacancies for a four-year term will occur on January 1, 2022. Current members who may be eligible for a second term in 2022 must reapply. HSRP maintains a pool of candidates and advertises once a year to fulfill the HSIA requirements on membership solicitation.

ADDRESSES: Nominations will be accepted by email and should be sent to: *Hydroservices.panel@noaa.gov*. You will receive a confirmation response.

FOR FURTHER INFORMATION CONTACT: Lynne Mersfelder-Lewis, NOAA HSRP program manager, email *Lynne.Mersfelder@noaa.gov* or phone: 240–523–0064.

SUPPLEMENTARY INFORMATION: In accordance with the Hydrographic Service Improvements Act Amendments of 2002, Public Law 107–372, the Administrator of the National Oceanic and Atmospheric Administration (NOAA) is required to solicit nominations for membership once a year for the Hydrographic Services Review Panel (HSRP). The HSRP, a Federal advisory committee, advises the Administrator on matters related to the responsibilities and authorities set forth in section 303 of the Hydrographic Services Improvement Act and such other appropriate matters as the Administrator refers to the Panel for review and advice. Those responsibilities and authorities include, but are not limited to: Acquiring and disseminating hydrographic data and providing hydrographic services, as those terms are defined in the Act; promulgating standards for hydrographic data and services; ensuring comprehensive geographic coverage of hydrographic services; and testing, developing, and operating vessels, equipment, and technologies necessary to ensure safe navigation and maintain operational expertise in hydrographic data acquisition and hydrographic services.

The Act states ''the voting members of the Panel shall be individuals who, by reason of knowledge, experience, or training, are especially qualified in one or more of the disciplines and fields relating to hydrographic data and hydrographic services, marine transportation, port administration, vessel pilotage, coastal and fishery management, and other disciplines as determined appropriate by the Administrator.'' The NOAA Administrator seeks and encourages individuals with expertise in marine navigation and technology, port administration, marine shipping or other intermodal transportation industries, cartography and geographic information systems, geodesy, physical oceanography, coastal resource management, including coastal preparedness and emergency response, and other related fields. Nominees are requested to submit five items including a cover letter that responds to the five questions below. The entire package should include all five components and be no longer than eight pages. NOAA is an equal opportunity employer.

(1) A cover letter that responds to the five questions listed below and serves as a statement of interest to serve on the

panel. Please see ''Short Response Questions'' below.

(2) Highlight the nominee's specific area(s) of expertise relevant to the purpose of the Panel from the list in the **Federal Register** Notice.

(3) A short biography of 300 to 350 words.

(4) A current resume.

(5) The nominee's full contact information including: Full name, work title, institutional affiliation, mailing address, email(s), phone, and fax.

Short Response Questions for the Cover Letter

(1) List your area(s) of expertise, from the list above.

(2) List the geographic region(s) of the country with which you primarily associate your expertise.

(3) Describe your leadership or professional experiences which you believe will contribute to the effectiveness of the HSRP panel.

(4) Describe your familiarity and experience with NOAA NOS navigation data, products, and services.

(5) Generally describe the breadth and scope of your knowledge of stakeholders, users, or other groups who interact with NOAA and whose views and input you believe you can share with the panel.

Under 33 U.S.C. 883a, *et seq.,* NOAA's National Ocean Service (NOS) is responsible for providing nautical charts and related information for safe navigation. NOS collects and compiles hydrographic, tidal and current, geodetic, and a variety of other data in order to fulfill this responsibility. The HSRP provides advice on current and emerging oceanographic and marine science technologies relating to operations, research and development; and dissemination of data pertaining to:

(a) Hydrographic surveying;

(b) Shoreline surveying;

(c) Nautical charting;

(d) Water level measurements;

(e) Current measurements;

(f) Geodetic measurements;

(g) Geospatial measurements;

(h) Geomagnetic measurements; and

(i) Other oceanographic/marine related sciences.

The Panel has fifteen voting members appointed by the NOAA Administrator in accordance with 33 U.S.C. 892c. Members are selected on a standardized basis, in accordance with applicable Department of Commerce guidance. The Co-Directors of the Center for Coastal and Ocean Mapping/Joint Hydrographic Center and two other NOAA employees serve as nonvoting members of the Panel. The Director, NOAA Office of Coast Survey, serves as the Designated Federal Official (DFO) along with two Alternate DFOs.

Voting members are individuals who, by reason of knowledge, experience, or training, are especially qualified in one or more disciplines relating to hydrographic surveying, tides, currents, geodetic and geospatial measurements, marine transportation, port administration, vessel pilotage, coastal or fishery management, and other oceanographic or marine science areas as deemed appropriate by the Administrator. Full-time officers or employees of the United States may not be appointed as a voting member. Any voting member of the Panel who is an applicant for, or beneficiary of (as determined by the Administrator) any assistance under 33 U.S.C. 892c shall disclose to the Panel that relationship, and may not vote on any other matter pertaining to that assistance.

Voting members of the Panel serve a four-year term, except that vacancy appointments are for the remainder of the unexpired term of the vacancy. Members serve at the discretion of the Administrator and are subject to government ethics standards. Any individual appointed to a partial or full term may be reappointed for one additional full term. A voting member may serve until his or her successor has taken office. The Panel selects one voting member to serve as the Chair and another to serve as the Vice Chair. The Vice Chair acts as Chair in the absence or incapacity of the Chair but will not automatically become the Chair if the Chair resigns. Public meetings occur at least twice a year, and at the call of the Chair or upon the request of a majority of the voting members or of the Administrator. Voting members receive compensation at a rate established by the Administrator, not to exceed the maximum daily rate payable under section 5376 of title 5, United States Code, when engaged in performing duties for the Panel during the public meeting. Members are reimbursed for actual and reasonable travel expenses incurred in performing such duties according to the Federal Travel Regulation.

Additional HSRP information and past HSRP public meeting summary reports, agendas, presentations, transcripts, webinars, and other information is available online at:

Membership: https://www.nauticalcharts.noaa.gov/hsrp/panel.html

Recommendations: https://www.nauticalcharts.noaa.gov/hsrp/recommendations.html

Meeting materials: https://www.nauticalcharts.noaa.gov/hsrp/meetings.html

Individuals Selected for Panel Membership

Upon selection and agreement to serve on the HSRP Panel, you become a Special Government Employee (SGE) of the United States Government. 18 U.S.C. 202(a) an SGE(s) is an officer or employee of an agency who is retained, designated, appointed, or employed to perform temporary duties, with or without compensation, not to exceed 130 days during any period of 365 consecutive days, either on a fulltime or intermittent basis. After the selection process is complete, applicants selected to serve on the Panel must complete the following actions before they can be appointed as a Panel member:

(a) Security Clearance (on-line Background Security Check process and fingerprinting conducted through NOAA Workforce Management); and

(b) Confidential Financial Disclosure Report—SGE are required to file a Confidential Financial Disclosure Report to avoid involvement in a real or apparent conflict of interest. You may find information on the Confidential Financial Disclosure Report at: *https://www.oge.gov/Web/oge.nsf/Resources/OGE+Form+450.*

Kathryn Ries,

Deputy Director, Office of Coast Survey, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2020–28746 Filed 12–28–20; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RTID 0648–XA741

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to State Route 520 Pontoon Pile Removal Project, Aberdeen, Grays Harbor County, Washington

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

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that NMFS has issued an incidental harassment authorization (IHA) to the Washington State Department of Transportation (WSDOT) to incidentally harass, by Level B harassment, marine

mammals during pile driving activities associated with the State Route 520 Pontoon Construction Site—Marine Piling Removal Project in Aberdeen, Grays Harbor County, Washington.

DATES: This Authorization is effective for a period of one year, from December 21, 2020 through December 20, 2021.

FOR FURTHER INFORMATION CONTACT: Bonnie DeJoseph, 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/permit/incidental-take-authorizations-under-marine-mammal-protection-act*. 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 issued or, if the taking is limited to harassment, a notice of a proposed incidental take authorization may be 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.

Summary of Request

On November 20, 2019, NMFS received a request from WSDOT for an IHA to take marine mammals incidental to the removal of 19-steel piles at the mouth of the Chehalis River where it enters Grays Harbor, WA. WSDOT submitted three revisions, including three between November 2019 and July 2020, with the last being deemed adequate and complete on July 30, 2020. WSDOT subsequently submitted a final update to their application on August 17, 2020. Their request is for take of a small number of Pacific harbor seals (*Phoca vitulina*); California sea lions (*Zalophus californianus*); Steller sea lions (*Eumetopias jubatus*); gray whales (*Eschrichtius robustus*); and harbor porpoises (*Phocoena phocoena*) by Level B harassment only. Neither WSDOT nor NMFS expects serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

Description of the Specified Activity

WSDOT plans to remove 19 steel piles and associated barge launch guide appurtenances from the footprint of the casting basin launch channel within the Washington State Department of Natural Resources (DNR) aquatic easement lease area in Grays Harbor (Figures 1 and 2). WSDOT must remove the 19 steel piles on state owned aquatic lands to comply with the terms and conditions of the lease agreement with the Washington DNR. The piles were used to guide completed pontoons out of the casting basin and into Grays Harbor for transport to Lake Washington for the replacement of the SR520 floating-bridge. As the action of pile driving is used in both the installation and removal of piles, the term ''pile driving'' is hereafter used in this document to refer to pile removal.

A vibratory extractor on a crane will be used to remove the piles over a seven-day period with one day for mobilization and another day for demobilization on either end, for a total of nine days of in-water work. Pile removal is estimated to take 14.25 hours over a seven-day period with one day for mobilization and another day for demobilization on either end, for a total of nine days (Table 1). The IHA is effective for a period of one year from date of issuance. WSDOT demarcated their in-water work window to 16 July–15 February to protect Endangered Species Act (ESA)-listed fish and plans to complete work during the current work window. The crane will be located on a barge or flexi float, positioned near the piles. Sound in the water from vibratory pile driving may result in behavioral disturbance (or Level B harassment) of five marine mammal species.

A detailed description of the planned State Route 520 Pontoon Construction Site—Marine Piling Removal project is provided in the **Federal Register** notice for the proposed IHA (85 FR 68042; October 27, 2020). Since that time, no changes have been made to the planned activities. Therefore, a detailed description is not provided here. Please refer to that **Federal Register** notice for the description of the specific activity.

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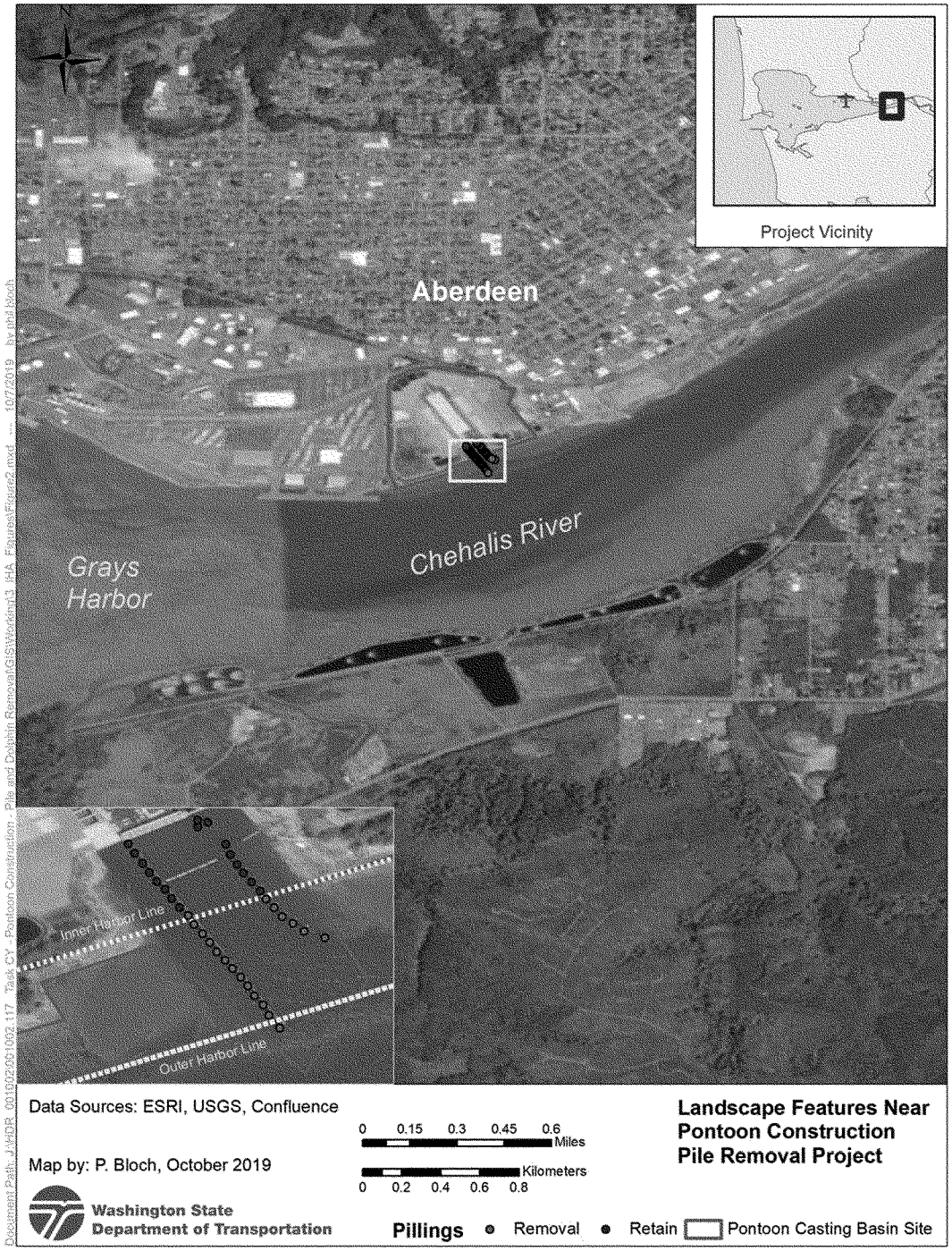

Figure 1. Project Location – Detailed

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TABLE 1—SUMMARY OF PILE DRIVING ACTIVITIES

Method	Pile type	Estimated noise level * (dB_{RMS})	Number of piles	Minutes per pile	Total time (hours)	Piles per day	Time per day (hours)	Activity period (days) **
Vibratory Removal	48-inch steel pile	171	1	45	0.75	1	0.75	1
Vibratory Removal	24-inch steel pile	162	17	45	12.75	4	3	5
Vibratory Removal	18-inch steel pile	162	1	45	0.75	1	0.75	1
TOTAL			19	45	14.25	6	14.25	7

* Origin of project sound source levels discussed in Estimated Take section.

** Pile removal activities will be conducted across 11-hour (at maximum) work days, but a ''day'' of work may not require 11 hours. NMFS increased the estimated removal time of the 18 and 48-inch piles from 0.5 day, as proposed by WSDOT, to 1 day, to reflect a more realistic representation of the potential schedule; *i.e.,* the potential that the two piles maybe removed on separated days.

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

Comments and Responses

A notice of NMFS's proposal to issue an IHA to WSDOT was published in the **Federal Register** on October 27, 2020 (85 FR 68042). That notice described, in detail, WSDOT's activity, the marine mammal species that may be affected by the activity, and the anticipated effects on marine mammals. During the 30-day public comment period, NMFS received comments from the Marine Mammal Commission (Commission). Please see the Commission's letter for full details regarding their recommendations and rationale. The letter is available online at: *https://www.fisheries.noaa.gov/action/incidental-take-authorization-state-route-520-pontoon-pile-removal-project-aberdeen-grays.* A summary of the Commission's recommendations as well as NMFS' responses is below.

Comment 1: The Commission recommended that NMFS re-estimate the (1) summer density for Steller sea lions based on adjusting the 2015 pup and non-pup data using the trend data from 2017, applying the non-pup growth rate to the non-pup counts and the pup growth rates to the pup counts, and applying the relevant growth rates up to at least 2020 and (2) winter density for California sea lions based on applying the relevant growth rates up to at least 2020 and increase the numbers of takes accordingly.

Response: NMFS does not concur and does not adopt the Commission's recommendation. The Navy Marine Species Density Database (NMSDD) technical report (2019) describes density estimates that were used in the Navy's acoustics effects model. To complete the modeling on schedule, the density data available at that time from the final 2016 SAR (Muto *et al.,* 2017) were used. Steller sea lion densities were calculated independently for regional populations in Washington, Oregon, California, and southeast Alaska, consistent with the stock assessment reports. No trend data were (or are currently) estimated for pups in Washington, therefore, the non-pup growth rate of 8.77 percent per year was used for the entire population. In addition, the baseline abundance for Washington sea lions was increased over the abundance from the stock assessment report based on data reported in Wiles (2015) before the growth rate was applied to project a 2017 abundance. In comparison, the non-pup growth rate was used for sea lions in Oregon, California, and southeast Alaska because the number of non-pups in each population was substantially greater than the number of pups. Using separate growth rates for pups and non-pups in all three regions results in less than a 1 percent increase in the projected 2017 abundance. The associated change in the density is minimal and would not change the results of NMFS' or WSDOT's analysis of acoustic impacts on Steller sea lions.

Comment 2: The Commission recommends that when NMFS uses Department of Navy pinniped densities for all future incidental take authorizations, it revise the density estimates based on the most recent abundance and trend data from the stock assessment reports (SARs) forward-projected into the year that the action proponent's activities are proposed to occur.

Response: NMFS appreciates the Commission's recommendation, and will consider it as appropriate when evaluating future requests for authorization.

Comment 3: The Commission recommends NMFS (1) consult with the Washington Department of Fish and Wildlife (WDFW) and determine whether the seal counts for Grays Harbor are correct as referenced in Jeffries *et al.* (2015), (2) if so, increase the density from 30.85 to 31.39 seals/ and revise the number of harbor seal takes to be 2,196 in the notice for issuance of the final authorization and the final authorization, and (3) if not, specify that the total seal counts originated from WDFW (pers. comm.) rather than Jeffries *et al.* (2015) in the notice for issuance of the final authorization.

Response: NMFS consulted with WDFW and determined that an updated data set of seal counts in Grays Harbor was used to calculate the density (personal communication WDFW, 2020), not Jeffries *et al.* (2015). The calculations are detailed in the Estimated Take section. WDFW is in the process of error checking and cleaning up the seal counts survey data set, and NMFS used the final data set supplied by WDFW for the density.

Comment 4: The Commission recommends that NMFS include in the final authorization the requirement that WSDOT conduct pile-removal activities during daylight hours only.

Response: We do concur with the Commission's recommendation and do not adopt it. While WSDOT has no intention of conducting pile driving activities at night, it is unnecessary to preclude such activity should the need arise (*e.g.,* on an emergency basis or to complete driving of a pile begun during daylight hours, should the construction operator deem it necessary to do so). We disagree with the statement that a prohibition on pile driving activity outside of daylight hours is necessary to meet the MMPA's least practicable adverse impact standard, and the Commission does not justify this assertion.

Comment 5: The Commission recommends that NMFS include in the final authorization the requirement that, if environmental conditions deteriorate such that marine mammals within the entire shut-down zone would not be visible (*e.g.,* fog, heavy rain), pile-removal activities must be delayed until the Protected Species Observer (PSO) is confident that marine mammals within the shut-down zone could be detected.

Response: NMFS concurs with this recommendation and has adopted it.

Comment 6: The Commission recommends that NMFS revise the final authorization to require WSDOT to report the number of individuals of each

species detected within the Level B harassment zones and estimates of the numbers of marine mammals taken by Level B harassment, by species. The Commission additionally recommends that NMFS require that WSDOT include in its monitoring report (1) the estimated percentage(s) of the Level B harassment zones that was not visible, (2) an extrapolation of the estimated takes by Level B harassment based on the number of observed exposures within the Level B harassment zone and the percentage of the Level B harassment zone that was not visible (*i.e.,* extrapolated takes), and (3) the total number of Level B harassment takes based on both the observed and extrapolated takes for each species.

Response: We do not fully concur with the Commission's recommendation and do not adopt it as stated. NMFS agrees with the recommendation to require WSDOT to report the number of individuals of each species detected within the Level B harassment zones and has included this requirement in both the proposed and final authorizations. (See condition 6(b)(ix).) NMFS does not agree with the recommendation to require WSDOT to report estimates of the numbers of marine mammals taken by Level B harassment. The Commission does not explain why it believes this requirement is necessary, nor does it provide recommendations for methods of generating such estimates in a manner that would lead to credible results. NMFS does not agree that the basic method described in footnote 22 of the Commission's letter should be expected to yield estimates of total take such that readers of WSDOT's report should have confidence that the estimates are reasonable representations of what may have actually occurred. NMFS does agree that WSDOT should report the estimated percentage(s) of the Level B harassment zones that were not visible, and has included this requirement in both the proposed and final authorizations. (See condition 6(b)(iii).) These pieces of information—numbers of individuals of each species detected within the harassment zones and the estimated percentage(s) of the harassment zones that were not visible—may be used to glean an approximate understanding of whether WSDOT may have exceeded the amount of take authorized. Although the Commission does not explain its reasoning for offering these recommendations, NMFS' recognizes the basic need to understand whether an IHA-holder may have exceeded its authorized take. The need to accomplish this basic function of reporting does not require that NMFS require applicants to use methods we do not have confidence in to generate estimates of ''total take'' that cannot be considered reliable.

Comment 7: The Commission recommends that NMFS reinforce that WSDOT must keep a running tally of the total Level B harassment takes, both observed and extrapolated, for each species consistent with condition 4(h) of the final authorization.

Response: The IHA indicates the number of takes authorized for each species. We agree that WSDOT must ensure they do not exceed authorized takes, but do not concur with the Commission's repeated recommendations regarding the need for NMFS to oversee IHA-holders' compliance with issued IHAs, including the use of a ''running tally'' of takes. Regardless of the Commission's substitution of the word ''reinforce'' for the word ''ensure,'' as compared with its prior recommendations for other actions, compliance with the terms of an issued IHA remains the responsibility of the IHA-holder.

Comment 9: The Commission recommends that NMFS refrain from issuing a renewal for any authorization unless it is consistent with the procedural requirements specified in section 101(a)(5)(D)(iii) of the MMPA.

Response: In prior responses to comments about IHA Renewals (*e.g.,* 84 FR 52464; October 02, 2019 and 85 FR 53342, August 28, 2020), NMFS has explained how the Renewal process, as implemented, is consistent with the statutory requirements contained in section 101(a)(5)(D) of the MMPA, provides additional efficiencies beyond the use of abbreviated notices, and, further, promotes NMFS' goals of improving conservation of marine mammals and increasing efficiency in the MMPA compliance process. Therefore, we intend to continue implementing the Renewal process.

Changes From the Proposed IHA to Final IHA

Corrections were made to reflect seven possible working days as shown in Table 1, with one day for mobilization and another day for demobilization on either end, totaling nine days of possible in-water work. Marine mammal density information used in take calculations was updated from fall to highest seasonal values (Navy 2019) to reflect the revised construction schedule as follows: (1) Off-shore Washington winter distribution density value of 0.649 California Sea Lions/kilometer squared (km^2), and (2) off-shore Washington summer distribution density value of 0.1993 Steller Sea Lions/km^2. See Estimated Take section below. We also clarified that harbor seal take calculations are based on the updated dataset of WDFW's seal surveys (personal communication WDFW 2020). Due to a calculation error, corrections were made to total take calculations of harbor porpoises from 28 to 31 and to Pacific harbor seals from 1187 to 2157 (see Tables 9 and 10). Level A harassment zones were corrected as shown in Table 8. Finally, NMFS clarified that driving proxies were used for three pile sizes because removal values are not available and median source levels of vibratory driving proxies were used for 18 and 24-inch piles.

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. Additional information regarding population trends and threats may be found in NMFS's Stock Assessment Reports (SARs; *https://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's website (*https://www.fisheries.noaa.gov/find-species*).

Table 2 lists all species or stocks for which take is expected and authorized for this action, and summarizes information related to the population or stock, including regulatory status under the MMPA and ESA and potential biological removal (PBR), where known. For taxonomy, we follow Committee on Taxonomy (2020). 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's SARs). While no 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's 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's U.S. Pacific SARs (*e.g.,* Carretta, *et al.,* 2020). All values presented in Table 2 are the most recent available at the time of publication and are available in the 2019 SARs (Carretta, *et al.,* 2020) (available online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/draft-marine-mammal-stock-assessment-reports*).

TABLE 2—MARINE MAMMALS POTENTIALLY PRESENT IN THE VICINITY OF THE STUDY AREAS

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 North Pacific	-, -, N	26,960 (0.05, 25,849, 2016).	801	139
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)						
Family Phocoenidae (porpoises):						
Harbor Porpoise	*Phocoena*	Northern OR/WA Coast	-, -, N	21,487 (0.44, 15,123, 2011).	151	≥3.0
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 [4] (see SAR, 43,201, 2017).	2,592	113
Family Phocidae (earless seals):						
Harbor Seal	*Phoca vitulina richardii*	Oregon/Washington Coastal.	-, -, N	24,732 [5] (UNK, UNK, 1999).	UND	10.6

[1] Endangered Species Act (ESA) status: Endangered I, 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-assessments.* CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance. In some cases, CV is not applicable.

[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 M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

[4] NEST is the best estimate of pup and non-pup counts, which have not been corrected to account for animals at sea during abundance surveys.

[5] Abundance estimate for this stock is not considered current. PBR is therefore considered undetermined, as there is no current minimum abundance estimate for use in calculation. We nevertheless present the most recent abundance estimate, as it represents the best available information for use in this document.

As indicated above, all five species (with five managed stocks) in Table 2 temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur, and we are authorizing it. All species that could potentially occur in the survey areas are included in Table 3–1 of the IHA application.

A detailed description of the of the species likely to be affected by the project, including brief introductions to the species and relevant stocks as well as available information regarding population trends and threats, and information regarding local occurrence, were provided in the **Federal Register** notice for the proposed IHA (85 FR 68042; October 27, 2020); since that time, we are not aware of any changes in the status of these species and stocks; therefore, detailed descriptions are not provided here. Please refer to that **Federal Register** notice for these descriptions. Please also refer to NMFS' website (*https://www.fisheries.noaa.gov/find-species*) for generalized species accounts.

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. Current data indicate that not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok & Ketten 1999; Au & Hastings 2008). To reflect this, Southall *et al.,* (2007) recommended that marine mammals be divided into functional hearing groups based on directly measured or estimated hearing ranges on the basis of available behavioral response data, audiograms derived using auditory evoked potential techniques, anatomical modeling, and other data. 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 3.

TABLE 3—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 & Holt 2013).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information. Five marine mammal species (2 cetacean and three pinniped (two otariid and one phocid) species) have the reasonable potential to co-occur with the planned activities. Please refer to Table 2. Of the cetacean species that may be present, one is classified as a low-frequency cetacean (*i.e.,* all mysticete species) and one is classified as a high-frequency cetacean (*i.e.,* harbor porpoise).

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

The effects of underwater noise from pile removal activities have the potential to result in behavioral harassment of marine mammals in the vicinity of the survey area. The notice of proposed IHA (85 FR 68042; October 27, 2020) included a discussion of the effects of anthropogenic noise on marine mammals and the potential effects of underwater noise from WSDOT's vibratory pile removal on marine mammals and their habitat. That information and analysis is incorporated by reference into this final IHA determination and is not repeated here; please refer to the notice of proposed IHA (85 FR 68042; October 27, 2020).

Estimated Take

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

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 be by Level B harassment only, in the form of disruption of behavioral patterns for individual marine mammals resulting from exposure to sound from vibratory pile removal. Based on the nature of the activity, Level A harassment is neither anticipated nor authorized.

As described previously, no mortality is anticipated or authorized for this activity. Below we describe how the take is estimated.

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) and the number of days of activities. We note that while these basic factors can contribute to a basic calculation to provide an initial prediction of 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 authorized take estimate.

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 permanent threshold shift (PTS) of some degree (equated to Level A harassment).

Level B Harassment for non-explosive sources—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 (*e.g.,* frequency, predictability, duty cycle), the environment (*e.g.,* bathymetry), and the receiving animals (hearing, motivation, experience, demography, behavioral context) and can be difficult to predict (Southall *et al.,* 2007, Ellison *et al.,* 2012). Based on what the available science indicates and the practical need to use a threshold based on a factor that is both predictable and measurable for most activities, NMFS uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS predicts that marine mammals are likely to be behaviorally harassed in a manner we consider Level B harassment when exposed to underwater anthropogenic noise above received levels of 120 dB re 1 micro Pascal (μPa) (root mean square (rms)) for continuous (*e.g.,* vibratory pile-driving, drilling) and above 160 dB re 1 μPa (rms) for non-explosive impulsive (*e.g.,* seismic airguns) or intermittent (*e.g.,* scientific sonar) sources.

WSDOT's activity includes the use of a continuous source (vibratory pile removal); therefore, the 120 dB re 1 μPa (rms) is applicable.

Level A harassment for non-explosive sources—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 activity includes the use of non-impulsive (vibratory pile removal) 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 *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

TABLE 4—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.
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 1μPa^{2}s. In this Table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI 2013). However, peak sound pressure is defined by ANSI 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 will feed into identifying the area ensonified above the acoustic thresholds, which include source levels and transmission loss coefficient.

The sound field in the project area is the existing background noise plus additional construction noise from the project. Marine mammals are expected to be affected via sound generated by vibratory pile removal.

Vibratory hammers produce constant sound when operating, and produce vibrations between 1,200 and 2,400 vibrations per minute that liquefy the sediment surrounding the pile, allowing it to be removed with an upward lift from the crane. The actual duration to remove each pile depends on the type and size of the pile, sediment characteristics, etc.

In order to calculate distances to the Level A harassment and Level B harassment sound thresholds for piles of various sizes being used in this project, NMFS used acoustic monitoring data from other locations to develop source levels for the various pile types, sizes and methods. NMFS derived the project sound source levels from reviewing vibratory pile driving source levels in the Naval Base Kitsap at Bangor Trident Support Facilities EHW–2 Project Acoustic Monitoring Report (2013), CALTRANS Compendium (2015), and Naval Base Kitsap at Bangor Test Pile Program Acoustic Monitoring Report (I&R 2012) (See Table 5). Since adequate data was not available for 18-inch steel piles the vibratory pile driving of 24-inch steel pile, with more than 100 data points, with a median source level of 162 dB rms was used as a proxy. NMFS believes the available data for 48-inch steel piles may be underestimated in comparison to more robust data for 30 and 36-inch steel piles. Hence, the 75th percentile of the sample was used rather than the median noise level (165 dB rms) to ensure the selected source level is adequately representative of actual source levels. All proxies used are derived from vibratory pile installation as removal values are unavailable. Use of source levels from installation events as a proxy for removal events is expected to be somewhat conservative.

TABLE 5—PROJECT SOUND SOURCE LEVELS

Pile driving activity		Source level
Hammer type	Pile type	dB rms
Vibratory Removal	18-inch steel pile	162
	24-inch steel pile	162
	48-inch steel pile	171

Note: Estimated sound source level at 10 meters without attenuation.

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 activity.

Using the practical spreading model, WSDOT determined underwater noise would fall below the behavioral effects threshold of 120 dB rms for marine mammals. NMFS independently estimated the Level B harassment areas using geographic information system (GIS) tools to eliminate land masses and other obstacles that block sound propagation at high tide. Such topographic barriers limit the maximum distance from being attained in all directions as shown by the actual ensonified areas calculated (Figure 2). The estimated Level B harassment distances and associated areas (as limited by topographic barriers), summarized in Table 6, determines the maximum potential Level B harassment zones for the project.

TABLE 6—LEVEL B ISOPLETHS FOR EACH PILE TYPE

Vibratory pile type	Level B isopleth (m)	Area (km^2)
18-inch steel pile	6,310	9.1
24-inch steel pile	6,310	9.1
48-inch steel pile	25,120	15.35

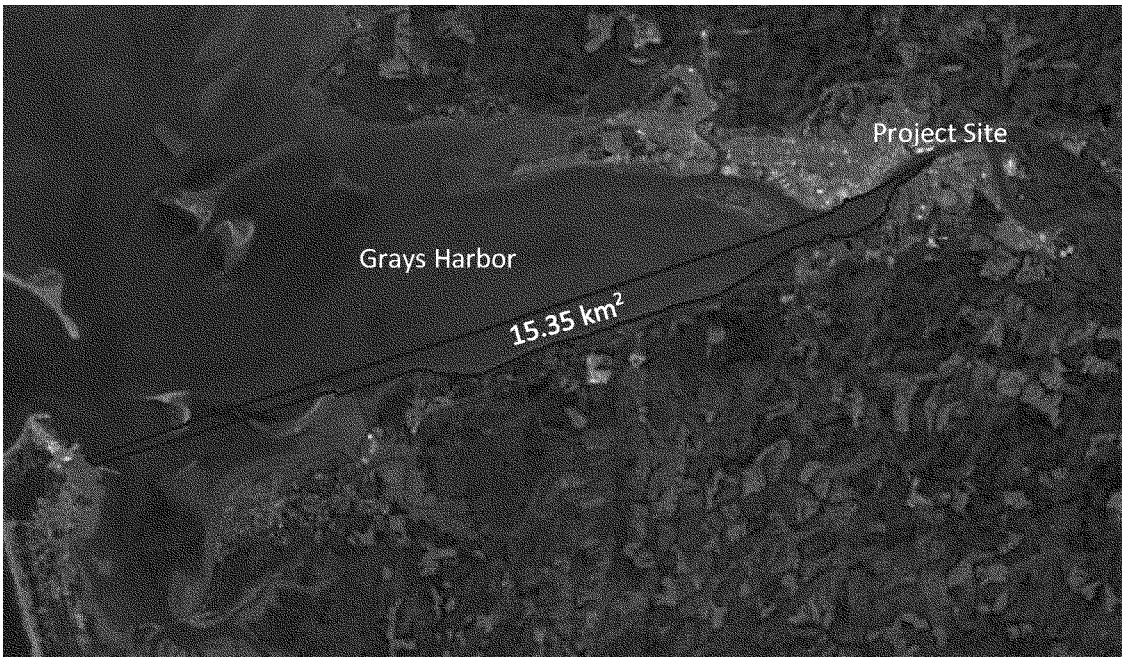

Figure 2. Estimated Area to be Ensonified to Level B Harassment Threshold for 48-inch Steel Piles

Level A Harassment Zones

When the NMFS Technical Guidance (2016) was published, in recognition of the fact that ensonified area/volume could be more technically challenging to predict because of the duration component in the new thresholds, we developed a User Spreadsheet that includes tools to help predict a simple isopleth that can be used in conjunction with marine mammal density or occurrence to help predict takes. We note that because of some of the assumptions included in the methods used for these tools, we anticipate that isopleths produced are typically going to be overestimates of some degree, which may result in some degree of overestimate of Level A harassment take. However, these tools offer the best way to predict appropriate isopleths when more sophisticated 3D modeling methods are not available, and NMFS continues to develop ways to quantitatively refine these tools, and will qualitatively address the output where appropriate. For stationary sources such as vibratory pile removal, NMFS User Spreadsheet predicts the distance at which, if a marine mammal remained at that distance the whole duration of the activity, it would incur PTS. Inputs used in the User Spreadsheet, and the resulting isopleths are reported below (Tables 7 and 8).

TABLE 7—NMFS TECHNICAL GUIDANCE USER SPREADSHEET INPUT TO CALCULATE LEVEL A HARASSMENT ISOPLETHS

Method	Vibratory removal		
Pile Type	48-inch steel pile	24-inch steel pile	18-inch steel pile.
Source Level (RMS SPL)	171 dB_{RMS}	162 dB_{RMS}	162 dB_{RMS}.

TABLE 7—NMFS TECHNICAL GUIDANCE USER SPREADSHEET INPUT TO CALCULATE LEVEL A HARASSMENT ISOPLETHS—Continued

Weighting Factor Adjustment (kHz)	2.5	2.5	2.5.
Number of Piles per day	1	4	1.
Duration to drive a single pile (min)	45	45	45.
Distance of source level measurement (m)	10	10	10.

The above input scenarios lead to PTS isopleth distances (Level A thresholds) of 0.3 to 39 meters (m) (128 feet (ft)), depending on the marine mammal group and scenario (Table 8).

TABLE 8—CALCULATED DISTANCES (m) TO LEVEL A HARASSMENT ISOPLETHS DURING PILE REMOVAL PER HEARING GROUP

Pile type	Level A harassment zone (m)				
	Low-frequency cetaceans	Mid-frequency cetaceans	High-frequency cetaceans	Phocid pinnipeds	Otariid pinnipeds
48-inch steel pile	26	2	39	16	1
24-inch steel pile	17	2	25	10	1
18-inch steel pile	7	1	10	4	0

Marine Mammal Occurrence

In this section we provide the information about the presence, density, or group dynamics of marine mammals that will inform the take calculations.

Gray Whale

Photo identification, monitoring data, and stranding data corroborates the presence of gray whales in Grays Harbor and the adjacent coastal waters, as described in the Description of Marine Mammals in the Area of Specified Activities section above. Yet, these sources do not provide density data specific to Grays Harbor. Calambokidis *et al.,* (1997, 2015, 2019) is a collection of more than 20 years of photo identification data, but it does not provide enough information suitable for derivation of a density value. The U.S. 101/Chehalis River Bridge Scour Repair Project Marine Mammal Monitoring Report (WSDOT 2019) showed no observations of this species. Approximately 29 gray whale strandings were documented in Grays Harbor and adjacent coastal area from February 2010 to August 2019 (NMMSD 2020); the closest to the project was found in mudflats near the tip of Bowerman Airfield, ~9.82 kilometers (km) (6.10 miles (mi)) from the project site, in 2018. The NMSDD (2019) estimated the offshore density of gray whales from July to December to be 0.020167 gray whales/km². Using it in estimated take calculations yielded a low value for gray whales (<2) in Grays Harbor that, in NMFS' estimation, did not properly reflect the variability of group sizes and the real likelihood of encounter.

Their group size is known to fluctuate by activity, which in turn correlates to season. During migration, they are solo or in small groups. On the feeding grounds, whales are customarily seen solo or in small, widely dispersed groups. Larger, loosely formed aggregations do occur on feeding and breeding grounds, but are in constant flux (Wursig *et al.,* 2018). Gray whale occurrence off the Washington coast is expected to consist primarily of PCFG whales from July–November, feeding from five Biological Important Areas (BIAs) before migrating to the southern breeding grounds for winter (NMSDD 2019).

Harbor Porpoise

Without the species count breakdown of aerial surveys in Grays Harbor (Adam *et al.,* 2014) or information necessary to derive density values from photo identification data (Calambokidis *et al.,* 2015), the NMSDD (2019) annual value for harbor porpoises offshore of Grays Harbor, 0.467/km² is the most appropriate data source to calculate take.

California Sea Lion

The closest of the 116 California sea lion strandings reported in Grays Harbor and adjacent coastal area from August 2010 to February 2020, was located in Aberdeen, approximately 1.86 km (1.6 mi) from the project site (NMMSD 2020). Without a correction factor to incorporate those sea lions in the water during aerial haulout surveys of Grays Harbor (Jeffries *et al.,* 2015), the density of only individuals hauled out from November to March is 0.12 seal lions/km². Since the appropriate data is not available to calculate the accurate density of all individuals using Grays Harbor, the offshore density of 0.6493 sea lions/km² during December through February (NMSDD 2020) was used.

Steller Sea Lion

Because density data is not available for Grays Harbor, the NMSDD (2020) summer offshore density of 0.1993 Steller sea lions/km² is used.

Harbor Seal

Because aerial surveys of harbor seals on land only produce a minimum assessment of the population a correction factor to account for the missing animals is necessary to estimate total abundance. The total counts from 2014 Grays Harbor aerial surveys (*pers comm.,* WDFW 2020) were multiplied by the regional correction factor of 1.43 (Huber *et al.,* 2001) to yield the estimated harbor seal abundance. The average survey count (7,495 seals/survey) was used to calculate density by dividing by the area of Grays Harbor:

$$((10{,}483 \text{ total count} * 1.43)/(2 \text{ surveys}))/(243 \text{ km}^2) = 30.85 \text{ km}^2$$

The density data specific to Grays Harbor (*pers comm.,* WDFW 2020) is preferred over the NMSDD's (2020) estimated density for waters offshore Washington, 0.3424 harbor seals/km².

Take Calculation and Estimation

Here we describe how the information provided above is brought together to produce a quantitative take estimate.

Level A harassment take is not likely because of the small injury zones; the largest Level A harassment distance is 40 m (131 ft) from the source for high-frequency cetaceans (harbor porpoise).

NMFS considers that WSDOT can effectively monitor such small zones to implement shutdown measures and avoid Level A harassment takes, and that harbor porpoise in particular are more likely to avoid the construction activity than remain within the zone for the full duration necessary to accumulate sufficient energy to incur injury. Therefore, no Level A harassment take of marine mammals is authorized.

Take numbers were calculated using the information aggregated in the NMSDD (U.S. Navy, 2020) for the harbor porpoise, California sea lion, and Steller sea lion. Where a low to high range of densities is given for a species, the high-end density value was used in the applicable season (*i.e.,* summer/fall/winter). In these cases, take numbers were calculated as:

Total Take = marine mammal density × ensonified area × pile removal days

Specific adjustments for calculating take numbers for gray whales and harbor seals are provided below.

• Evaluated use of data value (offshore) and result is what we consider underestimate of value. Because recent data for gray whales in Grays Harbor does not provide enough information to derive a density value, and because the Level B harassment zone stretches across the length of Grays Harbor, and the flexible group size correlated to season, we authorize Level B harassment take of 1 gray whale per day of construction activity 1 × 7 days = 7 gray whales.

• The density of harbor seals in Grays Harbor based on 2014 aerial surveys described above (*pers comm.,* WDFW 2020), replaces the NMSDD density value in the Total Take equation above.

TABLE 9—INPUT FOR LEVEL B HARASSMENT TAKE CALCULATIONS PER SPECIES

Species	Density (#/km^2)	Level B area 48-in (km^2)	Level B area 18/24-in (km^2)	Number of days 48-in*	Number of days 24-in	Number of days 18-in**	Level B take 48-in	Level B take 24-in	Level B take 18-in
Gray Whale	*0.020	15.35	9.1	1	5	1	0.3	0.9	0.2
Harbor Porpoise	0.467	15.35	9.1	1	5	1	7	21	4
CA Sea Lion	0.557	15.35	9.1	1	5	1	10	30	6
Steller Sea Lion	0.139	15.35	9.1	1	5	1	3	9	2
Harbor Seal	30.85	15.35	9.1	1	5	1	473	1403	281

*Density was not used in the calculation of estimated take for gray whales.

TABLE 10—AUTHORIZED LEVEL B HARASSMENT TAKE, BY SPECIES AND STOCK AND PERCENT OF TAKE BY STOCK

Species	Authorized take Level B	Percent of stock
Gray Whale	7	<0.1
Harbor Porpoise	31	0.1
CA Sea Lion	46	<0.1
Steller Sea Lion	14	<0.1
Harbor Seal	2157	8.7

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, we carefully consider 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, impact on operations, and, in the case of a military readiness activity, personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

The following mitigation measures are required through the IHA:

Temporal and Seasonal Restrictions

Timing restrictions would be used to avoid in-water work when ESA-listed salmonids are most likely to be present. Furthermore, work is planned to occur only during daylight hours, when visual monitoring of marine mammals can be effectively conducted (30 minutes after sunrise to 30 minutes before sunset).

Establishment of Shutdown Zone

WSDOT will establish a shutdown zone for all pile driving and removal activities. The purpose of a shutdown zone is generally to define an area within which shutdown of activity would occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area). Shutdown zones will vary based on the activity type and marine mammal hearing group (Table 4). The largest shutdown zones are generally for high frequency cetaceans, as shown in Table 11.

TABLE 11—SHUTDOWN ZONES DURING PILE DRIVING ACTIVITIES

Pile type	Low-frequency cetaceans	High-frequency cetaceans	Phocid pinnipeds	Otariid pinnipeds
48-inch steel pile	30	40	20	10
24-inch steel pile	20	30	15	10
18-inch steel pile	10	10	10	10

For in-water heavy machinery activities other than pile driving, if a marine mammal comes within 10 m, operations must cease and vessels must reduce speed to the minimum level required to maintain steerage and safe working conditions. WSDOT must also implement shutdown measures if the cumulative total number of individuals observed within the Level B harassment monitoring zones for any particular species reaches the number authorized under the IHA and if such marine mammals are sighted within the vicinity of the project area and are approaching the Level B Harassment zone during in-water construction activities. Should environmental conditions deteriorate such that marine mammals within the entire shutdown zone would not be visible (*e.g.,* fog, heavy rain), pile driving and removal must be delayed until the PSO are confident marine mammals within the shutdown zone could be detected.

Monitoring for Level B Harassment

WSDOT will monitor the Level B harassment and 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 area outside the shutdown zone and thus prepare for a potential halt of activity should the animal enter the shutdown zone. Placement of PSO will allow PSOs to observe marine mammals within the Level B harassment zones.

Pre-Activity Monitoring

Prior to the start of daily in-water construction activity, or whenever a break in pile removal of 30 minutes or longer occurs, PSOs will observe the shutdown and monitoring zones for a period of 30 minutes. The shutdown zone will 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 zone, operations cannot proceed until the animal has left the zone or has not been observed for 15 minutes. When a marine mammal for which Level B harassment take is authorized is present in the Level B harassment zone, activities may begin and Level B harassment take will be recorded. If work ceases for more than 30 minutes, the pre-activity monitoring of the shutdown zones will commence.

Non-Authorized Take Prohibited

If a species enters or approaches the Level B harassment zone and that species is not authorized for take, pile driving and removal activities must shut down immediately. Activities must not resume until the animal has been confirmed to have left the area or an observation time period of 15 minutes has elapsed.

Based on our evaluation of the applicant's mitigation measures, NMFS has determined that the required mitigation measures provide the means 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.

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 in the action area. 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 must be conducted in accordance with the Monitoring section of the application and Section 5 of the IHA. Marine mammal monitoring during pile removal must be conducted by NMFS-approved PSOs in a manner consistent with the following:

- Independent PSOs (*i.e.,* not construction personnel) who have no other assigned tasks during monitoring periods must be used;
- At least one PSO must 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
- WSDOT must submit PSO Curriculum Vitae for approval by NMFS prior to the onset of pile driving.

PSOs must 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.

Two PSOs will be employed. PSO locations will provide an unobstructed view of all water within the shutdown zone, and as much of the Level B harassment zones as possible. PSO locations are as follows:

(1) At the pile driving site or best vantage point practicable to monitor the shutdown zones; and

(2) On shore, south of Mid-harbor Flats or best vantage point to monitor the harbor seal haul-out site during construction activities.

Monitoring will be conducted 30 minutes before, during, and 30 minutes after pile driving/removal activities. In addition, observers shall record all incidents of marine mammal occurrence, regardless of distance from activity, and shall 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 or drilling equipment is no more than 30 minutes.

Reporting

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

• Dates and times (begin and end) of all marine mammal monitoring;

• Construction activities occurring during each daily observation period, including how many and what type of piles were removed;

• 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 (if less than the harassment zone distance);

• The number of marine mammals observed, by species, relative to the pile location and if pile driving or removal was occurring at time of sighting;

• Age and sex class, if possible, of all marine mammals observed;

• PSO locations during marine mammal monitoring;

• Distances and bearings of each marine mammal observed to the pile being driven or removed for each sighting (if pile driving or removal was occurring at time of sighting);

• Description of any marine mammal behavior patterns during observation, including direction of travel and estimated time spent within the Level A and Level B harassment zones while the source was active;

• Number of marine mammals detected within the harassment zones, by species;

• Detailed information about any implementation of any mitigation triggered (*e.g.,* shutdowns and delays), a description of specific actions that ensued, and resulting behavior of the animal, if any;

• Description of attempts to distinguish between the number of individual animals taken and the number of incidences of take, such as ability to track groups or individuals; and

• Submit all PSO datasheets and/or raw sighting data (in a separate file from the Final Report referenced immediately above).

If no comments are received from NMFS within 30 days, the draft final report will constitute the final report. If comments are received, a final report addressing NMFS comments must be submitted within 30 days after receipt of comments.

Reporting Injured or Dead Marine Mammals

In the event that personnel involved in the construction activities discover an injured or dead marine mammal, WSDOT shall report the incident to the Office of Protected Resources (OPR), NMFS and to the regional stranding coordinator as soon as feasible. If the death or injury was clearly caused by the specified activity, WSDOT must 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 IHA. The IHA-holder must not resume their activities until notified by NMFS. The report must include the following information:

• Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);

• Species identification (if known) or description of the animal(s) involved;

• Condition of the animal(s) (including carcass condition if the animal is dead);

• Observed behaviors of the animal(s), if alive;

• If available, photographs or video footage of the animal(s); and

• 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 responses (*e.g.,* intensity, duration), the context of any responses (*e.g.,* critical reproductive time or location, migration), 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's 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 environmental 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).

To avoid redundancy this introductory discussion of our analyses applies to all of the species listed in Table 10, given that many of the anticipated effects of this project on different marine mammal stocks are expected to be relatively similar in nature. Pile removal activities have the potential to disturb or displace marine mammals. Specifically, the project activities may result in take, in the form of Level B harassment from underwater sounds generated from pile removal. Potential takes could occur if individuals are present in the Level B harassment zone when these activities are underway.

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

- No mortality is anticipated or authorized;
- No takes by Level A harassment are anticipated or authorized. Takes by Level B harassment constitute less than 8 percent of the best available abundance estimates for all stocks;
- Take would occur over a short timeframe (6 days of active pile removal) during the IHA effective period) and not occur in places and/or times where take would be more likely to accrue to impacts on reproduction or survival, such as within ESA-designated or proposed critical habitat;
- Stock is not known to be declining or suffering from known contributors to decline (*e.g.,* unusual mortality event (UME), oil spill effects); and
- Monitoring reports from similar work from the Chehalis River Bridge Scour Repair Project have documented little to no effect on individuals of the same species impacted by the specified activities.

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 monitoring and mitigation measures, NMFS finds that the total marine mammal take from the planned 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.

The amount of take NMFS authorized of all species or stocks is below one third of the estimated stock abundance (in fact, take of individuals is less than 8 percent of the abundance for all affected stocks). These are all likely conservative estimates because they assume all takes are of different individual animals which is likely not the case. Some individuals may return multiple times in a day, but PSOs would count them as separate takes if they cannot be individually identified.

Based on the analysis contained herein of the activity (including the mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS finds that small numbers of marine mammals will 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.

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 action (*i.e.,* the issuance of an incidental harassment authorization) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (incidental harassment authorizations 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 determined that the issuance of the IHA qualifies to be categorically excluded from further NEPA review.

Endangered Species Act

Section 7(a)(2) of the 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 authorized 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.

Authorization

NMFS has issued an IHA to WSDOT for the potential harassment of small numbers of five marine mammal species incidental to the for conducting State Route 520 Pontoon Pile Removal Project, Aberdeen, Grays Harbor County, Washington over approximately seven days, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: December 22, 2020.

Donna S. Wieting,

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

[FR Doc. 2020–28752 Filed 12–28–20; 8:45 am]

BILLING CODE 3510–22–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities Under OMB Review

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (PRA), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Information and Regulatory Affairs (OIRA), of the Office of Management and Budget (OMB), for review and comment. The ICR describes

the nature of the information collection and its expected costs and burden.

DATES: Comments must be submitted on or before January 28, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be submitted within 30 days of this notice's publication to OIRA, at *https://www.reginfo.gov/public/do/PRAMain*. Please find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the website's search function. Comments can be entered electronically by clicking on the ''comment'' button next to the information collection on the ''OIRA Information Collections Under Review'' page, or the ''View ICR—Agency Submission'' page. A copy of the supporting statement for the collection of information discussed herein may be obtained by visiting *https://www.reginfo.gov/public/do/PRAMain*.

In addition to the submission of comments to *https://Reginfo.gov* as indicated above, a copy of all comments submitted to OIRA may also be submitted to the Commodity Futures Trading Commission (the ''Commission'' or ''CFTC'') by clicking on the ''Submit Comment'' box next to the descriptive entry for OMB Control No. 3038–0062, at *https://comments.cftc.gov/FederalRegister/PublicInfo.aspx*.

Or by either of the following methods:

- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail above.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments submitted to the Commission should include only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.[1] The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *https://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the ICR will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

FOR FURTHER INFORMATION CONTACT: Gregory Scopino, Special Counsel, Market Participants Division, Commodity Futures Trading Commission, (202) 418–5175; email: *gscopino@cftc.gov,* and refer to OMB Control No. 3038–0062.

SUPPLEMENTARY INFORMATION:

Title: Off-Exchange Foreign Currency Transactions. (OMB Control No. 3038–0062). This is a request for anextension of a currently approved information collection..

Abstract: Part 5 of the Commission's regulations under the CEA establishes rules applicable to retail foreign exchange dealers (''RFEDs''), futures commission merchants (''FCMs''), introducing brokers (''IBs''), commodity trading advisors (''CTAs''), and commodity pool operators (''CPOs'') engaged in the offer and sale of off-exchange forex contracts to retail customers. Specifically:

- Regulation 5.5 requires RFEDs, FCMs, and IBs to distribute risk disclosure statements to new retail forex customers.
- Regulation 5.6 requires RFEDs and FCMs to report any failures to maintain the minimum capital required by Commission regulations.
- Regulation 5.8 requires RFEDs and FCMs to calculate their total retail forex obligation.
- Regulation 5.10 requires RFEDs to maintain and preserve certain risk assessment documentation.
- Regulation 5.11(a)(1) requires RFEDs to submit certain risk assessment documentation to the Commission within 60 days of the effective date of their registration.
- Regulation 5.11(a)(2) requires RFEDs to submit certain financial documentation to the Commission within 105 calendar days of the end of each fiscal year. RFEDs must also submit additional information, if requested, regarding affiliates' financial impact on an RFED's organizational structure.
- Regulation 5.12(a) requires RFED applicants to submit a Form 1–FR–FCM concurrently with their registration application.
- Regulation 5.12(b) requires registered RFEDs to file a Form 1–FR–FCM on a monthly and annual basis.
- Regulation 5.12(g) states that, in the event that an RFED cannot file its Form 1–FR–FCM for any period within the time specified in Regulation 5.12(b), the RFED may file an application for an extension of time with its self-regulatory organization.
- Regulation 5.13(a) requires RFEDs and FCMs to provide monthly account statements to their customers.
- Regulation 5.13(b) requires RFEDs and FCMs to provide confirmation statements to their customers within one business day after the execution of any retail forex or forex option transaction.
- Regulation 5.14 requires RFEDs and FCMs to maintain current ledgers of each transaction affecting its asset, liability, income, expense and capital accounts.
- Regulation 5.18(g) requires each RFED, FCM, CPO, CTA, and IB subject to part 5 to maintain a record of all communications received that give rise to possible violations of the Act, rules, regulations or orders thereunder related to their retail forex business.
- Regulation 5.18(i) requires each RFED and FCM to prepare and maintain on a quarterly basis a calculation of non-discretionary retail forex customer accounts open for any period of time during the quarter that were profitable, and the percentage of such accounts that were not profitable.
- Regulation 5.18(j) requires the CCO of each RFED and FCM to certify annually that the firm has in place processes to establish, maintain, review, modify and test policies and procedures reasonably designed to achieve compliance with the Act, rules, regulations and orders thereunder.
- Regulation 5.19 requires each RFED, FCM, CPO, CTA, and IB subject to part 5 to submit to the Commission copies of any dispositive or partially dispositive decision for which a notice of appeal has been filed in any material legal proceeding (1) to which the firm is a party to or to which its property or assets is subject with respect to retail forex transactions, or (2) instituted against any person who is a principal of the firm arising from conduct in such person's capacity as a principal of that firm.
- Regulation 5.20 requires RFEDs, FCMs and IBs to submit documentation requested pursuant to certain types of special calls by the Commission.
- Regulation 5.23 requires RFEDs, FCMs and IBs to notify the Commission regarding bulk transfers and bulk liquidations of customer accounts.

The rules establish reporting and recordkeeping requirements that are necessary to implement the provisions

[1] 17 CFR 145.9.

of the Food, Conservation, and Energy Act of 2008 [2] regarding off-exchange transactions in foreign currency with members of the public. The rules are intended to promote customer protection by providing safeguards against irresponsible or fraudulent business practices.[3]

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.[4] On October 26, 2020, the Commission published in the **Federal Register** notice of the proposed extension of this information collection and provided 60 days for public comment on the proposed extension, 85 FR 67721 (''60-Day Notice''). The Commission did not receive any comments on the 60-Day Notice.

Burden Statement: The Commission is revising its estimate of the burden for this collection for 146 respondents, which include RFEDs, FCMs, IBs, CPOs, and CTAs. The respondent burden for this collection is estimated to be as follows:

Estimated Number of Respondents: 146.

Estimated Average Burden Hours per Respondent: 2,865.[5]

Estimated Total Annual Burden Hours: 418,286.

Frequency of Collection: As applicable.

There are no capital costs or operating and maintenance costs associated with this collection.

(Authority: 44 U.S.C. 3501 *et seq.*)

Dated: December 22, 2020.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2020–28711 Filed 12–28–20; 8:45 am]

BILLING CODE 6351–01–P

[2] Public Law 110–246, 122 Stat. 1651, 2189–220 (2008).

[3] *See* Regulation of Off-Exchange Retail Foreign Exchange Transactions and Intermediaries, 75 FR 55410, 55416 (Sept. 10, 2010).

[4] The OMB control numbers for the CFTC regulations were published on December 30, 1981. *See* 46 FR 63035 (Dec. 30, 1981).

[5] This figure has been rounded to the nearest one: 2,864.972 to 2865.

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[Docket DARS–2020–0007; OMB Control Number 0704–0519]

Information Collection; Defense Federal Acquisition Regulation Supplement (DFARS) Subpart 204.17, Service Contracts Inventory and Associated Clause; Submission for OMB Review; Comment Request

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Notice.

SUMMARY: The Defense Acquisition Regulations System has submitted to OMB for clearance the following proposal for a new collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by January 28, 2021.

SUPPLEMENTARY INFORMATION:

Title and OMB Number: Defense Federal Acquisition Regulation Supplement (DFARS); DFARS Subpart 204.17, Service Contracts Inventory and Associated Clause; OMB Control Number 0704–0519.

Affected Public: Businesses and other for-profit entities.

Respondent's Obligation: Required to obtain or retain benefits.

Type of Request: Approval of a new information collection.

Reporting Frequency: Annually.

Number of Respondents: 1,934.

Responses per Respondent: 2.267, approximately.

Annual Responses: 4,386.

Average Burden per Response: 2 hours.

Total Annual Burden Hours: 8,772.

Needs and Uses: 10 U.S.C. 2330a, as amended by section 812 of National Defense Authorization Act for Fiscal Year 2017, requires DoD to establish a data collection system to provide certain management information with regard to each purchase of services by a Military Department or Agency that is in excess of $3 million for services in the following service acquisition portfolio groups: Logistics management services, equipment-related services, knowledge-based services, and electronics and communications services. New DFARS clause 252.204–70XX, Reporting Requirements for Contracted Services, requires a contractor to report annually, in the System for Award Management, on the services performed under the contract or order, during the preceding Government fiscal year. Specifically, the contractor is required to report the total dollar amount invoiced for services performed during the preceding fiscal year and the number of direct labor hours, including subcontractor hours (when applicable), expended on services performed during the previous Government fiscal year.

The information collection will provide DoD with the ability to identify and report annually to Congress, in accordance with 10 U.S.C. 2330a, on the inventory of contractor service contract actions. As an adjunct, the information will support DoD's total force management and in making strategic workforce planning and budget decisions pursuant to 10 U.S.C. 129a.

Comments and recommendations on the proposed information collection should be sent to Ms. Susan Minson, DoD Desk Officer, at *Oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer, the Docket number, and title of the information collection.

You may also submit comments, identified by docket number and title, by the following method: *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

DoD Clearance Officer: Ms. Angela James. Requests for copies of the information collection proposal should be sent to Ms. Angela James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Jennifer D. Johnson,

Regulatory Control Officer, Defense Acquisition Regulations System.

[FR Doc. 2020–28774 Filed 12–28–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 20–84]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the

House of Representatives, Transmittal 20–84 with attached Policy Justification and Sensitivity of Technology.

Dated: December 21, 2020.

Kayyonne. T. Marston,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, SUITE 101
ARLINGTON, VA 22202-5408

December 1, 2020

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 20-84 concerning the Army's proposed Letter(s) of Offer and Acceptance to the Government of Croatia for defense articles and services estimated to cost $757.0 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Heidi H. Grant
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 20–84

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of Croatia

(ii) *Total Estimated Value:*

Major Defense Equipment *	$218.0 million
Other	$539.0 million
TOTAL	$757.0 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* The U.S. Government has offered Croatia, under the grant Excess Defense Articles (EDA) program, eighty-four (84) M2A2 Operation Desert Storm (ODS) Bradley Fighting vehicles in as-is, where is condition. This notification is for refurbishment/modernization and support of seventy-six (76) of the vehicles consisting of:

Major Defense Equipment (MDE):

Eighty-four (84) M240 Machine Guns

One thousand one hundred three (1,103) TOW 2A Radio Frequency (RF) Missiles

Sixteen (16) TOW 2A Radio Frequency (RF) Fly-to-Buy Lot Acceptance Missiles

One hundred (100) TOW 2B Radio Frequency (RF) Missiles

Eight (8) TOW 2B Radio Frequency (RF) Fly-to-Buy Lot Acceptance Missiles

Five hundred (500) TOW Bunker Buster (BB) Radio Frequency (RF) Missiles

Eight (8) TOW BB Fly-to-Buy Lot Acceptance Missiles

Non-MDE: Also included are M257 Smoke Grenade Launchers; ammunition; radios; simulator; special armor; Hunter/Killer technology, which may include an exportable Commander's Independent Viewer (CIV); spare and repair parts; support equipment; upgrade/maintenance of engines and transmissions; refurbishment of TOW launchers; depot level support; communication support equipment; tool and test equipment; training; U.S. Government and contractor engineering, technical, and logistics support services; and other related elements of logistics and program support.

(iv) *Military Department:* Army (HR–B–UBV)

(v) *Prior Related Cases, if any:* HR–B–IAG

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* December 1, 2020

*As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Croatia—Bradley Fighting Vehicle Refurbishment/Modernization

The Government of Croatia has requested to buy refurbishment/modernization and support for seventy-six (76) M2A2 Operation Desert Storm (ODS) Bradley Fighting vehicles consisting of: eighty-four (84) M240 machine guns; one thousand one hundred three (1,103) TOW 2A Radio Frequency (RF) missiles; sixteen (16) TOW 2A Radio Frequency (RF) fly-to-buy lot acceptance missiles; one hundred (100) TOW 2B Radio Frequency (RF) missiles; eight (8) TOW 2B Radio Frequency (RF) fly-to-buy lot acceptance missiles; five hundred (500) TOW Bunker Buster (BB) Radio Frequency (RF) missiles; and eight (8) TOW BB fly-to-buy lot acceptance missiles. Also included are M257 Smoke Grenade Launchers; ammunition; radios; simulator; special armor; Hunter/Killer technology, which may include an exportable Commander's Independent Viewer (CIV); spare and repair parts; support equipment; upgrade/maintenance of engines and transmissions; refurbishment of TOW launchers; depot level support; communication support equipment; tool and test equipment; training; U.S. Government and contractor engineering, technical, and logistics support services; and other related elements of logistics and program support. The total estimated program cost is $757 million.

This proposed sale will support the foreign policy and national security of the United States by improving the security of a NATO Ally that continues to be an important force for political stability and economic progress in Europe.

This proposed sale of the Bradley vehicle refurbishment/modernization will contribute to Croatia's goal of updating its military capability while further enhancing interoperability with the United States and other allies. Croatia will have no difficulty absorbing these equipment and support into its armed forces.

The proposed sale of this equipment will not alter the basic military balance in the region.

The prime contractors will be BAE Systems, York, Pennsylvania; and Raytheon Missile Systems, Tucson, Arizona. There are no known offset agreements proposed in connection with this potential sale.

Implementation of the proposed sale will require U.S. Government and contractor personnel to visit Croatia on a temporary basis in conjunction with program oversight and support requirements, as well as to provide training and maintenance support in country.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 20–84

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The Modernized Bradley M2 components which are considered to contain sensitive technology are as follow:

a. Exportable version of the Second Generation Thermal ''Night Vision'' Viewer, also known as the Second-Generation Forward Looking infrared (SG–FLIR). For the Modernized Bradley M2, the SG–FLIR system includes:

1) Improved Bradley Acquisition Subsystem (IBAS) is a second-generation forward looking infrared (FLIR) and an electro-optical/TV imaging system. The IBAS has direct-view optics (DVO) and the eye-safe laser rangefinder (ELRF). The IBAS interfaces with the Bradley fire control system and can be used for surveillance and as a back-up engagement sight for the commander.

2) Commander's Independent Thermal Viewer (CIV) is another version of the second-generation forward looking infrared (FLIR) and an electro-optical/TV imaging system. The CIV allows the commander to scan for targets and maintain situational awareness while remaining under armor and without interfering with the gunner's acquisition and engagement of targets.

3) High Definition (HD) Long-Wave SG–FLIR sight is currently under development for the Bradley Fighting Vehicle. The HD Long-wave FLIR is being developed as an eventual upgrade to the capability of the IBAS and CIV. This case may include the non-recurring engineering costs associated with developing an exportable version of HD Long-wave FLIR for International use.

b. Exportable version of the Drivers Vision Enhancer (DVE), the ''Night Vision'' Viewer utilized by the Bradley drivers is a passive thermal imaging system, or ''night vision'' device used to enhance a driver's viewing capabilities while operating during degraded visual

conditions, such as darkness, fog, smoke or dust. It provides for an improved situational awareness, applicable to both driving and surveillance. The DVE system consists of a Display Control Module (DCM), Sensor Module (SM), and Pan and Tilt Modules (PTM). The DVE is currently available in the standard and wide (DVE-Wide) configurations. The DVE-Wide provides drivers with wider fields of view.

c. Exportable version of the Inertial Navigation Unit (INU) is a navigation device that uses motion sensors or accelerometers and rotation sensors or gyroscopes to continuously calculate the position, the orientation, and the velocity of Bradley vehicle without the need for external references. It is a supplementary, and complementary to the global positioning system (GPS). In the event of a lack of a GPS signal, the INU maintains position, velocity, and situational awareness.

d. The Radio Frequency TOW 2A (RF) Missile (BGM–71E–4B–RF) is a direct attack missile designed to defeat armored vehicles, reinforced urban structures, field fortification and other such targets. TOW Missiles are fired from a variety of TOW Launchers in the U.S. Army, USMC and FMS customer forces. The TOW 2A RF missile can be launched from the same launcher platforms as the existing wire-guided TOW 2A missile without modification to the launcher. The TOW 2A missile (both wire and RF) contains two tracker beacons (Xenon and thermal) for the launcher to track and guide the missile in flight. Guidance commands from the launcher are provided to the missile by the RF link contained within the missile case. The hardware, software, and technical publications provided with the sale thereof are unclassified. However, the system itself contains sensitive technology that instructs the system on how to operate in the presence of countermeasures.

e. The Radio Frequency TOW 2B (RF) Missile (BGM–71F–3–RF) is a fly-over shoot-down missile designed to defeat armored vehicles. TOW Missiles are fired from a variety of TOW Launchers in the U.S. Army, USMC and FMS customer forces. The TOW 2B RF missile can be launched from the same launcher platforms as the existing wire-guided TOW 2B missile without modification to the launcher. The TOW 2B missile (both wire and RF) contains two tracker beacons (Xenon and thermal) for the launcher to track and guide the missile in flight. Guidance commands from the launcher are provided to the missile by the RF link contained within the missile case. The hardware, software, and technical publications provided with the sale thereof are unclassified. However, the system itself contains sensitive technology that instructs the system on how to operate in the presence of countermeasures.

f. The Radio Frequency TOW Bunker Buster (BB) Missile (BGM–71H–1–RF) is a variant of the TOW 2A that replaces the TOW 2A warhead with a high explosive blast-fragmentation warhead. The bulk charge warhead is effective against reinforced concrete walls, light armored vehicles, and earth and timber bunkers. Guidance commands from the launcher are provided to the missile by the RF link contained within the missile case.

2. The highest level of classification of defense articles, components, and services included in this potential sale is SECRET.

3. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures or equivalent systems which might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

4. A determination has been made that Croatia can provide the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the enclosed Policy Justification.

5. All defense articles and services listed in this transmittal have been authorized for release and export to Croatia.

[FR Doc. 2020–28640 Filed 12–28–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 20–52]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 20–52 with attached Policy Justification and Sensitivity of Technology.

Dated: December 21, 2020.

Kayyonne T. Marston,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, SUITE 101
ARLINGTON, VA 22202-5408

December 1, 2020

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 20-52 concerning the Navy's proposed Letter(s) of Offer and Acceptance to the Government of Brazil for defense articles and services estimated to cost $70 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Heidi H. Grant
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 20-52

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser*: Government of Brazil

(ii) *Total Estimated Value*:

Major Defense Equipment *	$40 million
Other	$30 million
Total	$70 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase*:

Major Defense Equipment (MDE): Twenty-two (22) MK 54 Conversion Kits—to Convert MK 46 Mod 5 A(S) Torpedoes to MK 54 Mod 0 Lightweight Torpedoes

Non-MDE: Also included are torpedo containers, Recoverable Exercise Torpedoes (REXTORP) with containers, Fleet Exercise Section (FES) and fuel tanks, air launch accessories for rotary wing, torpedo spare parts, propellant, lanyard start assembly suspensions bands, thermal batteries, training, publications, support and test equipment. U.S. Government and contractor engineering, technical, and logistics support services, and other related elements of logistics and program support.

(iv) *Military Department*: Navy (BR-P-GVU)

(v) *Prior Related Cases, if any*: None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid*: None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold*: See Attached Annex

(viii) *Date Report Delivered to Congress*: December 1, 2020

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Brazil—MK 54 Lightweight Torpedoes

The Government of Brazil has requested to buy twenty-two (22) MK 54 conversion kits—to convert MK 46 Mod 5 A(S) torpedoes to MK 54 Mod 0 lightweight torpedoes. Also included are torpedo containers, Recoverable Exercise Torpedoes (REXTORP) with containers, Fleet Exercise Section (FES) and fuel tanks, air launch accessories for rotary wing, torpedo spare parts, propellant, lanyard start assembly suspensions bands, thermal batteries, training, publications, support and test equipment. U.S. Government and contractor engineering, technical, and logistics support services, and other related elements of logistics and program support. The total estimated value is $70 million.

This proposed sale will support the foreign policy and national security objectives of the United States by improving the security of an important regional partner that is an important force for political stability and economic progress in South America.

The Government of Brazil intends to utilize MK 54 Lightweight Torpedoes on its Sikorsky S-70B ''Seahawk'' aircraft and surface ships.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor will be Raytheon Integrated Defense System, Portsmouth, RI. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require long-term assignment of any additional U.S. Government or contractor representatives to Brazil; however, U.S. Government Engineering and Technical Services may be required on an interim basis for training and technical assistance.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 20-52

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology*:

1. The MK 54 Torpedo is a conventional torpedo that can be launched from surface ships and rotary- and fixed-wing aircraft. The MK 54 is an upgrade from the MK 46 Torpedo. The upgrade to the MK 54 entails replacement of the torpedo's sonar and guidance and control systems with modem technology. The new guidance and control system uses a mixture of commercial-off-the-shelf and custom-built electronics. The warhead, fuel tank, and propulsion system from the MK 46 torpedo are re-used in the MK 54 configuration with minor modifications.

2. The highest level of classification of defense articles, components, and services included in this potential sale is SECRET.

3. If a technologically advanced adversary were to obtain knowledge of the specific hardware or software elements, the information could be used to develop countermeasures that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

4. A determination has been made that Brazil can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

5. All defense articles and services listed in this transmittal have been authorized for release and export to Brazil.

[FR Doc. 2020–28636 Filed 12–28–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 20–30]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 20–30 with attached Policy Justification.

Dated: December 21, 2020.

Kayyonne T. Marston,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, SUITE 101
ARLINGTON, VA 22202-5408

DEC 0 1 2020

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 20-30 concerning the Army's proposed Letter(s) of Offer and Acceptance to the Government of Lebanon for defense articles and services estimated to cost $55.5 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Heidi H. Grant
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Regional Balance (Classified document provided under separate cover)

BILLING CODE 5001–06–C

Transmittal No. 20–30

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of Lebanon

(ii) *Total Estimated Value:*

Major Defense Equipment*	$40.0 million
Other	$15.5 million
TOTAL	$55.5 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE): Up to three hundred (300) M1152 High Mobility Multi-purpose Wheeled Vehicles (HMMWVs) (2 purchases of one hundred fifty (150) each)

Non-MDE: Also included are spare and repair parts, publications and technical documentation, personnel training and training equipment, technical and logistics support services, and other related elements of logistical and program support.

(iv) *Military Department:* Army (LE–B–WCC)

(v) *Prior Related Cases, if any:* 7C–B–UWZ, LE–B–UAH, QE–B–URV

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* None

(viii) *Date Report Delivered to Congress:* December 1, 2020

*As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Lebanon—M1152 High Mobility Multi-purpose Wheeled Vehicles (HMMWVs)

The Government of Lebanon has requested to buy up to three hundred (300) M1152 High Mobility Multi-purpose Wheeled Vehicles (HMMWVs) (2 purchases of one hundred fifty (150) each). Also included are spare and repair parts, publications and technical documentation, personnel training and training equipment, technical and logistics support services, and other related elements of logistical and program support. The total estimated cost is $55.5 million.

This proposed sale will support the foreign policy and national security of the United States by helping to improve the security of a partner country that continues to be an important force for political stability and economic progress in the Middle East.

The proposed sale will provide sufficient modern transport vehicles to improve Lebanon's capability to meet current and future threats by improving its ability to move troops and supplies around the country to counter violent extremist organizations and to secure its border. Lebanon will have no difficulty absorbing this additional equipment and services into its armed forces as they currently operate over one thousand (1,000) HMMWVs of various variants.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor will be American General, South Bend, Indiana. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will require the assignment of two (2) U.S. contractor representatives to Lebanon for a duration of up to thirteen (13) weeks to conduct HMMWV operator and maintenance training.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 2020–28638 Filed 12–28–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 20–78]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 20–78 with attached Policy Justification and Sensitivity of Technology.

Dated: December 21, 2020.

Kayyonne T. Marston,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, SUITE 101
ARLINGTON, VA 22202-5408

December 4, 2020

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 20-78 concerning the Army's proposed Letter(s) of Offer and Acceptance to the Government of Australia for defense articles and services estimated to cost $132.2 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Heidi H. Grant
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001–06–C

Transmittal No. 20–78

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser*: Government of Australia

(ii) *Total Estimated Value*:

Major Defense Equipment *	$0
Other	$132.2 million
Total	$132.2 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase*:

Major Defense Equipment (MDE):
None

Non-MDE:
M825A1 155mm White Phosphorous projectile munitions, M782 Multi-Option Fuze for Artillery, M762A1 electronic-timed fuzes, M231 and M232A2 propelling charges, percussion primers, technical publications and books, technical data for operational maintenance, technical assistance and services, and other related elements of logistics and program support.

(iv) *Military Department*: Army (AT–B–ULC)

(v) *Prior Related Cases, if any*: AT–B–UGN

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be paid*: None

(vii) *Sensitivity of Technology Contained in the Defense Article or*

Defense Services Proposed to be Sold: See Attached Annex

(viii) *Date Report Delivered to Congress*: **December 4, 2020**

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Government of Australia—155mm Ammunition and Accessories

The Government of Australia has requested to buy M825A1 155mm White Phosphorous projectile munitions, M782 Multi-Option Fuze for Artillery, M762A1 electronic-timed fuzes, M231 and M232A2 propelling charges, percussion primers, technical publications and books, technical data for operational maintenance, technical assistance and services, and other related elements of logistics and program support. The total estimated program cost is $132.2 million.

This proposed sale will support the foreign policy and national security objectives of the United States. Australia is one of our most important allies in the Western Pacific. The strategic location of this political and economic power contributes significantly to ensuring peace and economic stability in the region.

This purchase will enable effective training and extend the Australian Defence Force's (ADF) capability to conduct combined operations. The ADF already has these rounds in service, and is trained and equipped to use them. Australia will not have any difficulty absorbing these weapons into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor will be determined at a later date. The material could potentially be sourced from a combination of DoD stocks and new procurement. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of U.S. Government or contractor representatives to Australia.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 20–78

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology*:

1. The M825A1 is a 155mm artillery projectile which utilizes a payload of white phosphorous impregnated felt to produce a smoke screen at a target location. The Government of Australia has stated their commitment to use these rounds exclusively for its intended purpose, which is to provide signaling and to obscure enemy visibility on the battlefield.

2. The M782 Multi-Option Fuze for Artillery (MOFA). The M782 is a selectable multi-option fuze that provides height of burst capability to artillery rounds. The M782 is a sensitive military technology and has been approved for release to the Government of Australia.

3. Also included in this case are propelling charges and other fuzes that enable the effective use of the M825A1 end item. While these technologies are controlled military hardware they do not represent a significant technology transfer risk.

4. The highest level of classified information associated with the sale of this equipment is SECRET.

5. If a technologically advanced adversary obtains knowledge of the specific hardware and software elements, the information could be used to develop countermeasures or equivalent systems that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

6. A determination has been made that Australia can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This proposed sale is necessary to further the U.S. foreign policy and national security objectives outlined in the Policy Justification.

7. All defense articles and services listed on this transmittal are authorized for release and export to the Government of Australia.

[FR Doc. 2020–28633 Filed 12–28–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

TRICARE; Proposed Rates for Reimbursing Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Parenteral and Enteral Nutrition (PEN) Items Not on the Medicare DMEPOS and PEN Fee Schedule

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Notice and request for comments.

SUMMARY: This notice is to advise interested parties of a Military Health System reimbursement change to certain DMEPOS and PEN items not included in Medicare's fee schedule. For these items, the Defense Health Agency (DHA) will create a TRICARE-specific fee schedule based on similar payment rules, to the extent practicable, as Medicare's DMEPOS and PEN fee schedule. A TRICARE-specific fee schedule will allow DHA to control costs, reduce beneficiary out-of-pocket expenses, discourage potential fraud and abuse, and prevent excessive TRICARE reimbursement rates when compared to state Medicaid programs and private health insurance. Under this change, TRICARE will align its reimbursement of certain DMEPOS and PEN items with similar reimbursement rules established under Medicare's DEMPOS and PEN fee schedule to the extent practicable, without incorporating any reimbursement rules associated with Medicare's Competitive Bidding Program (CBP).

DHA is soliciting comments on the proposed rates (located on the DHA website below) and other alternative payment options for reimbursing DMEPOS and PEN items without Medicare pricing. The comment period will end 30 days after the publication of this notice. DHA will receive and consider comments, but will not issue responses to comments unless such comments drive a substantive change to the methodology outlined in paragraphs A through C below, in which case a new notice will be published in the **Federal Register**.

DATES: The comment period will end on January 28, 2021. This change will be effective July 1, 2021.

ADDRESSES: Defense Health Agency, TRICARE, Medical Benefits and Reimbursement Section, 16401 East Centretech Parkway, Aurora, CO 80011–9066.

FOR FURTHER INFORMATION CONTACT: Mr. Jahanbakhsh Badshah, Medical Benefits and Reimbursement Section, TRICARE, telephone (303) 676–3881. Questions regarding payment of specific claims should be addressed to the appropriate TRICARE Managed Care Support Contractor in whose jurisdiction a claim would be filed.

SUPPLEMENTARY INFORMATION:

A. Background

Currently under TRICARE, DMEPOS and PEN items without Medicare pricing are reimbursed at the lower of the state prevailing charge or the billed charge. The state prevailing charge is calculated annually by TRICARE contractors on a statewide basis, using the 80th percentile of all qualified billed

charges on actual claims paid for a given service or item, during the 12-month period ending June 30th of the previous year. This method is problematic in that it can lead to the generation of very high-fee schedule amounts without validation that these amounts are realistic and equitable relative to the cost of furnishing the item. Recent Department of Defense Office of Inspector General (DoD OIG) reports, as well as internal DHA analysis, have identified patterns of excessive billed charges for DMEPOS and PEN items. If the billed charges are abusive and excessive, this rolls into the calculation for state prevailing amounts. Setting payment rates too high creates incentives for higher volume, financially burdens beneficiaries whose cost-sharing is based on a percentage of the allowable amount, and encourages fraud and abuse.

B. Description of the TRICARE DMEPOS and PEN Fee Schedule

To control costs, reduce beneficiary out-of-pocket expenses, discourage potential fraud and abuse, and prevent excessive TRICARE reimbursement rates when compared to state Medicaid programs and private health insurance for equipment and supplies, DHA proposes to develop fee schedule amounts for certain DMEPOS and PEN items not identified on any Medicare fee schedules. This proposal falls under the authority of Title 32 Code of Federal Regulation (CFR) 199.14(j)(4), which allows the Director, DHA, subject to the approval of the Assistant Secretary of Defense for Health Affairs, to establish an alternative reimbursement method designed to produce reasonable control over health care costs. In response to recent DoD OIG audits of TRICARE's overpayment of services and items without established fee schedule amounts, DHA will develop a fee schedule for these DMEPOS and PEN items on a statewide basis and create national ceilings and floors, utilizing a methodology similar to Medicare's fee schedule reimbursement methodology. TRICARE's fee schedule will not include Medicare's CBP rules, which would require making adjustments based on bids submitted for certain items and localities. This would be impossible to incorporate, as TRICARE does not have a bidding program.

Using Medicare's DMEPOS and PEN payment rules established under 42 CFR part 414, subparts C and D, to the extent practicable, DHA will create a TRICARE fee schedule for certain DMEPOS and PEN items without Medicare pricing. Given the similar attributes of the two programs, the statutory requirement that TRICARE reimbursement follow Medicare's methodology when practicable, and the fact that non-CBP payment rules are still used by Medicare for certain DMEPOS and PEN items, the adoption of these rules is appropriate for TRICARE reimbursement of DMEPOS and PEN items. Using a fee schedule is also consistent with the DoD OIG support of payment accuracy through the establishment of fee schedules. The resulting payment rates will be high enough to ensure beneficiary access to needed products and low enough to ensure sufficient provision of those products. DHA will also retain the flexibility to modify the payment rate for any procedure code when necessary to ensure access to care.

C. Methodology

TRICARE fee schedule rates will be established for services or items provided on or after July 1, 2021, and will be updated annually (January 1) by the same annual update factor Medicare uses to update its DMEPOS fee schedule. The update factor is based on the percentage increase in the Consumer Price Index for all Urban Consumers for the 12-month period ending June 30 of the previous year adjusted by the change in the economy-wide productivity equal to the 10-year moving average of changes in annual economy-wide private non-farm business multi-factor productivity. Healthcare Common Procedure Coding System (HCPCS) codes classified as unlisted, miscellaneous, not otherwise classified (NOC), custom, deluxe, or currently on the TRICARE No Government Pay List or the Medicare DMEPOS and PEN fee schedule will not be included on the TRICARE fee schedule. Any code added to Medicare's fee schedule will also be removed from TRICARE's fee schedule. Quarterly updates will occur as necessary (April 1, July 1, and October 1) so codes may be added, removed, and have their rates modified mid-year. Unlisted, miscellaneous, and NOC codes will be defined using Medicare's HCPCS NOC Codes list published on the Centers for Medicare & Medicaid Services website at *https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html.*

Codes will be assigned to a category (*e.g.,* surgical dressings and certain durable medical equipment, prosthetics and orthotics, parenteral and enteral, etc.) based on long description and if the item meets TRICARE's definition of DMEPOS and PEN as defined in regulation and policy.

TRICARE will establish national and statewide rates for existing and new HCPCS codes defined as a DMEPOS and PEN code. The rate in each state will be calculated by (1) Establishing base years and minimum data requirements, (2) calculating national floors and ceilings, and (3) calculating the average billed amount of claims TRICARE paid in that state during each base year, subject to minimum data requirements and national floors and ceilings. The base year will vary for each code and will be defined as the first year (no earlier than 1994) with at least enough charge data nationwide during a 12-month period beginning on July 1 and ending on June 30. Minimum data will be defined as any code for which there were at least 50 paid claims nationwide during the base year period; if there were fewer than 50 paid claims each year since 1994, then TRICARE's current reimbursement methodology will apply. Given the large number of codes and the lack of historical data, repricing based on 1986–87 levels (similar to Medicare) is not administratively feasible for TRICARE's fee schedule. Although claims from that year are stored in DHA archives (claims are more readily available from 1994 and later), it would be difficult to extract the data and obtain proper documentation. Once the base year for a code has been established, a national ceiling and floor will be calculated using Medicare's methodology. For example, for surgical dressings and certain Durable Medical Equipment, the national ceiling will be equal to the median of all paid claims nationwide during the base period, and the national floor will be equal to 85 percent of the national ceiling. The state-wide fee schedule for states outside the continental United States (*i.e.,* Alaska and Hawaii), as well as for United States territories and commonwealths, will not be subject to the ceilings and floors, in accordance with Medicare rules. When establishing the initial fee schedule amounts, the national floor and ceiling rates for any code cannot exceed the amount that would have been calculated using data during the 12-month period of July 1, 2019 through June 30, 2020. It is believed this will result in fee schedule amounts more reflective of reasonable charges for DMEPOS items. Therefore, the DHA is capping national floors and ceiling rates based on the most current base year period which is July 1, 2019 through June 30, 2020.

After establishing a national ceiling and floor for a given code, then the rate for the code can be calculated at the state level. To calculate a statewide rate using the average billed amount, there must be at least eight paid claims

(similar to state prevailing rates under the current TRICARE methodology) for a given code within that state during the base year. States without eight paid claims will be set at the national ceiling, unless stated otherwise in the TRICARE Reimbursement Manual or the TRICARE Policy Manual. The statewide rate must also fall within the national floor and ceiling. In states where the average billed amount of claims is lower than the national floor, then the statewide rate will be equivalent to the national floor. In states where the average billed amount of claims is higher than the national ceiling, then the statewide rate will be equivalent to the national ceiling. Rental items and equipment will be calculated based on 10 percent of the fee schedule amount for a purchased item and used items and equipment will be calculated based on 75 percent of the fee schedule amount for a new item.

There will be several deviations to the above methodology. For PEN items and items involving splints, casts, and inter-ocular lenses, the fee schedule amounts will use a national rate (*i.e.* there will be no national floors or ceilings and no state-to-state variation), which will be equal to the mean, or average, charges of all paid claims nationwide during the base period (updated and trended forward by Medicare's DMEPOS update factor). The base period for PEN items will use 2002 (or later) claims data, and 2013 or later claims data for splints, casts, and inter-ocular lenses. DHA may also establish fee schedule amounts using a cross-walk method to establish statewide rates for items comparable to DMEPOS items with already established rates (this method is consistent with Medicare's regulation to not pay more than a comparable item as identified in 42 CFR 405.502). For items removed from Medicare's fee schedule, DHA will use the last known Medicare fee schedule rate and trend it forward to the present using Medicare's annual DMEPOS update factor.

The following table provides a summary of methodologies for establishing rates in the TRICARE Fee Schedule:

Current methodology	Category	Methodology
Use the 80th percentile of all qualified billed charges within the state as the state prevailing rate. Pay the claim using the state prevailing rate or billed charges, whichever is lower.	Surgical Dressings and Certain DME.	Set national ceiling at median of all paid claims nationwide during base year. Set national floor at 85% of national ceiling. Calculate average billed charge for a state during base year. Trend forward the base year state average, floor, and ceiling using Medicare's update factor. —If state average is within the national floor and ceiling, it becomes the state rate.
	Prosthetics and Orthotics, including Therapeutic Shoes and Inserts.	Set national ceiling and floor at 90% and 120% respectively of the nationwide average of claims paid during base year. Calculate average billed charge for a state during base year. Trend forward the base year state average, floor, and ceiling using Medicare's update factor. —If state average is within the national floor and ceiling, it becomes the state rate.
	Parenteral and Enteral	Calculate average billed charge nationwide during base year and trend forward using Medicare's update factor.
	Splints, Casts, and IOLs	The national average becomes the state rate for every state (*i.e.,* no variation between states).
	Codes that require use of cross-walk method.	Use the same rate as a comparable code with an existing rate.
	Codes removed from Medicare's fee schedule.	Use the last rate from on Medicare's fee schedule and trend it upwards using Medicare's update factor.
	Codes with fewer than 50 paid claims nationally each year since 1994.	There is an insufficient number of national claims to establish a ceiling and floor. Use current methodology for reimbursement, and code will not be added to the fee schedule.

DHA will be responsible for establishing and updating and the accurate calculation of TRICARE's DMEPOS and PEN fee schedule prices. Proposed statewide rates are available for review on the DHA website at *https://health.mil/Military-Health-Topics/Business-Support/Rates-and-Reimbursement/Durable-Medical-Equipment-Prosthetics-Orthotics-and-Supplies.*

Dated: December 22, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–28762 Filed 12–28–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2020–SCC–0162]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; State Educational Agency and Local Educational Agency—School Data Collection and Reporting Under ESEA, Title I, Part A

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension without changes of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before January 28, 2021.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection

activities, please contact Todd Stephenson, (202) 205–1645.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: State Educational Agency and Local Educational Agency—School Data Collection and Reporting under ESEA, Title I, Part A.

OMB Control Number: 1810–0622.

Type of Review: Extension without changes of a currently approved collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 52.

Total Estimated Number of Annual Burden Hours: 2,080.

Abstract: Although the U.S. Department of Education (ED) determines Title I, Part A allocations for Local Educational Agencies (LEAs), State Educational Agencies (SEAs) must adjust ED-determined Title I, Part A LEA allocations to account for newly created LEAs and LEA boundary changes, to redistribute Title I, Part A funds to small LEAs (under 20,000 total population) using alternative poverty data, and to reserve funds for school improvement, State administration, and the State academic achievement awards program. This control number covers only the burden associated with the actual procedures an SEA must follow when adjusting ED-determined LEA allocations.

Dated: December 21, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2020–28635 Filed 12–28–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; State Personnel Development Grants

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications (NIA) for fiscal year (FY) 2021 for the State Personnel Development Grants (SPDG) program, Assistance Listing Number 84.323A. This notice relates to the approved information collection under OMB control number 1820–0028.

DATES:

Applications Available: December 29, 2020.

Deadline for Transmittal of Applications: March 9, 2021.

Pre-Application Webinar Information: No later than January 4, 2021, OSERS will post pre-recorded informational webinars designed to provide technical assistance to interested applicants. The webinars may be found at *www2.ed.gov/fund/grant/apply/osep/new-osep-grants.html.*

Deadline for Intergovernmental Review: May 10, 2021.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf.*

FOR FURTHER INFORMATION CONTACT: Jennifer Coffey, U.S. Department of Education, 400 Maryland Avenue SW, Room 5161, Potomac Center Plaza, Washington, DC 20202–5076. Telephone: (202) 245–6673. Email: *jennifer.coffey@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of this program is to assist State educational agencies (SEAs) in reforming and improving their systems for personnel preparation and professional development in early intervention, educational, and transition services in order to improve results for children with disabilities.

Priorities: This notice contains three absolute priorities. In accordance with 34 CFR 75.105(b)(2)(iv), Absolute Priority 1 is from the notice of final priorities and definitions published in the **Federal Register** on August 2, 2012 (77 FR 45944) (2012 NFP). Absolute Priority 2 is from sections 651 through 655 of the Individuals with Disabilities Education Act (IDEA), as amended by the Every Student Succeeds Act (ESSA). Absolute Priority 3 is from the notice of final priority and definitions for this program published in the **Federal Register** on July 29, 2020 (85 FR 45525) (2020 NFP).

Under this competition, Absolute Priority 3 constitutes its own funding category, and the Department intends to award one-third of the SPDG grants under this competition to grants under Absolute Priority 3 provided applications of sufficient quality are submitted. Applications will be rank ordered separately for Absolute Priority 3. Therefore, applicants must clearly identify if the proposed project addresses Absolute Priority 3.

Absolute Priorities: For FY 2021 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are absolute priorities. Applicants must address Absolute Priorities 1 and 2. They may also choose to address Absolute Priority 3. Under 34 CFR 75.105(c)(3), we consider only applications that meet all the priorities that they choose to address.

These priorities are:

Absolute Priority 1: Effective and Efficient Delivery of Professional Development.

The Department establishes a priority to assist SEAs in reforming and improving their systems for personnel (as that term is defined in section 651(b) of IDEA) preparation and professional development of individuals providing early intervention, educational, and transition services in order to improve results for children with disabilities.

In order to meet this priority, an applicant must demonstrate in the SPDG State Plan it submits, as part of its application under section 653(a)(2) of IDEA, that its proposed project will—

(1) Use evidence-based (as defined in this notice) professional development practices that will increase implementation of evidence-based practices and result in improved outcomes for children with disabilities;

(2) Provide ongoing assistance to personnel receiving SPDG-supported professional development that supports the implementation of evidence-based practices with fidelity (as defined in this notice); and

(3) Use technology to more efficiently and effectively provide ongoing professional development to personnel, including to personnel in rural areas and to other populations, such as personnel in urban or high-need local educational agencies (LEAs) (as defined in this notice).

Absolute Priority 2: State Personnel Development Grants.

Statutory Requirements. To meet this priority, an applicant must meet the following statutory requirements:

1. State Personnel Development Plan.

An applicant must submit a State Personnel Development Plan that identifies and addresses the State and local needs for the personnel preparation and professional development of personnel, as well as individuals who provide direct supplementary aids and services to children with disabilities, and that—

(a) Is designed to enable the State to meet the requirements of section 612(a)(14) of IDEA, as amended by the ESSA and section 635(a)(8) and (9) of IDEA;

(b) Is based on an assessment of State and local needs that identifies critical aspects and areas in need of improvement related to the preparation, ongoing training, and professional development of personnel who serve infants, toddlers, preschoolers, and children with disabilities within the State, including—

(1) Current and anticipated personnel vacancies and shortages; and

(2) The number of preservice and inservice programs;

(c) Is integrated and aligned, to the maximum extent possible, with State plans and activities under the Elementary and Secondary Education Act of 1965, as amended (ESEA); the Rehabilitation Act of 1973, as amended; and the Higher Education Act of 1965, as amended (HEA);

(d) Describes a partnership agreement that is in effect for the period of the grant, which agreement must specify—

(1) The nature and extent of the partnership described in accordance with section 652(b) of IDEA and the respective roles of each member of the partnership, including, if applicable, an individual, entity, or agency other than the SEA that has the responsibility under State law for teacher preparation and certification; and

(2) How the SEA will work with other persons and organizations involved in, and concerned with, the education of children with disabilities, including the respective roles of each of the persons and organizations;

(e) Describes how the strategies and activities the SEA uses to address identified professional development and personnel needs will be coordinated with activities supported with other public resources (including funds provided under Part B and Part C of IDEA and retained for use at the State level for personnel and professional development purposes) and private resources;

(f) Describes how the SEA will align its personnel development plan with the plan and application submitted under sections 1111 and 2101(d), respectively, of the ESEA;

(g) Describes strategies the SEA will use to address the identified professional development and personnel needs and how such strategies will be implemented, including—

(1) A description of the programs and activities that will provide personnel with the knowledge and skills to meet the needs of, and improve the performance and achievement of, infants, toddlers, preschoolers, and children with disabilities; and

(2) How such strategies will be integrated, to the maximum extent possible, with other activities supported by grants funded under section 662 of IDEA, as amended by the ESSA;

(h) Provides an assurance that the SEA will provide technical assistance to LEAs to improve the quality of professional development available to meet the needs of personnel who serve children with disabilities;

(i) Provides an assurance that the SEA will provide technical assistance to entities that provide services to infants and toddlers with disabilities to improve the quality of professional development available to meet the needs of personnel serving those children;

(j) Describes how the SEA will recruit and retain teachers who meet the qualifications described in section 612(a)(14)(C) of IDEA, as amended by the ESSA, and other qualified personnel in geographic areas of greatest need;

(k) Describes the steps the SEA will take to ensure that economically disadvantaged and minority children are not taught at higher rates by teachers who do not meet the qualifications described in section 612(a)(14)(C) of IDEA, as amended by the ESSA; and

(l) Describes how the SEA will assess, on a regular basis, the extent to which the strategies implemented have been effective in meeting the performance goals described in section 612(a)(15) of IDEA, as amended by the ESSA.

2. Partnerships.

(a) Required Partners.

Applicants must establish a partnership with LEAs and other State agencies involved in, or concerned with, the education of children with disabilities, including—

(1) Not less than one institution of higher education (IHE); and

(2) The State agencies responsible for administering Part C of IDEA, early education, childcare, and vocational rehabilitation programs.

(b) Other Partners.

An SEA must work in partnership with other persons and organizations involved in, and concerned with, the education of children with disabilities, which may include—

(1) The Governor;

(2) Parents of children with disabilities ages birth through 26;

(3) Parents of nondisabled children ages birth through 26;

(4) Individuals with disabilities;

(5) Parent training and information centers or community parent resource centers funded under sections 671 and 672 of IDEA, respectively;

(6) Community-based and other nonprofit organizations involved in the education and employment of individuals with disabilities;

(7) Personnel as defined in section 651(b) of IDEA;

(8) The State advisory panel established under Part B of IDEA;

(9) The State interagency coordinating council established under Part C of IDEA;

(10) Individuals knowledgeable about vocational education;

(11) The State agency for higher education;

(12) Public agencies with jurisdiction in the areas of health, mental health, social services, and juvenile justice;

(13) Other providers of professional development who work with infants, toddlers, preschoolers, and children with disabilities;

(14) Other individuals; and

(15) An individual, entity, or agency as a partner in accordance with section 652(b)(3) of IDEA, if State law assigns responsibility for teacher preparation

and certification to an individual, entity, or agency other than the SEA.

3. Use of Funds.

(a) Professional Development Activities—Each SEA that receives a grant under this program must use the grant funds to support activities in accordance with the State's Personnel Development Plan, including one or more of the following:

(1) Carrying out programs that provide support to both special education and regular education teachers of children with disabilities and principals, such as programs that—

(i) Provide teacher mentoring, team teaching, reduced class schedules and caseloads, and intensive professional development;

(ii) Use standards or assessments for guiding beginning teachers that are consistent with challenging State academic achievement standards and with the requirements for professional development, as defined in section 8101 of the ESEA; and

(iii) Encourage collaborative and consultative models of providing early intervention, special education, and related services.

(2) Encouraging and supporting the training of special education and regular education teachers and administrators to effectively use and integrate technology—

(i) Into curricula and instruction, including training to improve the ability to collect, manage, and analyze data to improve teaching, decision making, school improvement efforts, and accountability;

(ii) To enhance learning by children with disabilities; and

(iii) To effectively communicate with parents.

(3) Providing professional development activities that—

(i) Improve the knowledge of special education and regular education teachers concerning—

(A) The academic and developmental or functional needs of students with disabilities; or

(B) Effective instructional strategies, methods, and skills, and the use of State academic content standards and student academic achievement standards, and State assessments, to improve teaching practices and student academic achievement;

(ii) Improve the knowledge of special education and regular education teachers and principals and, in appropriate cases, paraprofessionals, concerning effective instructional practices, and that—

(A) Provide training in how to teach and address the needs of children with different learning styles and children who are English learners;

(B) Involve collaborative groups of teachers, administrators, and, in appropriate cases, related services personnel;

(C) Provide training in methods of—

(I) Positive behavioral interventions and supports to improve student behavior in the classroom;

(II) Scientifically based reading instruction, including early literacy instruction;

(III) Early and appropriate interventions to identify and help children with disabilities;

(IV) Effective instruction for children with low-incidence disabilities;

(V) Successful transitioning to postsecondary opportunities; and

(VI) Classroom-based techniques to assist children prior to referral for special education;

(D) Provide training to enable personnel to work with and involve parents in their child's education, including parents of low income and children with disabilities who are English learners;

(E) Provide training for special education personnel and regular education personnel in planning, developing, and implementing effective and appropriate individualized education programs (IEPs); and

(F) Provide training to meet the needs of students with significant health, mobility, or behavioral needs prior to serving those students;

(iii) Train administrators, principals, and other relevant school personnel in conducting effective IEP meetings; and

(iv) Train early intervention, preschool, and related services providers, and other relevant school personnel in conducting effective individualized family service plan (IFSP) meetings.

(4) Developing and implementing initiatives to promote the recruitment and retention of special education teachers who meet the qualifications described in section 612(a)(14)(C) of IDEA, as amended by the ESSA, particularly initiatives that have proven effective in recruiting and retaining teachers who meet those qualifications, described in section 612(a)(14)(C) of IDEA, as amended by the ESSA, including programs that provide—

(i) Teacher mentoring from exemplary special education teachers, principals, or superintendents;

(ii) Induction and support for special education teachers during their first three years of employment as teachers; or

(iii) Incentives, including financial incentives, to retain special education teachers who have a record of success in helping students with disabilities.

(5) Carrying out programs and activities that are designed to improve the quality of personnel who serve children with disabilities, such as—

(i) Innovative professional development programs (which may be provided through partnerships with IHEs), including programs that train teachers and principals to integrate technology into curricula and instruction to improve teaching, learning, and technology literacy and that are consistent with the definition of professional development in section 8101 of the ESEA; and

(ii) The development and use of proven, cost effective strategies for the implementation of professional development activities, such as through the use of technology and distance learning.

(6) Carrying out programs and activities that are designed to improve the quality of early intervention personnel, including paraprofessionals and primary referral sources, such as—

(i) Professional development programs to improve the delivery of early intervention services;

(ii) Initiatives to promote the recruitment and retention of early intervention personnel; and

(iii) Interagency activities to ensure that early intervention personnel are adequately prepared and trained.

(b) Other Activities—Each SEA that receives a grant under this program must use the grant funds to support activities in accordance with the State's Personnel Development Plan, including one or more of the following:

(1) Reforming special education and regular education teacher certification (including re-certification) or licensing requirements to ensure that—

(i) Special education and regular education teachers have—

(A) The training and information necessary to address the full range of needs of children with disabilities across disability categories; and

(B) The necessary subject matter knowledge and teaching skills in the academic subjects that the teachers teach;

(ii) Special education and regular education teacher certification (including re-certification) or licensing requirements are aligned with challenging State academic content standards; and

(iii) Special education and regular education teachers have the subject matter knowledge and teaching skills, including technology literacy, necessary to help students with disabilities meet challenging State academic achievement standards.

(2) Programs that establish, expand, or improve alternative routes for State certification of special education teachers for individuals with a baccalaureate or master's degree who meet the qualifications described in section 612(a)(14)(C)of IDEA, as amended by the ESSA, including mid-career professionals from other occupations, paraprofessionals, and recent college or university graduates with records of academic distinction who demonstrate the potential to become highly effective special education teachers.

(3) Teacher advancement initiatives for special education teachers that promote professional growth and emphasize multiple career paths (such as paths to becoming a career teacher, mentor teacher, or exemplary teacher) and pay differentiation.

(4) Developing and implementing mechanisms to assist LEAs and schools in effectively recruiting and retaining special education teachers who meet the qualifications described in section 612(a)(14)(C) of IDEA, as amended by the ESSA.

(5) Reforming tenure systems, implementing teacher testing for subject matter knowledge, and implementing teacher testing for State certification or licensure, consistent with title II of the HEA (20 U.S.C. 1021 *et seq.*).

(6) Funding projects to promote reciprocity of teacher certification or licensing between or among States for special education teachers, except that no reciprocity agreement developed under this absolute priority may lead to the weakening of any State teacher certification or licensing requirement.

(7) Assisting LEAs to serve children with disabilities through the development and use of proven, innovative strategies to deliver intensive professional development programs that are both cost effective and easily accessible, such as strategies that involve delivery through the use of technology, peer networks, and distance learning.

(8) Developing, or assisting LEAs in developing, merit-based performance systems and strategies that provide differential and bonus pay for special education teachers.

(9) Supporting activities that ensure that teachers are able to use challenging State academic content standards and student academic achievement standards, and State assessments for all children with disabilities, to improve instructional practices and improve the academic achievement of children with disabilities.

(10) When applicable, coordinating with, and expanding centers established under section 2113(c)(18) of the ESEA, as amended by the No Child Left Behind Act of 2002, to benefit special education teachers.

(c) Contracts and Subgrants—An SEA that receives a grant under this program—

(1) Must award contracts or subgrants to LEAs, IHEs, parent training and information centers, or community parent resource centers, as appropriate, to carry out the State Personnel Development Plan; and

(2) May award contracts and subgrants to other public and private entities, including the lead agency under Part C of IDEA, to carry out the State plan.

(d) Use of Funds for Professional Development—An SEA that receives a grant under this program must use—

(1) Not less than 90 percent of the funds the SEA receives under the grant for any fiscal year for the Professional Development Activities described in paragraph (a); and

(2) Not more than 10 percent of the funds the SEA receives under the grant for any fiscal year for the Other Activities described in paragraph (b).

Absolute Priority 3: Choice in Professional Development.

The purpose of this priority is to fund SPDG grants to SEAs that empower teachers and other personnel to select professional development activities that meet their individual needs to improve results for children with disabilities. States will meet the priority if they describe in their application how they will develop personalized professional development projects to carry out their State plan under section 653 of IDEA and implement professional development activities that are consistent with the use of funds provisions in section 654 of IDEA. This would be accomplished by using funds under the SPDG program for stipends or other mechanisms to provide personnel with choice in selecting professional development options that will count toward State or local professional development requirements, as appropriate, such as the number of hours personnel must fill or the competencies they must acquire to obtain or retain certification, and that are designed to meet their individual needs and thus improve results for children with disabilities.

Applicants must—

(a) Demonstrate, in the narrative section of the application under ''Significance,'' how the proposed project will develop personalized professional development activities using stipends or other mechanisms that provide personnel choice in professional development options designed to meet their individual needs and count toward State or local professional development requirements and thus improve results for children with disabilities;

(b) Describe how the State will select the individual(s) or groups of personnel that will be provided with professional development options, including the extent to which applicants will prioritize selecting individuals or groups of personnel serving rural children with disabilities or disadvantaged children with disabilities, such as children from low-income families. If applicable, applicants should specify how they will prioritize personnel if demand for professional development among the individuals or groups of personnel that the applicant proposes to serve exceeds what available funds can support;

(c) Describe how the State will create a list of approved professional development options that meet the requirements of the SPDG program. This description should include how the applicant will engage with a range of stakeholders, including school administrators, personnel serving students with disabilities, families of students with disabilities and individuals with disabilities, and other State or local agencies serving individuals with disabilities, such as juvenile justice agencies, to determine which professional development options it will offer. Specifically, professional development options must—

(1) Use evidence-based (as defined in this notice) professional development methods that will increase implementation of evidence-based practices and result in improved outcomes for children with disabilities;

(2) Include ongoing assistance that supports the implementation of evidence-based practices with fidelity (as defined in this notice); and

(3) Use technology to more efficiently and effectively provide ongoing professional development to personnel, including to personnel in rural areas and in urban or high-need local educational agencies (LEAs) (as defined in this notice);

(d) If applicable, describe the steps that personnel would need to take to request professional development options not already on a list of approved professional development options, the justification that personnel would need to provide to demonstrate how the selected options would improve results for children with disabilities, and how personnel would be notified if their

request was approved or disapproved in writing and within 14 days; and

(e) Describe—

(1) The extent to which the proposed project will use professional development practices supported by evidence to support the attainment of identified competencies;

(2) How improvement in implementation of SPDG-supported practices over time will be demonstrated by participants in SPDG professional development activities;

(3) The extent to which the proposed project will use SPDG professional development funds to provide activities designed to sustain the use of SPDG-supported practices;

(4) How the proposed project will determine whether special education teachers who meet the qualifications described in section 612(a)(14)(C) of IDEA, as amended by the ESSA, that have participated in SPDG-supported special education teacher retention activities remain as special education teachers two years after their initial participation in these activities; and

(5) How the proposed project will assess whether and to what extent the project improves outcomes for children with disabilities.

Program Requirements: For FY 2021 and any subsequent year in which we make awards from the list of unfunded applications from this competition, the following program requirements apply.

Projects funded under this program must—

(a) Budget for a three-day project directors' meeting in Washington, DC, during each year of the project;

(b) Budget $4,000 annually for support of the SPDG program website currently administered by the University of Oregon (*www.signetwork.org*); and

(c) If a project receiving assistance under this program authority maintains a website, include relevant information and documents in a form that meets a government or industry-recognized standard for accessibility.

Definitions

The following definitions apply to this competition. We provide the source of the definitions in parentheses.

Demonstrates a rationale means a key project component included in the project's logic model is informed by research or evaluation findings that suggest the project component is likely to improve relevant outcomes. (34 CFR 77.1)

Evidence-based means, for purposes of Absolute Priority 1, practices for which there is strong evidence or moderate evidence of effectiveness (2012 NFP); and for purposes of Absolute Priority 3, the proposed project component is supported by one or more of strong evidence, moderate evidence, promising evidence, or evidence that demonstrates a rationale. (2020 NFP)

Experimental study means a study that is designed to compare outcomes between two groups of individuals (such as students) that are otherwise equivalent except for their assignment to either a treatment group receiving a project component or a control group that does not. Randomized controlled trials, regression discontinuity design studies, and single-case design studies are the specific types of experimental studies that, depending on their design and implementation (*e.g.,* sample attrition in randomized controlled trials and regression discontinuity design studies), can meet What Works Clearinghouse (WWC) standards without reservations as described in the WWC Handbooks:

(i) A randomized controlled trial employs random assignment of, for example, students, teachers, classrooms, or schools to receive the project component being evaluated (the treatment group) or not to receive the project component (the control group).

(ii) A regression discontinuity design study assigns the project component being evaluated using a measured variable (*e.g.,* assigning students reading below a cutoff score to tutoring or developmental education classes) and controls for that variable in the analysis of outcomes.

(iii) A single-case design study uses observations of a single case (*e.g.,* a student eligible for a behavioral intervention) over time in the absence and presence of a controlled treatment manipulation to determine whether the outcome is systematically related to the treatment. (34 CFR 77.1)

Fidelity means the delivery of instruction in the way in which it was designed to be delivered. (2012 NFP)

High-need LEA means, in accordance with section 2102(3) of the ESEA, an LEA—

(a) That serves not fewer than 10,000 children from families with incomes below the poverty line (as that term is defined in section 8101(41) of the ESEA), or for which not less than 20 percent of the children served by the LEA are from families with incomes below the poverty line; and

(b) For which there is (1) a high percentage of teachers not teaching in the academic subjects or grade levels that the teachers were trained to teach, or (2) a high percentage of teachers with emergency, provisional, or temporary certification or licensing. (2012 NFP)

Lead agency means the agency designated by the State's Governor under section 635(a)(10) of IDEA and 34 CFR 303.120 that receives funds under section 643 of IDEA to administer the State's responsibilities under part C of IDEA. (34 CFR 303.22)

Local educational agency (LEA) means a public board of education or other public authority legally constituted within a State for either administrative control or direction of, or to perform a service function for, public elementary schools or secondary schools in a city, county, township, school district, or other political subdivision of a State, or for such combination of school districts or counties as are recognized in a State as an administrative agency for its public elementary schools or secondary schools. (Section 602(19) of IDEA (20 U.S.C. 1401(19)))

Moderate evidence means that there is evidence of effectiveness of a key project component in improving a relevant outcome for a sample that overlaps with the populations or settings proposed to receive that component, based on a relevant finding from one of the following:

(i) A practice guide prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a ''strong evidence base'' or ''moderate evidence base'' for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks reporting a ''positive effect'' or ''potentially positive effect'' on a relevant outcome based on a ''medium to large'' extent of evidence, with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single experimental study or quasi-experimental design study reviewed and reported by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks, or otherwise assessed by the Department using version 4.1 of the WWC Handbooks, as appropriate, and that—

(A) Meets WWC standards with or without reservations;

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome;

(C) Includes no overriding statistically significant and negative effects on relevant outcomes reported in the study or in a corresponding WWC intervention report prepared under version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbooks; and

(D) Is based on a sample from more than one site (*e.g.,* State, county, city, school district, or postsecondary campus) and includes at least 350 students or other individuals across sites. Multiple studies of the same project component that each meet requirements in paragraphs (iii)(A), (B), and (C) of this definition may together satisfy the requirement in this paragraph (iii)(D). (34 CFR 77.1)

Project component means an activity, strategy, intervention, process, product, practice, or policy included in a project. Evidence may pertain to an individual project component or to a combination of project components (*e.g.,* training teachers on instructional practices for English learners and follow-on coaching for these teachers). (34 CFR 77.1)

Promising evidence means that there is evidence of the effectiveness of a key project component in improving a relevant outcome, based on a relevant finding from one of the following—

(i) A practice guide prepared by WWC reporting a ''strong evidence base'' or ''moderate evidence base'' for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC reporting a ''positive effect'' or ''potentially positive effect'' on a relevant outcome with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single study assessed by the Department, as appropriate, that—

(A) Is an experimental study, a quasi-experimental design study, or a well-designed and well-implemented correlational study with statistical controls for selection bias (*e.g.,* a study using regression methods to account for differences between a treatment group and a comparison group); and

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome. (34 CFR 77.1)

Quasi-experimental design study means a study using a design that attempts to approximate an experimental study by identifying a comparison group that is similar to the treatment group in important respects. This type of study, depending on design and implementation (*e.g.,* establishment of baseline equivalence of the groups being compared), can meet WWC standards with reservations, but cannot meet WWC standards without reservations, as described in the WWC Handbook. (34 CFR 77.1)

Relevant outcome means the student outcome(s) or other outcome(s) the key project component is designed to improve, consistent with the specific goals of the program. (34 CFR 77.1)

State educational agency means the State board of education or other agency or officer primarily responsible for the State supervision of public elementary schools and secondary schools, or, if there is no such officer or agency, an officer or agency designated by the Governor or by State law. (Section 602(32) of IDEA (20 U.S.C. 1401(32)))

Strong evidence means that there is evidence of the effectiveness of a key project component in improving a relevant outcome for a sample that overlaps with the populations and settings proposed to receive that component, based on a relevant finding from one of the following—

(i) A practice guide prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbook reporting a ''strong evidence base'' for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbook reporting a ''positive effect'' on a relevant outcome based on a ''medium to large'' extent of evidence, with no reporting of a ''negative effect'' or ''potentially negative effect'' on a relevant outcome; or

(iii) A single experimental study reviewed and reported by the WWC using version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbook, or otherwise assessed by the Department using version 4.1 of the WWC Handbook, as appropriate, and that—

(A) Meets WWC standards without reservations;

(B) Includes at least one statistically significant and positive (*i.e.,* favorable) effect on a relevant outcome;

(C) Includes no overriding statistically significant and negative effects on relevant outcomes reported in the study or in a corresponding WWC intervention report prepared under version 2.1, 3.0, 4.0, or 4.1 of the WWC Handbook; and

(D) Is based on a sample from more than one site (*e.g.,* State, county, city, school district, or postsecondary campus) and includes at least 350 students or other individuals across sites. Multiple studies of the same project component that each meet requirements in paragraphs (iii)(A), (B), and (C) of this definition may together satisfy this requirement. (34 CFR 77.1)

What Works Clearinghouse Handbooks (WWC Handbooks) means the standards and procedures set forth in the WWC Standards Handbook, Versions 4.0 or 4.1, and WWC Procedures Handbook, Versions 4.0 or 4.1, or in the WWC Procedures and Standards Handbook, Version 3.0 or Version 2.1 (all incorporated by reference, see § 77.2). Study findings eligible for review under WWC standards can meet WWC standards without reservations, meet WWC standards with reservations, or not meet WWC standards. WWC practice guides and intervention reports include findings from systematic reviews of evidence as described in the WWC Handbooks documentation. (34 CFR 77.1)

Program Authority: 20 U.S.C. 1451–1455.

Note: Projects must be awarded and operated in a manner consistent with the nondiscrimination requirements contained in the U.S. Constitution and the Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The 2012 NFP. (e) The 2020 NFP.

Note: The regulations in 34 CFR part 86 apply to IHEs only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: The Administration has requested $38,630,000 for the SPDG program for FY 2021, of which we intend to use an estimated $9,202,413 for this competition. The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2022 from the list of unfunded applications from this competition.

Estimated Range of Awards: $500,000–$2,100,000 (for the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico). In the case of outlying areas (United States Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands), awards will be not less than $80,000.

Note: We will set the amount of each award after considering—

(1) The amount of funds available for making the grants;

(2) The relative population of the State or outlying area;

(3) The types of activities proposed by the State or outlying area;

(4) The alignment of proposed activities with section 612(a)(14) of IDEA, as amended by the ESSA;

(5) The alignment of proposed activities with State plans and applications submitted under sections 1111 and 2101(d), respectively, of the ESEA; and

(6) The use, as appropriate, of research and instruction supported by evidence.

Using the same considerations, the Secretary funded successful applications for FY 2020 at the following levels:

State	FY 2020 funding amount
Guam	$250,000
Indiana	500,000
Minnesota	500,000
Montana	500,000
Idaho	511,717
Nevada	597,769
District of Columbia	600,000
Tennessee	652,526
Washington	927,420
Arkansas	1,066,761
Illinois	1,200,000
New York	1,247,000

Estimated Average Size of Awards: $900,000 excluding the outlying areas.

Estimated Number of Awards: 8–10.

Note: The Department is not bound by any estimates in this notice.

Project Period: Not less than one year and not more than five years.

III. Eligibility Information

1. *Eligible Applicants:* An SEA of one of the 50 States, the District of Columbia, or the Commonwealth of Puerto Rico or an outlying area (United States Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands).

Note: Public Law 95–134, which permits the consolidation of grants to the outlying areas, does not apply to funds received under this competition.

2a. *Cost Sharing or Matching:* This competition does not require cost sharing or matching.

b. *Indirect Cost Rate Information:* This program uses an unrestricted indirect cost rate. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www2.ed.gov/about/offices/list/ocfo/intro.html.*

c. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

3. *Subgrantees:* A grantee under this competition must award contracts and subgrants as described in Absolute Priority 2 (paragraph (3)(C) under Statutory Requirements, Use of Funds). See section 654(c) of the IDEA, as amended by ESSA.

4. *Other General Requirements:*

(a) Recipients of funding under this competition must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

(b) Applicants for, and recipients of, funding must, with respect to the aspects of their proposed project relating to Absolute Priorities 2 and 3, involve individuals with disabilities, or parents of individuals with disabilities ages birth through 26, in planning, implementing, and evaluating the project (see section 682(a)(1)(A) of IDEA).

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf,* which contain requirements and information on how to submit an application.

2. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

3. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

4. *Recommended Page Limit:* The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 70 pages and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, reference citations, and captions, as well as all text in charts, tables, figures, graphs, and screen shots.
- Use a font that is 12 point or larger.
- *Use one of the following fonts:* Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the abstract (follow the guidance provided in the application package for completing the abstract), the table of contents, the list of priority requirements, the resumes, the reference list, the letters of support, or the appendices. However, the recommended page limit does apply to all of the application narrative, including all text in charts, tables, figures, graphs, and screen shots.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210 and are as follows:

(a) *Significance (20 points).*

(1) The Secretary considers the significance of the proposed project.

(2) In determining the significance of the proposed project, the Secretary considers the following factors:

(i) The extent to which the proposed project is part of a comprehensive effort to improve teaching and learning and support rigorous academic standards for students.

(ii) The extent to which specific gaps or weaknesses in services, infrastructure, or opportunities have been identified and will be addressed by the proposed project, including the nature and magnitude of those gaps or weaknesses.

(iii) The extent to which the training or professional development services to be provided by the proposed project are of sufficient quality, intensity, and duration to lead to improvements in practice among the recipients of those services.

(iv) The likelihood that the proposed project will result in system change or improvement.

(b) *Quality of the project design (25 points).*

(1) The Secretary considers the quality of the design of the proposed project.

(2) In determining the quality of the design of the proposed project, the Secretary considers the following factors:

(i) The extent to which the goals, objectives, and outcomes to be achieved

by the proposed project are clearly specified and measurable.

(ii) The extent to which the design of the proposed project is appropriate to, and will successfully address, the needs of the target population or other identified needs.

(iii) The extent to which the services to be provided by the proposed project involve the collaboration of appropriate partners for maximizing the effectiveness of project services.

(iv) The extent to which the design of the proposed project reflects up-to-date knowledge from research and effective practice.

(v) The extent to which the proposed project will establish linkages with other appropriate agencies and organizations providing services to the target population.

(c) *Quality of the project personnel (10 points).*

(1) The Secretary considers the quality of the personnel who will carry out the proposed project.

(2) In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the following factors:

(i) The qualifications, including relevant training and experience, of the project director or principal investigator.

(ii) The qualifications, including relevant training and experience, of key project personnel.

(d) *Adequacy of resources and management plan (20 points).*

(1) The Secretary considers the adequacy of resources and management plan for the proposed project.

(2) In determining the adequacy of resources for the proposed project, the Secretary considers the following factors:

(i) The relevance and demonstrated commitment of each partner in the proposed project to the implementation and success of the project.

(ii) The extent to which the budget is adequate to support the proposed project.

(iii) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

(iv) How the applicant will ensure that a diversity of perspectives are brought to bear in the operation of the proposed project, including those of parents, teachers, the business community, a variety of disciplinary and professional fields, recipients or beneficiaries of services, or others, as appropriate.

(v) The potential for continued support of the project after Federal funding ends, including, as appropriate, the demonstrated commitment of appropriate entities to such support.

(e) *Quality of the project evaluation (25 points).*

(1) The Secretary considers the quality of the evaluation to be conducted of the proposed project.

(2) In determining the quality of the evaluation, the Secretary considers the following factors:

(i) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project.

(ii) The extent to which the methods of evaluation are appropriate to the context within which the project operates.

(iii) The extent to which the methods of evaluation provide for examining the effectiveness of project implementation strategies.

(iv) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible.

(v) The extent to which the evaluation will provide guidance about effective strategies suitable for replication or testing in other settings.

(vi) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes.

(vii) The extent to which the evaluation plan clearly articulates the key project components, mediators, and outcomes, as well as a measurable threshold for acceptable implementation.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Additional Review and Selection Process Factors:* In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The standing panel requirements under section 682(b) of IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within specific groups. This procedure will make it easier for the Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications.

4. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose specific conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

5. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.205(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal

Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

5. *Performance Measures:* For the purposes of the Government Performance and Results Act of 1993 (GPRA) and reporting under 34 CFR 75.110, the Department has established a set of performance measures, including long-term measures, that are designed to yield information on various aspects of the effectiveness and quality of the SPDG program. These measures assess the extent to which—

- Projects use professional development practices supported by evidence to support the attainment of identified competencies;
- Participants in SPDG professional development demonstrate improvement in implementation of SPDG-supported practices over time;
- Projects use SPDG professional development funds to provide activities designed to sustain the use of SPDG-supported practices;
- Special education teachers who meet the qualifications described in section 612(a)(14)(C) of IDEA, as amended by the ESSA, and who have participated in SPDG-supported special education teacher retention activities remain as special education teachers two years after their initial participation in these activities; and
- Projects improve outcomes for children with disabilities.

Each grantee funded under this competition must collect and annually report data related to its performance on these measures in the project's annual and final performance report to the Department in accordance with section 653(d) of IDEA and 34 CFR 75.590. Applicants should discuss in the application narrative how they propose to collect performance data for these measures.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* 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 Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also 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.

Mark Schultz,

Commissioner, Rehabilitation Services Administration. Delegated the authority to perform the functions and duties of the Assistant Secretary for the Office of Special Education and Rehabilitative Services.

[FR Doc. 2020–28684 Filed 12–28–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0198]

Agency Information Collection Activities; Comment Request; Formula Grant EASIE Annual Performance Report

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension without change of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before March 1, 2021.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2020–SCC–0198. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the PRA Coordinator of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W208D, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Crystal Moore, (202) 453–5593.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Formula Grant EASIE Annual Performance Report.

OMB Control Number: 1810–0726.

Type of Review: Extension without change of a currently approved collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 1,300.

Total Estimated Number of Annual Burden Hours: 14,300.

Abstract: The purpose of Indian Education Formula Grant to Local Agencies, as authorized under section 6116 of the Elementary and Secondary Education Act of 1965 (ESEA), as amended by the Every Student Succeeds Act (ESSA) is to assist grantees to provide Indian students with the opportunity to meet the same challenging state standards as all other students and meet the unique educational and culturally related academic needs of American Indian and Alaska Native students. The Indian Education Formula Grant (CFDA 84.060A), is neither competitive nor discretionary and requires the annual submission of the application from either a local education agency, tribe, Indian organization, or Indian community-based organization. The amount of the award for each applicant is determined by a formula based on the reported number of American Indian/Alaska Native students identified in the application, the state per pupil expenditure, and the total appropriation available. The Office of Indian Education (OIE) of The Department of Education (ED) collects annual performance data within the same system that collects the annual application. The application and the annual performance report are both be housed in the Education Data Exchange Network (EDEN) Submission System. The 524B Annual Performance Report (APR) was designed for discretionary grants, however the title VI program is a formula grant program. The EASIE APR goes beyond the generic 524B APR and facilitates the collection of more specific and comprehensive data due to grantees entering project specific data into an online database.

Dated: December 22, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2020–28685 Filed 12–28–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

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

Docket Numbers: EC21–36–000.

Applicants: Lea Power Partners, LLC, Waterside Power, LLC, Badger Creek Limited, Bear Mountain Limited, Chalk Cliff Limited, Double C Generation Limited Partnership, High Sierra Limited, Kern Front Limited, Live Oak Limited, McKittrick Limited, WGP Redwood Holdings, LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act of Lea Power Partners, LLC, et. al.

Filed Date: 12/18/20.

Accession Number: 20201218–5373.

Comments Due: 5 p.m. ET 1/8/21.

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

Docket Numbers: ER10–1123–005; ER10–1119 005.

Applicants: Union Electric Company, Ameren Illinois Company.

Description: Triennial Market Power Update for Central Region of Ameren Companies.
Filed Date: 12/18/20.
Accession Number: 20201218–5255.
Comments Due: 5 p.m. ET 2/16/21.

Docket Numbers: ER10–1257–008; ER10–1258–008.
Applicants: Wabash Valley Power Association, Inc., Wabash Valley Energy Marketing, Inc.
Description: Triennial Market Power Update for Central Region of Wabash Valley Power Association, Inc., et al.
Filed Date: 12/18/20.
Accession Number: 20201218–5252.
Comments Due: 5 p.m. ET 2/16/21.

Docket Numbers: ER10–1819–028; ER10–1820–031.
Applicants: Northern States Power Company, a Minnesota corporation, Northern States Power Company, a Wisconsin corporation.
Description: Triennial Market Power Analysis for Central Region of Northern States Power Company, a Minnesota corporation, et al.
Filed Date: 12/18/20.
Accession Number: 20201218–5257.
Comments Due: 5 p.m. ET 2/16/21.

Docket Numbers: ER16–323–009.
Applicants: Ohio Valley Electric Corporation.
Description: Triennial Market Power Analysis for Central Region of Ohio Valley Electric Corporation.
Filed Date: 12/18/20.
Accession Number: 20201218–5258.
Comments Due: 5 p.m. ET 2/16/21.

Docket Numbers: ER18–807–006; ER10–1852–046; ER10–1951–028; ER11–4462–049; ER17–838–024.
Applicants: Pinal Central Energy Center, LLC, Florida Power & Light Company, NEPM II, LLC, NextEra Energy Services Massachusetts, LLC, NextEra Energy Marketing, LLC.
Description: Notice of Change in Status of NextEra Entities.
Filed Date: 12/18/20.
Accession Number: 20201218–5248.
Comments Due: 5 p.m. ET 1/8/21.

Docket Numbers: ER20–486–001.
Applicants: Golden Fields Solar III, LLC.
Description: Notice of Change in Status of Golden Fields Solar III, LLC.
Filed Date: 12/18/20.
Accession Number: 20201218–5250.
Comments Due: 5 p.m. ET 1/8/21.

Docket Numbers: ER21–690–000.
Applicants: Midcontinent Independent System Operator, Inc., Otter Tail Power Company.
Description: § 205(d) Rate Filing: 2020–12–21_SA 3605 OTP–CPEC FCA (WAPA Jamestown) to be effective 2/20/2021.
Filed Date: 12/21/20.
Accession Number: 20201221–5030.
Comments Due: 5 p.m. ET 1/11/21.

Docket Numbers: ER21–691–000.
Applicants: Public Service Company of Colorado.
Description: § 205(d) Rate Filing: 2020–12–21 PSC–GndVly–NonConf–SISA–619–0.0.0 to be effective 12/22/2020.
Filed Date: 12/21/20.
Accession Number: 20201221–5062.
Comments Due: 5 p.m. ET 1/11/21.

Docket Numbers: ER21–692–000.
Applicants: Southern California Edison Company.
Description: § 205(d) Rate Filing: Letter Agreement Corona Porphyry Interconnection Project SA No. 1132 to be effective 12/22/2020.
Filed Date: 12/21/20.
Accession Number: 20201221–5064.
Comments Due: 5 p.m. ET 1/11/21.

Docket Numbers: ER21–693–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2020–12–21_LMR Performance Evaluation Filing to be effective 7/1/2021.
Filed Date: 12/21/20.
Accession Number: 20201221–5112.
Comments Due: 5 p.m. ET 1/11/21.

Docket Numbers: ER21–694–000.
Applicants: PacifiCorp.
Description: § 205(d) Rate Filing: BPA Construction Agmt—Conversion Ross-Lex-Swift Rev 3 to be effective 2/20/2021.
Filed Date: 12/21/20.
Accession Number: 20201221–5115.
Comments Due: 5 p.m. ET 1/11/21.

Docket Numbers: ER21–695–000.
Applicants: Avista Corporation.
Description: § 205(d) Rate Filing: Avista Corp. BPA Walla Walla Wanapum Construction Agreement SA T1168 to be effective 12/22/2020.
Filed Date: 12/21/20.
Accession Number: 20201221–5155.
Comments Due: 5 p.m. ET 1/11/21.

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

Docket Numbers: ES21–10–000.
Applicants: California Independent System Operator Corporation.
Description: Supplement to November 5, 2020 Application and Request for Shortened Comment Period of California Independent System Operator Corporation.
Filed Date: 12/17/20.
Accession Number: 20201217–5216.
Comments Due: 5 p.m. ET 12/28/20.

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: December 21, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–28718 Filed 12–28–20; 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:

Docket Numbers: RP21–323–000.
Applicants: Southern Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: AGL Negotiated Rate to be effective 1/1/2021.
Filed Date: 12/18/20.
Accession Number: 20201218–5013.
Comments Due: 5 p.m. ET 12/30/20.

Docket Numbers: RP21–324–000.
Applicants: Midship Pipeline Company, LLC.
Description: § 4(d) Rate Filing: Non-Conforming/Negotiated Rate Gulfport 2nd Amendment to be effective 12/31/9998.
Filed Date: 12/18/20.
Accession Number: 20201218–5226.
Comments Due: 5 p.m. ET 12/30/20.

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: December 21, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–28713 Filed 12–28–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CD21–3–000]

Skagit Public Utility District; Notice of Preliminary Determination of a Qualifying Conduit Hydropower Facility and Soliciting Comments and Motions To Intervene

On December 16, 2020, Skagit Public Utility District filed a notice of intent to construct a qualifying conduit hydropower facility, pursuant to section 30 of the Federal Power Act (FPA). The proposed Division Booster Pump Station Project would have an installed capacity of 25 kilowatts (kW), and would be located in parallel to an existing pressure reducing valve within the applicant's municipal water supply system in Mount Vernon, Skagit County, Washington.

Applicant Contact: Susan Priddy, InPipe Energy, 222 NW 8th Ave., Portland, OR 97209, Phone No. (503) 380–8487, Email: *susan@inpipeenergy.com.*

FERC Contact: Christopher Chaney, Phone No. (202) 502–6778, Email: *christopher.chaney@ferc.gov.*

Qualifying Conduit Hydropower Facility Description: The proposed project would consist of: (1) One 25-kW centrifugal hydroelectric turbine; and (2) appurtenant facilities. The proposed project would have an estimated annual generation of approximately 94 megawatt-hours.

A qualifying conduit hydropower facility is one that is determined or deemed to meet all the criteria shown in the table below.

TABLE 1—CRITERIA FOR QUALIFYING CONDUIT HYDROPOWER FACILITY

Statutory provision	Description	Satisfies (Y/N)
FPA 30(a)(3)(A)	The conduit the facility uses is a tunnel, canal, pipeline, aqueduct, flume, ditch, or similar man-made water conveyance that is operated for the distribution of water for agricultural, municipal, or industrial consumption and not primarily for the generation of electricity.	Y
FPA 30(a)(3)(C)(i)	The facility is constructed, operated, or maintained for the generation of electric power and uses for such generation only the hydroelectric potential of a non-federally owned conduit.	Y
FPA 30(a)(3)(C)(ii)	The facility has an installed capacity that does not exceed 40 megawatts	Y
FPA 30(a)(3)(C)(iii)	On or before August 9, 2013, the facility is not licensed, or exempted from the licensing requirements of Part I of the FPA.	Y

Preliminary Determination: The proposed Division Booster Pump Station Project will not alter the primary purpose of the conduit, which is used to distribute water for municipal consumption. Therefore, based upon the above criteria, Commission staff preliminarily determines that the proposal satisfies the requirements for a qualifying conduit hydropower facility, which is not required to be licensed or exempted from licensing.

Comments and Motions to Intervene: Deadline for filing comments contesting whether the facility meets the qualifying criteria is 30 days from the issuance date of this notice.

Deadline for filing motions to intervene is 30 days from the issuance date of this notice.

Anyone may submit comments or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210 and 385.214. Any motions to intervene must be received on or before the specified deadline date for the particular proceeding.

Filing and Service of Responsive Documents: All filings must (1) bear in all capital letters the ''COMMENTS CONTESTING QUALIFICATION FOR A CONDUIT HYDROPOWER FACILITY'' or ''MOTION TO INTERVENE,'' as applicable; (2) state in the heading the name of the applicant and the project number of the application to which the filing responds; (3) state the name, address, and telephone number of the person filing; and (4) otherwise comply with the requirements of sections 385.2001 through 385.2005 of the Commission's regulations.[1] All comments contesting Commission staff's preliminary determination that the facility meets the qualifying criteria must set forth their evidentiary basis.

The Commission strongly encourages electronic filing. Please file motions to intervene and 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 send 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. 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 18 CFR 385.2010.

Locations of Notice of Intent: 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 (*i.e.,* CD21–3) in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/*

[1] 18 CFR 385.2001–2005 (2020).

esubscription.asp to be notified via email of new filings and issuances related to this or other pending projects. Copies of the notice of intent can be obtained 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, call toll-free 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659.

Dated: December 21, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–28715 Filed 12–28–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER21–685–000]

Trieve, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Centerfield Cooper Solar, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is January 11, 2021.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, 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 Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. 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, (886) 208–3676 or TYY, (202) 502–8659.

Dated: December 21, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–28719 Filed 12–28–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP20–481–000]

Rio Bravo Pipeline Company, LLC; Notice of Availability of the Environmental Assessment for the Proposed Rio Bravo Pipeline Project Amendment

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared an environmental assessment (EA) for the Rio Bravo Pipeline Project Amendment (Project Amendment), proposed by Rio Bravo Pipeline Company, LLC (RB Pipeline) in the above-referenced docket. RB Pipeline filed an application in Docket No. CP20–481–000 requesting a Certificate of Public Convenience and Necessity pursuant to Section 7(c) of the Natural Gas Act to construct and operate certain natural gas pipeline facilities. The proposed Project Amendment would modify the pipeline system facilities approved in the Commission's *Order Granting Authorizations under Sections 3 and 7 of the Natural Gas Act* (Order) issued on November 22, 2019, that will transport natural gas to Rio Grande LNG, LLC's previously approved (but not yet constructed) liquefied natural gas (LNG) Terminal in Cameron County, Texas. RB Pipeline's entire pipeline system as authorized, and as modified by the Project Amendment, is located entirely in Texas.

The EA assesses the potential environmental effects of the construction and operation of the Project Amendment in accordance with the requirements of the National Environmental Policy Act (NEPA). The FERC staff concludes that approval of the proposed project, with appropriate mitigating measures, would not constitute a major federal action significantly affecting the quality of the human environment.

The U.S. Army Corps of Engineers and the U.S. Department of Transportation's Pipeline and Hazardous Materials Safety Administration participated as cooperating agencies in the preparation of the EA. Cooperating agencies have jurisdiction by law or special expertise with respect to resources potentially affected by the proposal and participate in the NEPA analysis.

The Rio Bravo Pipeline Project, as authorized in the November 2019 Order, consists of a 2.4-mile-long, 42-inch-diameter pipeline, including 0.8 mile of dual pipeline (referred to as the Header System) in Kleberg and Jim Wells Counties; 135.5 miles of parallel 42-inch-diameter pipelines originating in Kleberg County and terminating at Rio Grande LNG, LLC's Rio Grande LNG Terminal in Cameron County (referred to as Pipelines 1 and 2); four metering sites along the Header System; two interconnect booster compressor stations, each with a metering site; three compressor stations (one at the Rio Grande LNG Terminal); and other associated utilities, systems, and facilities, all in Texas. As part of the Project Amendment, RB Pipeline proposes various facility modifications to the authorized pipeline system:

- Decrease the maximum allowable operating pressure (MAOP) of the 2.4-mile-long Header System pipeline from 1,480 pounds per square inch gauge (psig) to 1,200 psig;
- construct an extension of 0.2 mile of mainline pipeline for each of

Pipelines 1 and 2 for a total of 135.7 miles each;

• increase the diameter of Pipeline 1 from 42 inches to 48 inches and increase the MAOP of both pipelines from 1,480 psig to 1,825 psig (Pipeline 2 will remain a 42-inch-diameter pipeline); and

• increase the transportation capacity of Pipeline 1 from 2.25 billion cubic feet per day (Bcf/d) to 2.6 Bcf/d, and decrease the transportation capacity of Pipeline 2 from 2.25 Bcf/d to 1.9 Bcf/d, resulting in the total authorized capacity of 4.5 Bcf/d remaining unchanged.

The Project Amendment also includes modifications to the following aboveground facilities that are authorized (but as yet unbuilt) along the Rio Bravo Pipeline right-of-way:

• Eliminate Compressor Station 2 in Kenedy County;

• eliminate Compressor Station 3 within the Rio Grande LNG Terminal in Cameron County, except for a meter and other ancillary facilities within the LNG Terminal;

• eliminate all facilities associated with Booster Stations 1 and 2, including related meter stations, in Kenedy County; and

• increase the horsepower (hp) at Compressor Station 1 from 180,000 hp to 282,000 hp by switching from six 30,000-hp natural gas compressor units to four 43,000-hp natural gas compressor units and two 55,000-hp compressor units.

The Commission mailed a copy of the *Notice of Availability* to federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American tribes; potentially affected landowners and other interested individuals and groups; and newspapers and libraries in the project area. The EA is only available in electronic format. It may be viewed and downloaded from the FERC's website (*www.ferc.gov*), on the natural gas environmental documents page (*https://www.ferc.gov/industries-data/natural-gas/environment/environmental-documents*). In addition, the EA may be accessed by using the eLibrary link on the FERC's website. Click on the eLibrary link (*https://elibrary.ferc.gov/eLibrary/search*), select ''General Search'' and enter the docket number in the ''Docket Number'' field, excluding the last three digits (*i.e.,* CP20–481). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

The EA is not a decision document. It presents Commission staff's independent analysis of the environmental issues for the Commission to consider when addressing the merits of all issues in this proceeding. Any person wishing to comment on the EA may do so. Your comments should focus on the EA's disclosure and discussion of potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that the Commission has the opportunity to consider your comments prior to making its decision on the Project Amendment, it is important that we receive your comments in Washington, DC on or before 5:00 p.m. Eastern Time on January 20, 2021.

For your convenience, there are three methods you can use to file your comments to the Commission. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208–3676 or *FercOnlineSupport@ferc.gov.* Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the eComment feature on the Commission's website (*www.ferc.gov*) under the link to FERC Online. This is an easy method for submitting brief, text-only comments on a project;

(2) You can also file your comments electronically using the eFiling feature on the Commission's website (*www.ferc.gov*) under the link to FERC Online. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You must select the type of filing you are making. If you are filing a comment on a particular project, please select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments by mailing them to the Commission. Be sure to reference the project docket number (CP20–481–000) on your letter. 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.

Filing environmental comments will not give you intervenor status, but you do not need intervenor status to have your comments considered. Only intervenors have the right to seek rehearing or judicial review of the Commission's decision. At this point in this proceeding, the timeframe for filing timely intervention requests has expired. Any person seeking to become a party to the proceeding must file a motion to intervene out-of-time pursuant to Rule 214(b)(3) and (d) of the Commission's Rules of Practice and Procedures (18 CFR 385.214(b)(3) and (d)) and show good cause why the time limitation should be waived. Motions to intervene are more fully described at *https://www.ferc.gov/ferc-online/ferc-online/how-guides.*

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website (*www.ferc.gov*) using the eLibrary link. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *https://www.ferc.gov/ferc-online/overview* to register for eSubscription.

Dated: December 21, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–28712 Filed 12–28–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. IC20–23–000 and RD20–9–000]

Commission Information Collection Activities (FERC–725R); Comment Request; Revision

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of revised information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the renewal with revisions of currently approved FERC–

725R (Mandatory Reliability Standards: BAL Reliability Standards). The Commission is submitting FERC–725R with revisions to the Office of Management and Budget (OMB) for review. Any interested person may file comments directly with OMB and should address a copy of those comments to the Commission as explained below.

DATES: Comments on the collection of information are due January 28, 2021.

ADDRESSES: Send written comments on FERC–725R, as revised, to OMB through *www.reginfo.gov/public/do/PRAMain,* Attention: Federal Energy Regulatory Commission Desk Officer. Please identify the OMB control number (1902–0268) in the subject line. Your comments should be sent within 30 days of publication of this notice in the **Federal Register**.

Please submit copies of your comments to the Commission (identified by Docket Nos. IC20–23–000 and RD20–9–000) by one of the following methods:

- *eFiling at Commission's Website: http://www.ferc.gov/docs-filing/efiling.asp.*
- *U.S. Postal Service Mail:* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.
- Effective July 1, 2020, delivery of filings other than by eFiling or the U.S. Postal Service should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Instructions

OMB submissions must be formatted and filed in accordance with submission guidelines at *www.reginfo.gov/public/do/PRAMain;* Using the search function under the ''Currently Under Review field,'' select Federal Energy Regulatory Commission; click ''submit'' and select ''comment'' to the right of the subject collection.

FERC submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov.* For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov* and telephone at (202) 502–8663.

SUPPLEMENTARY INFORMATION:

Title: FERC–725R, Mandatory Reliability Standards: BAL Reliability Standards.

OMB Control No.: 1902–0268.

Type of Request: Three-year request for renewal with revisions of the FERC–725R information collection (IC) requirements.

Abstract: On August 8, 2005, Congress enacted into law the Electricity Modernization Act of 2005, which is Title XII, Subtitle A, of the Energy Policy Act of 2005 (EPAct 2005).[1] EPAct 2005 added a new section 215 to the Federal Power Act (FPA), which requires a Commission-certified Electric Reliability Organization (ERO) to develop mandatory and enforceable Reliability Standards, which are subject to Commission review and approval. Once approved, the Reliability Standard may be enforced by the ERO subject to Commission oversight, or the Commission may independently enforce Reliability Standards.[2]

On February 3, 2006, the Commission issued Order No. 672, implementing section 215 of the FPA.[3] Pursuant to Order No. 672, the Commission certified one organization, the North American Electric Reliability Corporation (NERC), as the ERO.[4] The Reliability Standards developed by the ERO and approved by the Commission apply to users, owners and operators of the Bulk-Power System as set forth in each Reliability Standard.

Information Collection Components Not Affected by Docket No. RD20–9–000

On August 28, the Commission published a notice that it is seeking renewal of FERC–725R (85 FR 53358). The Commission invited public comments, but received none. At present, FERC–725R includes the following nation-wide Reliability Standards that would not be affected by Docket No. RD20–9–000:[5]

- BAL–001–2,[6] Real Power Balancing Control Performance. Reliability Standard BAL–001–2 is designed to ensure that applicable entities balance generation and load by maintaining system frequency within narrow bounds around a scheduled value, and it improves reliability by adding a frequency component to the measurement of a Balancing Authority's Area Control Error (ACE).[7]
- BAL–002–3,[8] Disturbance Control Standard—Contingency Reserve for Recovery from a Balancing Contingency Event. This standard ensures that a responsible entity, either a balancing authority or reserve sharing group, is able to recover from system contingencies by deploying adequate reserves to return their Area Control Error to defined values and replacing the capacity and energy lost due to generation or transmission equipment outages.
- BAL–005–1,[9] Balancing Authority Control. This standard establishes requirements for acquiring data necessary to calculate Reporting Area Control Error (Reporting ACE). The standard also specifies a minimum periodicity, accuracy, and availability requirement for acquisition of the data and for providing the information to the System Operator. It requires balancing authorities to maintain minimum levels of annual availability of 99.5% for each balancing authority system for calculating Reporting ACE.

Information Collection Components Affected by Docket No. RD20–9–000

On December 19, 2019, NERC submitted a petition seeking Commission approval for proposed Reliability Standard BAL–003–2. On May 20, 2020, the Commission noticed the petition in Docket No. RD20–9–000. Interventions, comments, and protests were due on or before June 29, 2020. None were received. The Commission approved Reliability Standard BAL–003–2 on July 15, 2020 in a Delegated Letter Order (DLO).[10]

On August 26, 2020, the Commission published a notice of revision of FERC–725R in Docket No. RD20–9–000 (85 FR

[1] Energy Policy Act of 2005, Public Law 109–58, Title XII, Subtitle A, 119 Stat. 594, 941 (codified at 16 U.S.C. 824*o*).

[2] 16 U.S.C. 824*o*(e)(3).

[3] *Rules Concerning Certification of the Electric Reliability Organization; and Procedures for the Establishment, Approval, and Enforcement of Electric Reliability Standards,* Order No. 672, FERC Stats. & Regs. ¶ 31,204, *order on reh'g,* Order No. 672–A, FERC Stats. & Regs. ¶ 31,212 (2006).

[4] *North American Electric Reliability Corp.,* 116 FERC ¶ 61,062, *order on reh'g and compliance,* 117 FERC ¶ 61,126 (2006), *order on compliance,* 118 FERC ¶ 61,190, *order on reh'g,* 119 FERC ¶ 61,046 (2007), *aff'd sub nom. Alcoa Inc.* v. *FERC,* 564 F.3d 1342 (D.C. Cir. 2009).

[5] There are also regional BAL Reliability Standards. They are not included in FERC–725R and are not discussed here. The regional BAL Reliability Standards are covered under other OMB Control Nos.

[6] It was approved in Docket No. RM14–10.

[7] Area Control Error is the ''instantaneous difference between a Balancing Authority's net actual and scheduled interchange, taking into accounts the effects of Frequency Bias, correction for meter error, and Automatic Time Error Correction (ATEC), if operating in the ATEC mode. ATEC is only applicable to Balancing Authorities in the Western Interconnection.'' NERC Glossary.

[8] It was approved in Docket No. RD18–7.

[9] It was approved in Docket No. RM16–13.

[10] The DLO is posted in eLibrary at *http://elibrary.ferc.gov/idmws/common/OpenNat.asp?fileID=15585069.*

52584). The Commission received no comments in response to the notice of revision. The Commission now seeks renewal of FERC–725R with the revisions that the Commission has approved in Docket No. RD20–9–000.

Type of Respondent: Balancing Authorities, Response Sharing Group, and Frequency Response Sharing Group.

Estimate of Annual Burden: [11] Our estimate of the number of respondents affected is based on the NERC Compliance Registry as of July 17, 2020.[12] According to the Compliance Registry, NERC has registered 97 Balancing Authorities (BA), 11 Response Sharing Groups (RSG), and 1 Frequency Response Sharing Group (FRSG) within the United States, as noted. The burden estimates reflect the number of affected entities for each standard. Estimates for the average annual burden and cost [13] follow.

FERC–725R, AS REVISED BY RD20–9

Function	Number & type of respondents (1)	Number of annual responses per respondent (2)	Total number of annual responses (1) × (2) = (3)	Average burden hours & cost ($) per response (4)	Total annual burden hours & total annual cost ($) (3) × (4) = (5)
BAL–001–2					
BA Reporting Requirements	97	1	97	8 hrs.; $561.52	776 hrs.; $54,467.44.
BA Recordkeeping Requirements	97	1	97	4 hrs.; $164.12	388 hrs.; $15,919.64.
BAL–002–3					
BA & RSG Reporting Requirements	108	1	108	8 hrs.; $561.52	864 hrs.; $60,644.16.
BA & RSG Recordkeeping Requirements.	108	1	108	4 hrs.; $164.12	432 hrs.; $17,724.96.
BAL–003–2 (as approved in Docket No. RD20–9–000)					
BA & FRSG Reporting Requirements	98	28	2,744	8 hrs.; $561.52	21,952 hrs.; $1,540,810.88.
BA & FRSG Recordkeeping Requirements.	98	1	98	2 hrs.; $82.06	196 hrs.; $8,041.88.
BAL–005–1					
BA Reporting Requirements	97	1	97	1 hr.; $70.19	97 hrs.; $6,808.43.
BA Recordkeeping Requirements	97	1	97	1 hr.; $41.03	97 hrs.; $3,979.91.
Sub-Total for Reporting Requirements.					23,689 hrs.; $1,662,730.91.
Sub-Total for Recordkeeping Requirements.					1,113 hrs.; $45,666.39.
Total for Ferc–725R (rounded)					24,802 hrs.; $1,708,397.30.

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collr.ection techniques or other forms of information technology.

Dated: December 21, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–28716 Filed 12–28–20; 8:45 am]

BILLING CODE 6717–01–P

[11] ''Burden'' is the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to 5 CFR 1320.3.

[12] NERC Compliance Registry (July 17, 2020), *available at https://www.nerc.com/pa/comp/Registration%20and%20Certification%20DL/NERC_Compliance_Registry_Matrix_Excel.xlsx.*

[13] The hourly cost estimates are based on wage data from the Bureau of Labor Statistics for May 2019 (at *https://www.bls.gov/oes/current/naics2_22.htm*) and benefits data for Dec. 2019 (issued March 2020, at *https://www.bls.gov/news.release/ecec.nr0.htm*). For reporting requirements, the estimated hourly cost is $70.19, based on the wages and benefits for Occupation Code 17–2071 (Electrical Engineer). For recordkeeping requirements, the estimated hourly cost is $41.03, based on the wages and benefits for Occupation Code 43–4199 (Information and Record Clerk).

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OLEM–2020–0571; FRL–10017–09–OLEM]

Hazardous Waste Electronic Manifest System (''e-Manifest'') Advisory Board; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) will convene the Hazardous Waste Electronic System (''e-

Manifest'') Advisory Board for a three (3) day virtual public meeting. The purpose of the meeting is for EPA to seek the Board's consultation and recommendations regarding the e-Manifest system (Meeting Theme: ''*Looking Ahead: Setting e-Manifest Program Priorities and User Fees for FY2022 and FY2023*'').

DATES: The meeting will be held on March 2–4, 2021, from approximately 10:00 a.m. to 6:00 p.m. EST.

ADDRESSES: This public meeting will be conducted virtually. Registration is required to attend and/or provide oral public comment during this meeting. Please refer to the e-Manifest Advisory Board website at *https://www.epa.gov/e-manifest/hazardous-waste-electronic-manifest-system-e-manifest-advisory-board* for information on how to register either as a public audience attendee or as an oral public commenter.

Comments. To make oral comments during the public meeting and be included on the meeting agenda, please register by noon on February 23, 2021. Registration instructions will be posted on the e-Manifest Advisory Board website at *https://www.epa.gov/e-manifest/hazardous-waste-electronic-manifest-system-e-manifest-advisory-board.* Any written comments submitted for the e-Manifest Advisory Board meeting on or before February 23, 2021, should be submitted in the public docket under Docket number EPA–HQ–OLEM–2020–0571 at *http://www.regulations.gov.* Written comments submitted to the public docket on or before February 23, 2021, will be provided to the e-Manifest Advisory Board for their consideration before the meeting. Anyone who wishes to submit comments after February 23, 2021, must send their written public comments or their oral comment requests directly to the Designated Federal Officer (DFO) listed under **FOR FURTHER INFORMATION CONTACT**. For additional instructions, see section I.B. under **SUPPLEMENTARY INFORMATION**.

Special accommodations. For information on access or services for individuals with disabilities, and to request accommodation of a disability, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** at least ten (10) days prior to the meeting to give the EPA as much time as possible to process your request.

FOR FURTHER INFORMATION CONTACT: Fred Jenkins, Designated Federal Officer (DFO), U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, email: *jenkins.fred@epa.gov;* phone: 703–308–7049.

SUPPLEMENTARY INFORMATION: This meeting will be open to the public. The full agenda and meeting materials will be available in the docket for the meeting and at the e-Manifest Advisory Board website at *https://www.epa.gov/e-manifest/hazardous-waste-electronic-manifest-system-e-manifest-advisory-board.* This public meeting will be conducted virtually, and registration is required to attend and/or participate. Registration instructions will be posted on the e-Manifest Advisory Board website at *https://www.epa.gov/e-manifest/hazardous-waste-electronic-manifest-system-e-manifest-advisory-board.* In the event EPA needs to make subsequent changes to this meeting, EPA will post future notices to its e-Manifest Board meeting website (*https://www.epa.gov/e-manifest/hazardous-waste-electronic-manifest-system-e-manifest-advisory-board.*). EPA strongly encourages the public to refer to the e-Manifest website for the latest meeting information, as sudden changes may be necessary.

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may be of particular interest to persons who are or may be subject to the Hazardous Waste Electronic Manifest Establishment (e-Manifest) Act.

B. How may I participate in this meeting?

You may participate in this meeting by providing public comments via the instructions in this document. To ensure proper receipt of your public comments by the EPA, it is imperative that you submit your comments, identified by docket ID number EPA–HQ–OLEM–2020–0571, at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically 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. The EPA will generally not consider comments or comment contents located outside of the primary submission (*e.g.,* 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.*

1. *Written comments.* EPA encourages the electronic submission of written comments via *http://www.regulations.gov,* into docket ID number EPA–HQ–OLEM–2020–0571 on or before February 23, 2021, to provide the e-Manifest Advisory Board the time necessary to consider and review the written comments. Written comments are accepted until the date of the meeting, but anyone submitting written comments after February 23, 2021, should contact the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

2. *Oral comments.* EPA encourages each individual or group wishing to make brief oral comments to the e-Manifest Advisory Board to please register as an oral commenter for the meeting at the e-Manifest Advisory Board website, *https://www.epa.gov/e-manifest/hazardous-waste-electronic-manifest-system-e-manifest-advisory-board,* by noon on February 23, 2021, in order to be included on the meeting agenda. Requests to present oral comments will be accepted until the date of the meeting. Registration is required to attend and/or participate as an oral public commenter in this public meeting. Please refer to the e-Manifest Advisory Board website at *https://www.epa.gov/e-manifest/hazardous-waste-electronic-manifest-system-e-manifest-advisory-board* for information on how to register either as an oral public commenter or public audience attendee. Anyone submitting an oral public comments request after February 23, 2021, should also contact the DFO listed under **FOR FURTHER INFORMATION CONTACT**. To the extent that time permits, the Chair of the e-Manifest Advisory Board may permit the presentation of oral comments at the meeting by interested persons who have not previously requested time. The request should identify the name of the individual making the presentation, the organization (if any) that the individual represents, and any requirements for audiovisual presentation support. Oral comments before the e-Manifest Advisory Board are limited to approximately five (5) minutes unless prior arrangements have been made. In addition, each speaker should provide a copy of his or her comments and presentation to the DFO so that they can be distributed to the e-Manifest Advisory Board at the meeting.

C. Purpose of the e-Manifest Advisory Board

The Hazardous Waste Electronic Manifest System Advisory Board is established in accordance with the provisions of the Hazardous Waste Electronic Manifest Establishment Act, 42 U.S.C. 6939g, and the Federal Advisory Committee Act (FACA), 5 U.S.C. App.2. The e-Manifest Advisory Board is in the public interest and supports the EPA in performing its duties and responsibilities. The Board shall meet annually to discuss, evaluate the effectiveness of, and provide recommendations about the system to the EPA Administrator.

The sole duty of the Advisory Board is to provide advice and recommendations to the EPA Administrator. As required by the e-Manifest Act, the e-Manifest Advisory Board is composed of nine (9) members. One (1) member is the EPA Administrator (or a designee), who serves as Chairperson of the Advisory Board. The rest of the committee is composed of:

- At least two (2) members who have expertise in information technology;
- At least three (3) members who have experience in using or represent users of the manifest system to track the transportation of hazardous waste under the e-Manifest Act;
- At least three (3) members who are state representatives responsible for processing manifests.

All members of the e-Manifest Advisory Board, except for the EPA Administrator, are appointed as Special Government Employees or Representatives.

D. Public Meeting

EPA launched the e-Manifest system on June 30, 2018. e-Manifest provides those persons required to use a Resource Conservation and Recovery Act (RCRA) manifest under either federal or state law the option of using electronic manifests to track shipments of hazardous waste and to meet certain RCRA requirements. By enabling the transition from a paper-intensive process to an electronic system, EPA estimates e-Manifest will ultimately save state and industry users more than $50 million annually, once electronic manifests are widely adopted.

Under the Hazardous Waste Electronic Manifest Establishment Act (e-Manifest Act) of 2012, EPA must collect user fees to offset the costs of developing and operating the e-Manifest system. In January 2018, EPA published regulations establishing the methodology which the Agency will use to set and collect user fees for the e-Manifest system. Under the final rule, EPA charges a fee to receiving facilities for each manifest submitted to EPA's e-Manifest system. User fees are tailored to the method used to submit manifests to EPA, *e.g.,* different fees apply for electronic manifests than for paper manifests uploaded to the system. In addition, EPA is required to publish revised user fee schedules at two-year intervals.

The purpose of this March 2–4, 2021, e-Manifest Advisory Board meeting is for the Board to advise EPA on its proposed program priorities and user fees for the FY2022/FY2023 cycle.

E. e-Manifest Advisory Board Documents and Meeting Minutes

The meeting background paper along with related supporting materials including the charge/questions to the Advisory Board, the Advisory Board membership roster (*i.e.,* members attending this meeting), and the meeting agenda will be available by approximately mid-January 2021. In addition, EPA may provide additional background documents as the materials become available. You may obtain electronic copies of these documents, and certain other related documents that might be available at *http://www.regulations.gov* via the docket ID number EPA–HQ–OLEM–2020–0571 and at the e-Manifest Advisory Board website at: *https://www.epa.gov/e-manifest/hazardous-waste-electronic-manifest-system-e-manifest-advisory-board.*

The e-Manifest Advisory Board will prepare meeting minutes summarizing its recommendations to EPA approximately ninety (90) days after the meeting. The meeting minutes will be posted on the e-Manifest Advisory Board website, or they may be obtained from the public docket at *http://www.regulations.gov* via the docket ID number EPA–HQ–OLEM-2020–0571.

Carolyn Hoskinson,

Director, Office of Resource Conservation and Recovery, Office of Land and Emergency Management.

[FR Doc. 2020–28731 Filed 12–28–20; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0120, OMB 3060–XXXX; FRS 17334]

Information Collections Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, 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. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) 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 OMB control number.

DATES: Written comments and recommendations for the proposed information collection should be submitted on or before January 28, 2021.

ADDRESSES: Comments should be sent to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Your comment must be submitted into *www.reginfo.gov* per the above instructions for it to be considered. In addition to submitting in *www.reginfo.gov* also send a copy of your comment on the proposed information collection to Nicole Ongele, FCC, via email to *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Nicole Ongele at (202) 418–2991. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page *http://www.reginfo.gov/*

public/do/PRAMain, (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) 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; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) 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. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

OMB Control Number: 3060–0120.

Title: Broadcast EEO Program Model, FCC Form 396–A.

Form Number: FCC–396–A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, Not-for-profit institutions.

Number of Respondents and Responses: 5,000 respondents, 5,000 responses.

Estimated Time per Response: 1 hour.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain benefits. The statutory authority for this collection of information is contained in Section 154(i) and 303 of the Communications Act of 1934, as amended.

Total Annual Burden: 5,000 hours.

Total Annual Cost: No Cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: The Broadcast Equal Employment Opportunity (EEO) Model Report, FCC Form 396–A, is filed in conjunction with applicants seeking authority to construct a new broadcast station, to obtain assignment of construction permit or license and/or seeking authority to acquire control of an entity holding construction permit or license. This program is designed to assist the applicant in establishing an effective EEO program for its stations.

OMB Control Number: 3060–XXXX.

Title: Improving Outage Reporting for Submarine Cables and Enhanced Submarine Outage Data.

Form Number: Not applicable.

Type of Review: New information collection.

Respondents: Business or other for-profit.

Number of Respondents and Responses: 75 respondents; 336 responses.

Estimated Time per Response: 6 hours.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Mandatory. Statutory authority for this information collection is contained in 47 U.S.C. 151, 154(i)–(j) & (o), 405, and the Cable Landing License Act of 1921, 47 U.S.C. 34–39, and 3 U.S.C. 301, and Exec. Order No. 10530.

Total Annual Burden: 2,016 hours.

Total Annual Cost: No Cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: Outage reports filed with the Commission pursuant to Part 4 are presumed confidential. The information in those filings may be shared with the Department of Homeland Security only under appropriate confidential disclosure protections. Other persons seeking disclosure must follow the procedures delineated in 47 CFR 0.457 and 0.459 for requests for and disclosure of information. The information collection discussed here does not affect the confidential treatment of information submitted to the Commission's Network Outage Reporting System (NORS), an internet portal that collects submitted outage filings.

Needs and Uses: Section 151 of the Communications Act of 1934 (Act), as amended, requires the Commission to promote the safety of life and property through the use of wire and radio communications. Additionally, the Cable Landing License Act, (47 U.S.C. 34–39), and Executive Order 10530, provide the Commission with authority to grant, withhold, condition and revoke submarine cable landing licenses. Further, the Cable Landing License Act and Executive Order 10530 provide that the Commission may place conditions on the grant of a submarine cable landing license in order to assure just and reasonable rates and service in the operation and use of cables so licensed. ''Just and reasonable service'' entails assurance that the cable infrastructure will be reasonably available. Availability of submarine cables is also critically important for national security and the economy because submarine cables carry approximately 95 percent of international communications traffic and are the primary means of connectivity for numerous U.S. states and territories. Currently, submarine cable licensees provide information to the Commission on a voluntary, ad hoc basis through the Undersea Cable Information System (UCIS).

This is a new collection that will be part of the Commission's NORS outage reporting regime. As with the other information collection collected in NORS (under OMB Control No. 3060–0484), this new collection will facilitate FCC monitoring, analysis, and investigation of the reliability and security of submarine cable networks, and to identify and action on potential threats to our Nation's telecommunications infrastructure. Drawing from a decade of experience in outage reporting, the Commission will seek an ongoing dialogue with submarine cable licensees, as well as with the industry at large, regarding lessons learned from the new information collection. These efforts will help the Commission develop a better understanding of the root causes of significant outages, and to explore preventive measures to mitigate the impact of such outages on the Nation and the American public.

The addition of mandatory submarine cable outage data will provide the Commission with greater visibility into the availability and health of these networks, allowing the Commission to better track and analyze submarine cable resiliency. This enhanced visibility into submarine cable network outages will allow the Commission to take appropriate actions to mitigate disruptions, if necessary, and to avoid the development of larger, more significant problems which could impact national security and public safety interests. Submarine cable

outages do not typically occur with the same frequency as terrestrial outages, but when they do occur have a greater impact on the Nation's telecommunications due to the volume and nature of communications carried over such cables. Damages to submarine cables are usually caused by weather or inadvertent slicing by underseas equipment. However, submarine cables are also susceptible to intentional damage for nefarious purposes that could lead to a severe degradation of crucial government, as well as non-government, communications.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2020–28617 Filed 12–28–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[WC Docket No. 19–195, 11–10; DA 20–1460; FRS 17313]

Office of Economics and Analytics Reminds Providers That Form 477 Mobile Speed and Coverage Data Are Not Confidential

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this Public Notice, the Office of Economics and Analytics (Office) reminds mobile broadband service providers that their minimum advertised or expected speed data are not confidential on FCC Form 477, notwithstanding checkbox options in the Form 477 filing application.

DATES: The Commission issued this Public Notice on December 7, 2020.

ADDRESSES: Federal Communications Commission, 45 L Street NE, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Kenneth Lynch, Chief, Industry Analysis Division, Office of Economics and Analytics, (202) 418–7356, *Kenneth.Lynch@fcc.gov.*

SUPPLEMENTARY INFORMATION: The Office of Economics and Analytics (Office) reminds mobile broadband service providers that their minimum advertised or expected speed data are no longer treated as confidential on FCC Form 477. Speed data will be included in the public releases of provider-specific coverage data, beginning with the December 2019 filing.

In the Digital Opportunity Data Collection First Report and Order, the Commission concluded that minimum advertised or expected speed data filed for mobile broadband services will not be treated as confidential and that such data will be publicly released. The Commission found that the bulk of speed data that providers filed had been treated as confidential and that such treatment ''unnecessarily limits the ability of consumers and policy makers to effectively analyze the data submitted.'' The Commission also concluded that public release of provider-specific coverage data is ''necessary to ensure that consumers can easily use the information that is disclosed to the public'' because speed data are ''only beneficial if consumers know where the service coverage is available.''

The Commission already makes provider-specific coverage data publicly available on its website by publishing each provider's shapefiles, and Form 477 filers are no longer permitted to request confidential treatment for such information. As the Commission did not subsequently and immediately update the Form 477 filing application to remove the checkbox used to request confidential treatment of these data, some providers may mistakenly believe that confidentiality is available for such data.

Accordingly, the Office reiterates that, notwithstanding the presence of the checkbox in the Form 477 filing application, the Commission has concluded that these data will not be treated as confidential. Moreover, the corresponding Form 477 information that was included in the December 2019 and June 2020 filings will be released no sooner than ten (10) days after **Federal Register** publication of this Public Notice.

For further information, contact Kenneth Lynch, Chief, Industry Analysis Division, Office of Economics and Analytics, at *Kenneth.Lynch@fcc.gov.*

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2020–28781 Filed 12–28–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0174; FRS 17335]

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 of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. 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 Office of Management and Budget (OMB) 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 OMB control number.

DATES: Written PRA comments should be submitted on or before March 1, 2021. 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 Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0174.

Title: Sections 73.1212, 76.1615 and 76.1715, Sponsorship Identification.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for profit entities; Individuals or households.

Number of Respondents and Responses: 22,900 respondents and 1,877,000 responses.

Estimated Time per Response: .0011 to .2011 hours.

Frequency of Response: Recordkeeping requirement; Third party

disclosure requirement; On occasion reporting requirement.

Total Annual Burden: 249,043 hours.

Total Annual Cost: $34,623.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in sections 4(i), 317 and 507 of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: The FCC is preparing a system of records, FCC/MB–2, ''Broadcast Station Public Inspection Files,'' to cover the personally identifiable information (PII) that may be included in the broadcast station public inspection files. 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.

Privacy Impact Assessment(s): The FCC is preparing a PIA.

Needs and Uses: The information collection requirements that are approved under this collection are as follows:

47 CFR 73.1212 requires a broadcast station to identify at the time of broadcast the sponsor of any matter for which consideration is provided. For advertising commercial products or services, generally the mention of the name of the product or service constitutes sponsorship identification. In the case of television political advertisements concerning candidates for public office, the sponsor shall be identified with letters equal to or greater than four (4) percent of the vertical height of the television screen that airs for no less than four (4) seconds. In addition, when an entity rather than an individual sponsors the broadcast of matter that is of a political or controversial nature, licensee is required to retain a list of the executive officers, or board of directors, or executive committee, etc., of the organization paying for such matter. Sponsorship announcements are waived with respect to the broadcast of ''want ads'' sponsored by an individual but the licensee shall maintain a list showing the name, address and telephone number of each such advertiser. These lists shall be made available for public inspection.

47 CFR 73.1212(e) states that, when an entity rather than an individual sponsors the broadcast of matter that is of a political or controversial nature, the licensee is required to retain a list of the executive officers, or board of directors, or executive committee, etc., of the organization paying for such matter in its public file. Pursuant to the changes contained in 47 CFR 73.1212(e) and 47 CFR 73.3526(e)(19), this list, which could contain personally identifiable information, would be located in a public inspection file to be located on the Commission's website instead of being maintained in the public file at the station. Burden estimates for this change are included in OMB Control Number 3060–0214.

47 CFR 76.1615 states that, when a cable operator engaged in origination cablecasting presents any matter for which money, service or other valuable consideration is provided to such cable television system operator, the cable television system operator, at the time of the telecast, shall identify the sponsor. Under this rule section, when advertising commercial products or services, an announcement stating the sponsor's corporate or trade name, or the name of the sponsor's product is sufficient when it is clear that the mention of the name of the product constitutes a sponsorship identification. In the case of television political advertisements concerning candidates for public office, the sponsor shall be identified with letters equal to or greater than four (4) percent of the vertical height of the television screen that airs for no less than four (4) seconds.

47 CFR 76.1715 state that, with respect to sponsorship announcements that are waived when the broadcast/origination cablecast of ''want ads'' sponsored by an individual, the licensee/operator shall maintain a list showing the name, address and telephone number of each such advertiser. These lists shall be made available for public inspection.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2020–28620 Filed 12–28–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0986; FRS 17340]

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 of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. 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 Office of Management and Budget (OMB) 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 OMB control number.

DATES: Written PRA comments should be submitted on or before March 1, 2021. 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: 3060–0986.

Title: High-Cost Universal Service Support.

Form Number: FCC Form 481 and FCC Form 525.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions and state, local or tribal government.

Number of Respondents and Responses: 2,049 respondents; 14,358 responses.

Estimated Time per Response: 0.1–15 hours.

Frequency of Response: On occasion, quarterly and annual reporting requirements, recordkeeping requirement and third-party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory

authority for this information collection is contained in 47 U.S.C. 151–154, 155, 201–206, 214, 218–220, 251, 252, 254, 256, 303(r), 332, 403, 405, 410, and 1302.

Total Annual Burden: 53,955 hours.

Total Annual Cost: No Cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: The Commission notes that the Universal Service Administrative Company (USAC) must preserve the confidentiality of all data obtained from respondents and contributors to the universal service support program mechanism; must not use the data except for purposes of administering the universal service program; must not use the data except for purposes of administering the universal support program; and must not disclose data in company-specific form unless directed to do so by the Commission. Parties may submit confidential information in relation pursuant to a protective order. Also, respondents may request materials or information submitted to the Commission or to the Administrator believed confidential to be withheld from public inspection under 47 CFR 0.459 of the FCC's rules.

Needs and Uses: The Commission is requesting the Office of Management and Budget (OMB) approval for this revised information collection. On November 18, 2011, the Commission adopted an order reforming its high-cost universal service support mechanisms. *Connect America Fund; A National Broadband Plan for Our Future; Establish Just and Reasonable Rates for Local Exchange Carriers; High-Cost Universal Service Support; Developing a Unified Intercarrier Compensation Regime; Federal-State Joint Board on Universal Service; Lifeline and Link-Up; Universal Service Reform—Mobility Fund,* WC Docket Nos. 10–90, 07–135, 05–337, 03–109; GN Docket No. 09–51; CC Docket Nos. 01–92, 96–45; WT Docket No. 10–208, Order and Further Notice of Proposed Rulemaking, 26 FCC Rcd 17663 (2011) (*USF/ICC Transformation Order*), and the Commission and Wireline Competition Bureau have since adopted a number of orders that implement the *USF/ICC Transformation Order; see also Connect America Fund et al.,* WC Docket No. 10–90 et al., Third Order on Reconsideration, 27 FCC Rcd 5622 (2012); *Connect America Fund et al.,* WC Docket No. 10–90 et al., Order, 27 FCC Rcd 605 (Wireline Comp. Bur. 2012); *Connect America Fund et al.,* WC Docket No. 10–90 et al., Fifth Order on Reconsideration, 27 FCC Rcd 14549 (2012); *Connect America Fund et al.,* WC Docket No. 10–90 et al., Order, 28 FCC Rcd 2051 (Wireline Comp. Bur. 2013); *Connect America Fund et al.,* WC Docket No. 10–90 et al., Order, 28 FCC Rcd 7227 (Wireline Comp. Bur. 2013); *Connect America Fund,* WC Docket No. 10–90, Report and Order, 28 FCC Rcd 7766 (Wireline Comp. Bur. 2013); *Connect America Fund,* WC Docket No. 10–90, Report and Order, 28 FCC Rcd 7211 (Wireline Comp. Bur. 2013); *Connect America Fund,* WC Docket No. 10–90, Report and Order, 28 FCC Rcd 10488 (Wireline Comp. Bur. 2013); *Connect America Fund et al.,* WC Docket No. 10–90 et al., Report and Order, Order and Order on Reconsideration and Further Notice of Proposed Rulemaking, 31 FCC Rcd 3087 (2016); *Connect America Fund et al.,* WC Docket Nos. 10–90, 16–271; WT Docket No. 10–208, Report and Order and Further Notice of Proposed Rulemaking, 31 FCC Rcd 10139 (2016); *Connect America Fund; ETC Annual Reports and Certifications,* WC Docket Nos. 10–90, 14–58, Order, 32 FCC Rcd 968 (2017); *Connect America Fund et al.,* WC Docket No. 10–90 et al., Report and Order, Further Notice of Proposed Rulemaking, and Order on Reconsideration, 33 FCC Rcd 11893 (2018); *Connect America Fund; ETC Annual Reports and Certifications,* WC Docket Nos. 10–90, 14–58, Report and Order, 32 FCC Rcd 5944 (2017). The Commission has received OMB approval for most of the information collections required by these orders.

Through several orders, the Commission has recently changed or modified reporting obligations for high-cost support.

In September 2019, the Commission adopted the *Puerto Rico/U.S. Virgin Islands Stage 2 Order,* which allocated nearly a billion additional dollars to United States territories that had suffered extensive infrastructure damage due to Hurricanes Irma and Maria. *The Uniendo a Puerto Rico Fund and the Connect USVI Fund, et al.,* WC Docket No. 18–143, et al., Report and Order and Order on Reconsideration, 34 FCC Rcd 9109 (2019) (*Puerto Rico and USVI Stage 2 Order).* The Commission adopted similar accountability measures for recipients of this support as required of other high-cost support recipients to ensure that providers receive support ''only for the provision, maintenance, and upgrading of facilities and services for which the support is intended.'' *Puerto Rico and USVI Stage 2 Order,* 34 FCC Rcd at 9149, para. 72.

In the *2019 Supply Chain Order,* the Commission adopted a rule prohibiting the use of USF support to purchase or obtain any equipment or services produced or provided by a covered company posing a national security threat to the integrity of communications networks or the communications supply chain. *Protecting Against National Security Threats to the Communications Supply Chain Through FCC Programs,* WC Docket No. 18–89, Report and Order, Further Notice of Proposed Rulemaking, and Order, 34 FCC Rcd 11423, 11433, para. 26. *See also* 47 CFR 54.9. In June 2020, the Public Safety and Homeland Security Bureau issued final designations of Huawei Technologies Company (Huawei) and ZTE Corp. (ZTE) as covered companies for the purposes of this rule. *Protecting Against National Security Threats to the Communications Supply Chain Through FCC Programs—Huawei Designation,* WC Docket No. 19–351, Order, 35 FCC Rcd 6604 (PSHSB June 30, 2020) (*Huawei Designation Order*); *Protecting Against National Security Threats to the Communications Supply Chain Through FCC Programs—ZTE Designation,* WC Docket No. 19–352, Order, 35 FCC Rcd 6633 (PSHSB June 30, 2020) (*ZTE Designation Order*). Accordingly, USF recipients may not use USF funds to purchase, obtain, maintain, improve, modify, manage, or otherwise support Huawei or ZTE equipment or services in any way, including upgrades to existing Huawei or ZTE equipment and services. *Huawei Designation Order,* 35 FCC Rcd at 6608, para. 10; *ZTE Designation Order,* 35 FCC Rcd at 6637, para. 10. Moreover, USF recipients must certify that they are in compliance with this rule. *2019 Supply Chain Order,* 34 FCC Rcd at 11454, para. 79; *see also* 47 CFR 54.9.

In the *CAF Phase II Auction Order,* in addition to rules requiring Connect America Phase II auction support recipients to report regarding support used for capital expenditures, certify regarding available funds, and certify that the Phase II-funded network meets performance requirements, the Commission also adopted rules requiring that Phase II auction support recipients must report information on served community anchor institutions and certify regarding bidding on FCC Form 470 postings for eligible schools and libraries in census blocks where the carrier receives auction support. *Connect America Fund, et al.,* WC Docket No. 10–90, et al., Report and Order and Further Notice of Proposed Rulemaking, 31 FCC Rcd 5949 (2016) (*CAF Phase II Auction Order*). Recipients of Uniendo a Puerto Rico Fund and Connect USVI Fund Stage 2 support must also observe these

requirements in addition to the general requirements for high-cost support recipients and requirements specific to the Uniendo a Puerto Rico Fund and Connect USVI Fund programs. *See Puerto Rico and USVI Stage 2 Order,* 34 FCC Rcd at 9150, para. 74.

We therefore propose to revise this information collection, as well as Form 481 and its accompanying instructions, to reflect these new and revised requirements. We also eliminate one requirement that is associated with obligations no longer in effect for certain carriers. Finally, we propose to increase the burdens associated with existing reporting requirements to account for additional carriers that will be subject to those requirements.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2020–28783 Filed 12–28–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0647; FRS 17345]

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 of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. 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 Office of Management and Budget (OMB) 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 OMB control number.

DATES: Written PRA comments should be submitted on or before March 1, 2021. 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: 3060–0647.

Title: Biennial Survey of Cable Industry Prices, FCC Form 333.

Form Number: FCC Form 333.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; State, local or Tribal Government.

Number of Respondents and Responses: 70 respondents and 524 responses.

Estimated Time per Response: 7 hours.

Frequency of Response: Biennial reporting requirement.

Total Annual Burden: 1,834 hours.

Total Annual Cost: None.

Obligation to Respond: Mandatory. The statutory authority for this information collection is in Sections 4(i) and 623(k) of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: If individual respondents to this survey wish to request confidential treatment of any data provided in connection with this survey, they can do so upon written request, in accordance with Sections 0.457 and 0.459 of the Commission's rules. To request confidential treatment of their data, respondents must describe the specific information they wish to protect and provide an explanation of why such confidential treatment is appropriate. If a respondent submits a request for confidentiality, the Commission will review it and make a determination.

Privacy Act Impact Assessment: No impact(s).

Needs and Uses: The Cable Television Consumer Protection and Competition Act of 1992 (''Cable Act'') requires the Commission to publish biennially a report on average rates for basic cable service, cable programming service, and equipment. The report must compare the prices charged by cable operators subject to effective competition and those that are not subject to effective competition. The Biennial Cable Industry Price Survey is intended to collect the data needed to prepare that report. The data from these questions are needed to complete this report.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2020–28782 Filed 12–28–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

[Docket No. 20–19]

Astra Supply Chain, LLC and TDS Management, LLC, Complainants v. Orient Star Transport Int'l LTD., *Respondent*; Notice of Filing of Complaint and Assignment

SERVED: December 14, 2020.

Notice is given that a complaint has been filed with the Federal Maritime Commission (Commission) by Astra Supply Chain, LLC., and TDS Management, LLC, hereinafter ''Complainants'', against Orient Star Transport Int'l. Ltd., hereinafter ''Respondent''.

Complainant alleges that Respondent violated sections 10(b)(11) and 10(b)(12) of the Shipping Act of 1984, 46 U.S.C. 41102(c), and 46 CFR 515.32(c) with regard to a failure to release containers. The full text of the complaint can be found in the Commission's Electronic Reading Room at *https://www2.fmc.gov/readingroom/proceeding/20-19/.*

This proceeding has been assigned to Office of Administrative Law Judges. The initial decision of the presiding office in this proceeding shall be issued by December 16, 2021, and the final decision of the Commission shall be issued by June 16, 2022.

Rachel E. Dickon,

Secretary.

[FR Doc. 2020–28611 Filed 12–28–20; 8:45 am]

BILLING CODE 6730–02–P

FEDERAL MARITIME COMMISSION

[Docket No. 20–20]

Astra Supply Chain, LLC and TDS Management, LLC, *Complainants* v. B&Q Freight China Limited, *Respondent;* Notice of Filing of Complaint and Assignment

SERVED: December 17, 2020.

Notice is given that a complaint has been filed with the Federal Maritime Commission (Commission) by Astra Supply Chain, LLC., and TDS Management, LLC, hereinafter ''Complainants'', against B&Q Freight China Limited, hereinafter ''Respondent''. Complainant alleges that Respondent is a foreign NVOCC registered with the Commission.

Complainant alleges that Respondent violated sections 10(b)(11) and 10(b)(12) of the Shipping Act of 1984, 46 U.S.C. 41102(c), and 46 CFR 515.32(c) with regard to a failure to release containers. The full text of the complaint can be found in the Commission's Electronic Reading Room at *https://www2.fmc.gov/readingroom/proceeding/20-20/*.

This proceeding has been assigned to Office of Administrative Law Judges. The initial decision of the presiding office in this proceeding shall be issued by December 17, 2021, and the final decision of the Commission shall be issued by June 17, 2022.

Rachel E. Dickon,

Secretary.

[FR Doc. 2020–28614 Filed 12–28–20; 8:45 am]

BILLING CODE 6730–02–P

FEDERAL MARITIME COMMISSION

[DOCKET NO. 20–21]

Astra Supply Chain, LLC and TDS Management, LLC, Complainants v. Qingdao Perimeter Global Logistics Co. Ltd. and Premier Global Logistics LLC, Respondents; Notice of Filing of Complaint and Assignment; Served: December 18, 2020

Notice is given that a complaint has been filed with the Federal Maritime Commission (Commission) by Astra Supply Chain, LLC., and TDS Management, LLC, hereinafter ''Complainants'', against Qingdao Perimeter Global Logistics Co, Ltd. (Qingdao PGL), and Premier Global Logistics LLC (SC PGL), hereinafter ''Respondents''. Complainant alleges that Respondent Qingdao is a Chinese ocean transportation intermediary not registered with the Commission, and that Respondent SC PGL is a South Carolina limited liability company and an ocean transportation intermediary not licensed by the Commission.

Complainant alleges that Respondents violated sections 19(b)(1) of the Shipping Act of 1984 with regard performance of ocean transportation intermediary services without establishing financial responsibility, and 46 U.S.C. 41102(c), and 46 CFR 515.32(c) with regard to a failure to release containers. The full text of the complaint can be found in the Commission's Electronic Reading Room at *https://www2.fmc.gov/readingroom/proceeding/20-20/*.

This proceeding has been assigned to Office of Administrative Law Judges. The initial decision of the presiding office in this proceeding shall be issued by December 18, 2021, and the final decision of the Commission shall be issued by June 20, 2022.

Rachel E. Dickon,

Secretary.

[FR Doc. 2020–28624 Filed 12–28–20; 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 January 28, 2021.

A. Federal Reserve Bank of Richmond (Adam M. Drimer, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23219. Comments can also be sent electronically to or *Comments.applications@rich.frb.org:*

1. *Virginia National Bankshares Corporation, Charlottesville, Virginia;* to acquire Fauquier Bankshares, Inc., and thereby indirectly acquire Fauquier Bank, both of Warrenton, Virginia.

B. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *WNB Holdings, LLC, North Platte, Nebraska;* to become a bank holding company by acquiring voting shares of Western Bancshares, Inc., and thereby indirectly acquire voting shares of Western Nebraska Bank, both of Curtis, Nebraska.

Board of Governors of the Federal Reserve System, December 22, 2020.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2020–28701 Filed 12–28–20; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

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 paragraph 7 of the Act.

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 January 13, 2021.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *The Kelly J. Green and Jessica E. Green Trust, Kelly J. Green and Jessica E. Green, as co-trustees, all of Hamilton, Missouri; Judson B. Snyder and Cara L. Snyder, Winnetka, Illinois; and Blythe L. Heits and Brian A. Heits, both of Kansas City, Missouri;* to be approved as members of the Snyder Family control group, a group acting in concert, to acquire voting shares of The Prism Group, Inc., and thereby indirectly acquire voting shares of The Hamilton Bank, both of Hamilton, Missouri.

Board of Governors of the Federal Reserve System, December 22, 2020.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2020–28702 Filed 12–28–20; 8:45 am]

BILLING CODE P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0291; Docket No. 2020–0001; Sequence No. 10]

Submission for OMB Review; FSRS Registration Requirements for Prime Grant Awardees

AGENCY: Office of the Integrated Award Environment, General Services Administration (GSA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve a renewal of the currently approved information collection requirement regarding FSRS Registration Requirements for Prime Grant Awardees.

DATES: Submit comments on or before January 28, 2021.

ADDRESSES: Written comments and recommendations for this information collection should be sent within 30 days of publication of this notice to *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.

FOR FURTHER INFORMATION CONTACT: John Corro, Procurement Analyst, Office of the Integrated Award Environment, GSA, at telephone number 703–605–2733; or via email at *john.corro@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

The Federal Funding Accountability and Transparency Act (Pub. L.109–282, as amended by section 6202(a) of Pub. L.110–252), known as FFATA or the Transparency Act, requires information disclosure of entities receiving Federal financial assistance through Federal awards such as Federal contracts, sub-contracts, grants and sub-grants, FFATA 2(a),(2),(i),(ii). The system that collects this information is called the FFATA Sub-award Reporting System (FSRS, *www.fsrs.gov*). This information collection requires information necessary for prime awardee registration in FSRS to create a user log-in and enable sub-award reporting for their entity. To register in FSRS for a user log-in, an entity is required to provide their Data Universal Numbering System (DUNS) number. FSRS then pulls core data about the entity from their System for Award Management (SAM) registration to include the legal business name, physical address, mailing address and Commercial and Government Entity (CAGE) code. The entity completes the FSRS registration by providing contact information within the entity for approval.

If a prime awardee has already registered in FSRS to report contracts-related Transparency Act financial data, a new log-in will not be required. In addition, if a prime awardee had a user account in the Electronic Subcontract Reporting System (eSRS), a new log-in will not be required.

B. Annual Reporting Burden

Respondents: 2,662.
Responses per Respondent: 1.
Total annual responses: 2,662.
Hours per Response: .5.
Total Burden Hours: 1,331.

C. Public Comments

A 60-day notice published in the **Federal Register** at 85 FR 66982 on October 21, 2020. No comments were received.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.*

Please cite OMB Control No. 3090–0291, FSRS Registration Requirements for Prime Grant Awardees, in all correspondence.

Beth Ann Killoran,

Chief Information Officer, General Services Administration.

[FR Doc. 2020–28647 Filed 12–28–20; 8:45 am]

BILLING CODE 6820–XY–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0157; Docket No. 2020–0053; Sequence No, 12]

Submission for OMB Review; Architect-Engineer Qualifications (SF–330)

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division has submitted to the Office of Management and Budget (OMB) a request to review and approve a revision and renewal of a previously approved information collection requirement regarding architect-engineer qualifications (Standard Form (SF) 330).

DATES: Submit comments on or before January 28, 2021.

ADDRESSES: Written comments and recommendations for this information collection should be sent within 30 days of publication of this notice to *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.

Additionally, submit a copy to GSA through *http://www.regulations.gov* and follow the instructions on the site. This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments.

Instructions: All items submitted must cite OMB Control No. 9000–0157, Architect-Engineer Qualifications (SF–330). Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two-to-three days after

submission to verify posting. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.*

FOR FURTHER INFORMATION CONTACT: Zenaida Delgado, Procurement Analyst, at telephone 202–969–7207, or *zenaida.delgado@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. OMB Control Number, Title, and Any Associated Form(s)

9000–0157, Architect-Engineer Qualifications (SF–330).

B. Need and Uses

This clearance covers the information that offerors must submit to comply with the following Federal Acquisition Regulation (FAR) requirement:

Standard Form (SF) 330, Architect-Engineer Qualifications

As specified in FAR 36.702(b), an architect-engineer firm must provide information about its qualifications for a specific contract when the contract amount is expected to exceed the simplified acquisition threshold. Part I of the SF 330 may be used when the contract amount is expected to be at or below the simplified acquisition threshold, if the contracting officer determines that its use is appropriate. Part II of the SF 330 is used to obtain information from an architect-engineer firm about its general professional qualifications.

The SF 330 accomplishes the following:

- Expands essential information about qualifications and experience data including:
- An organizational chart of all participating firms and key personnel.
- For all key personnel, a description of their experience in 5 relevant projects.
- A description of each example project performed by the project team (or some elements of the project team) and its relevance to the agency's proposed contract.
- A matrix of key personnel who participated in the example projects. This matrix graphically illustrates the degree to which the proposed key personnel have worked together before on similar projects.
- Reflects current architect-engineer disciplines, experience types and technology.
- Permits limited submission length thereby reducing costs for both the architect-engineer industry and the Government. Lengthy submissions do not necessarily lead to a better decision on the best-qualified firm. The proposed SF 330 indicates that agencies may limit the length of firm's submissions, either certain sections or the entire package. The Government's right to impose such limitations was established in case law (*Coffman Specialties, Inc.,* B–284546. N–284546/2, 2000 U.S.Comp.Gen.LEXIS 58, May 10, 2000).

The contracting officer uses the information provided on the SF 330 to evaluate firms to select an architect-engineer firm for a contract.

C. Annual Burden

Respondents: 411.
Total Annual Responses: 1,644.
Total Burden Hours: 47,676.

D. Public Comment

A 60-day notice was published in the **Federal Register** at 85 FR 66983, on October 21, 2020. No comments were received.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control No. 9000–0157, Architect-Engineer Qualifications (SF–330).

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2020–28720 Filed 12–28–20; 8:45 am]

BILLING CODE 6820–EP–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0322; Docket No. 2020–0001; Sequence No. 5]

General Services Administration Acquisition Regulation; Submission for OMB Review; Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment Under Lease Acquisitions and Commercial Solution Opening Procurements

AGENCY: Office of the Chief Acquisition Officer, General Services Administration (GSA).

ACTION: Notice of request for comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement for Prohibition to Certain Telecommunications and Video Surveillance Services or Equipment under Lease Acquisitions and Commercial Solution Openings.

DATES: Submit comments on or before January 28, 2021.

ADDRESSES: Written comments and recommendations for this information collection should be sent within 30 days of publication of this notice to *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.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Carroll, Procurement Analyst, General Services Acquisition Policy Division, 817–253–7858 or via email at *gsarpolicy@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

The Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*) provides that an agency generally cannot conduct or sponsor a collection of information, and no person is required to respond to, nor be subject to, a penalty for failure to comply with a collection of information, unless that collection has obtained Office of Management and Budget (OMB) approval and displays a currently valid OMB Control Number.

GSA requested and OMB authorized emergency processing of an information collection, as OMB Control Number 3090–0322, for the provision at FAR 52.204–24, Representation Regarding Certain Telecommunications and Video Surveillance Services and the clause at FAR 52.204–25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment, as used under lease acquisitions and commercial solution openings. GSA has determined the following conditions have been met:

a. The collection of information is needed prior to the expiration of time periods normally associated with a routine submission for review under the provisions of the Paperwork Reduction Act, because the prohibitions in Section 889 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115–232) went into effect on August 13, 2020.

b. The collection of information is essential to GSA's mission to ensure GSA complies with Section 889 in order to protect the Government supply chain from risks posed by covered telecommunications equipment or services.

c. GSA cannot comply with the normal clearance procedures because public harm is reasonably likely to

result if current clearance procedures are followed.

This requirement supports implementation of Section 889 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115–232) under lease acquisitions and commercial solution openings. This section prohibits agencies from procuring, obtaining, extending or renewing a contract with contractors that will provide or use covered telecommunication equipment or services as a substantial or essential component of any system, or as a critical technology as part of any system on or after August 13, 2020 unless an exception applies.

This requirement is implemented in the Federal Acquisition Regulation (FAR) through the provision at FAR 52.204–24, Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment and the clause at FAR 52.204–25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. GSA's Class Deviation CD–2020–15 extends these requirements to lease acquisitions and commercial solution opening procurements.

This clearance covers the following requirements:

FAR 52.204–24 requires an offer or to represent whether they will provide or whether they will use any covered telecommunications equipment or services and if so, describe in more detail the use of the covered telecommunications equipment or services; and

FAR 52.204–25 requires contractors to report covered telecommunications equipment, systems and services identified during performance of a contract.

GSA requested approval of this information collection in order to implement the law. The information will be used by agency personnel to identify and remove prohibited equipment, systems, or services from Government use. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor.

B. Annual Reporting Burden

1. FAR 52.204–24 for GSA Lease Acquisitions

Respondents: 3,128.
Responses per Respondent: 1.
Total Responses: 3,128.
Hours per Response: 3.
Total Burden Hours: 9,384.

2. FAR 52.204–25 for GSA Lease Acquisitions

Respondents: 313.
Responses per Respondent: 5.
Total Responses: 1,565.
Hours per Response: 3.
Total Burden Hours: 4,695.

C. Public Comments

A 60-day notice was published in the **Federal Register** at 85 FR 61748 on September 30, 2020. No comments were received.

Obtaining copies of proposals: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division, by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.*

Please cite ''Information Collection 3090–0322'', in all correspondence.

Jeffrey Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2020–28704 Filed 12–28–20; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Contact After Adoption or Guardianship: Child Welfare Agency and Family Interactions (New Collection)

AGENCY: Office of Planning, Research, and Evaluation; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services (HHS) seeks approval for a one-time study to examine child welfare agency family contact activities. The primary objective of this study is to describe how public child welfare agencies are in contact with or receive information about the well-being of children and youth who have exited the foster care system through adoption or guardianship, particularly the experiences of these children with instability. A secondary objective is to understand what types of information child welfare agencies systematically track about these children.

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: The proposed study would conduct web surveys with state child welfare agency adoption program managers. The study will also include stakeholder videoconference interviews with selected child welfare agency representatives. The web surveys and stakeholder interviews are designed to collect information about the types of routine contact between agencies and families after adoption or guardianship as well as agency procedures to track child instability experiences after adoption or guardianship.

Respondents: Child welfare agency staff.

ANNUAL BURDEN ESTIMATES

Instrument	Total/annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Agency Web Survey on Adoption	50	1	.33	17
Agency Web Survey on Guardianship	45	1	.25	11
Stakeholder Interview Discussion Guide—Adoption	30	1	1.5	45
Stakeholder Interview Discussion Guide—Guardianship	12	1	1.5	18

Estimated Total Annual Burden Hours: 91.

Authority: Child Abuse Prevention and Treatment and Adoption Reform Act of 1978

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–28786 Filed 12–28–20; 8:45 am]

BILLING CODE 4184–25–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Refugee Resettlement

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Administration for Children and Families, HHS.

ACTION: Notice.

SUMMARY: The Administration for Children and Families (ACF) has realigned the Office of Refugee Resettlement. It renames the Division of Influx Planning and Logistics to the Division of Planning and Logistics. It also creates one new division, which is the Division of Office Operations.

FOR FURTHER INFORMATION CONTACT: Heidi Stirrup, Office of Refugee Resettlement, 330 C Street SW, Washington, DC 20201; (202) 401–4556.

SUPPLEMENTARY INFORMATION: This notice amends Part K of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), Administration for Children and Families (ACF), as follows: Chapter KR, Office of Refugee Resettlement, as last amended by 80 FR 33269–33270, June 11, 2015.

I. Under Chapter KR, Office of Refugee Resettlement, delete KR.10 Organization in its entirety and replace with the following:

KR.10 Organization. The Office of Refugee Resettlement (ORR) is headed by a Director, who reports directly to the Assistant Secretary for Children and Families. ORR is organized, as follows:

Office of the Director (KRA)
Division of Policy and Procedures (KRA1)
Division of Strategic Planning, Budget and Data Analysis (KRA2)
Division of Office Operations (KRA3)
Refugee Programs (KRB)
Division of Refugee Assistance (KRB1)
Division of Refugee Services (KRB2)
Division of Refugee Health (KRB3)
Unaccompanied Alien Children's Programs (KRC)
Division of Unaccompanied Alien Children's Operations (KRC1)
Division of Planning and Logistics (KRC2)
Division of Health for Unaccompanied Alien (KRC3)

II. Under Chapter KR, Office of Refugee Resettlement, deletes KR.20 Functions in its entirety and replaces it with the following:

KR.20 Function.

A. The Office of the Director is directly responsible to the Assistant Secretary for Children and Families for carrying out ORR's mission and providing guidance and general supervision to the components of ORR. The ORR Director provides direction in the development of program policy and budget and in the formulation of salaries and expense budgets. Program oversight is carried out by the Deputy Director for Unaccompanied Children's Program and the Deputy Director for Refugee Programs.

The ORR Director coordinates with the lead refugee and entrant program offices of other federal departments; provides leadership in representing refugee and entrant programs, policies and administration to a variety of governmental entities and other public and private interests; and acts as the coordinator of the total refugee and entrant resettlement effort for ACF and the Department. The ORR Director oversees the care and custody of unaccompanied alien children, grants specific consent for those who wish to invoke the jurisdiction of a state court for a dependency order to seek Special Immigrant Juvenile status, and makes placement determinations for those eligible for the Unaccompanied Refugee Minors (URM) Program. The Office of the Director develops regulations, legislative proposals, and routine interpretations of policy, implementing strategic initiatives and management priorities, and oversees communications for the office, including responses to media requests, congressional inquiries, and stakeholder engagements. Within the Office of the Director, the Public Affairs (PA) team provides leadership on tactical message development, relationship management, and content engagement planning for all ORR Divisions. ORR has a unique set of communication requirements demanding timely and strategic planning for engagement with the media, stakeholders, Congress, and its care provider network of grantee organizations.

ORR's PA team prioritizes the day-to-day strategic communication assignments to accommodate moderate to heavy workloads, shifting demands, emergency situations, and other operational needs. The Team provides strategic advice and recommendations to operational divisions, as well as senior officials on media relations activities, particularly message development and strategy for high-profile issues and complex communication challenges.

The Director of the Division of Policy and Procedures assesses and evaluates ORR programs and their legal authorities and proactively recommends policy development, regulation updates and changes, legislative proposals, and operational and management actions to comply with statutory parameters as they relate to each of the program areas. The Division advises the ORR Director, deputies, division directors, and staff on a wide range of significant and sensitive policy-related matters and strategies for attaining ORR policy objectives. The Division identifies major emerging policy issues, develops policy options and strategies, and implements policy initiatives, including the drafting of policies, guidance, and regulations. The Division consults with the ORR operating divisions in the creation and clearance of procedures, consistent with established regulations, policies and guidance, and implements training on policies and procedures for ORR staff. The Division of Policy and Procedures develops clearance and informational memoranda, briefing materials and summary statements for ORR, ACF, and the Department's leadership on complex and sensitive ORR matters. The Division collaborates with the ORR operating divisions and regional staff to clarify and enhance existing policies and guidance, particularly in areas where the work of two or more divisions overlap. The Director of the Division of Policy and Procedures serves as the ORR point of contact for other ACF and HHS offices related to legal and evaluation issues, such as the Office of the General Counsel (OGC), the Office of Legislative Affairs and Budget, the U.S. Government Accountability Office, and the Office of the Inspector General. The Division represents ORR on interagency working groups and collaborates with both government and private sector leaders on ORR policy-related issues and developments.

The Director of the Division of Strategic Planning, Budget and Data Analysis leads ORR in the development, tracking and implementation of strategic goals, and performs budget, data analysis and compliance functions for the office. The Division prepares annual budget estimates and related materials and performs allocation and tracking of

funds for all programs. The Division performs analysis on the changing needs of the populations served by ORR programs, provides leadership to identify data needs and sources, and formulates data and reporting requirements. The Division also leads the office in the development of strategic goals and objectives and ensures that policies and operational and management activities are designed to achieve ORR, ACF, and Departmental goals.

This notice creates a new Division for Office Operations (DOO). The Director of DOO, in collaboration and coordination with ACF, provides advice and assistance to ORR managers in their personnel management activities, including recruitment, selection, position management, performance management, designated performance and incentive awards and employee assistance programs, and other services. DOO provides management, direction, and oversight of the following personnel administrative services: The exercise of appointing authority, position classification, awards authorization, performance management evaluation, personnel action processing and record keeping, merit promotion, special hiring, and placement programs. DOO serves as liaison between ACF, the Department, Staffing, Recruitment and Operations Center, and the Office of Personnel Management. It provides technical advice and assistance on personnel policy, regulations, and laws. DOO formulates and interprets policies pertaining to existing personnel administration and management matters, and formulates and interprets new human resource programs and strategies.

DOO administers the ACF Ethics program, the Personnel Security program, and the Drug Testing program in coordination with the Department's Office of Government Ethics, OGC, and the Office of Security and Drug Testing. The Office implements ACF travel policies and procedures consistent with federal requirements. The Office provides technical assistance and oversight, coordinates ORR use of the Travel Management System, manages employee participation in the Travel Charge Card program, and coordinates Travel Management Center services for ORR. It purchases and tracks common use supplies, stationery, and publications. The Division develops and implements policies and procedures for the Personal Property Management program, including managing the Personal Property Inventory, and other personal property activities. DOO performs the duties and responsibilities of managing Freedom of Information Act, SWIFT, Case Files, and Records Management. Creating DOO and consolidating teams will enhance mission and service delivery. DOO will centralize and better coordinate team's efforts, reduce administrative costs, and make it easier for managers to run programs to meet the comprehensive needs of their workforce.

B. The Refugee Programs are responsible for carrying out programs that provide assistance to refugees, asylees, Cuban and Haitian entrants, and certain Amerasians and victims of severe forms of trafficking in persons. In addition, Refugee Programs supports services to survivors of torture. The Deputy Director reports directly to the Director of ORR.

The Refugee Programs consist of the Division of Refugee Assistance, the Division of Refugee Services, the Division of Refugee Health, and the Unaccompanied Refugee Minors (URM) program.

The Director of the Division of Refugee Assistance represents ORR in coordinating services and capacity for refugees in a manner that helps refugees become employed and economically self-sufficient soon after their arrival in the United States. The Division monitors and provides technical assistance to the state-administered domestic assistance programs and Wilson/Fish projects. The Division works closely with each state in designing a resettlement program specific to the needs of incoming populations. The Division develops guidance and procedures for their implementation; manages special initiatives to increase refugee self-sufficiency such as through state funded discretionary grants or pilot programs. The Division also assists public and private agencies on data reporting and the resolution of reporting problems. The Division develops and supports the flow of information on refugee profiles and community resources in support of effective placement at the state and local level. The Division works closely with the Department of State to ensure effective and seamless orientation from overseas to local resettlement community. The Division manages the effective allocation of formula social services and targeted assistance in support of newly arriving populations and secondary resettlement. The Division tracks all state costs related to refugee assistance.

The Director of the Division of Refugee Services manages effective refugee resettlement through the programmatic implementation of grants, contracts, and special initiatives, such as the Match Grant Program. The Division oversees and monitors most ORR discretionary grants, recommends grantee allocation, coordinates with the grants management office to review the financial expenditures under discretionary grant programs, provides data in support of apportionment requests, and provides technical assistance on discretionary grants operations. The Division coordinates and provides liaison with the Department and other federal agencies on discretionary grant operational issues and other activities, as specified by the Director or required by Congressional mandate. The Division works to promote economic independence among refugees through social services, educational services, and intensive case management and community development initiatives.

The Director of the Division of Refugee Health provides direction for assuring that refugees are provided medical assistance and mental health services through the state-administered program and alternative privately administered programs. The Division ensures the quality of medical screening and initial medical treatment of refugees through its administration of grant programs, technical assistance and interagency agreements in support of comprehensive medical and mental health services. The Division also supports mental health services to victims of torture. The Division works closely with State Refugee Health Coordinators in the planning and provision of medical and mental health services to meet the individual needs of incoming populations. The Division monitors programs and tracks all state costs related to refugee medical assistance and screening.

Under the purview of the Deputy Director, the Unaccompanied Refugee Minors (URM) team provides oversight of foster care placement and services to unaccompanied refugee children and other special populations of youth in the United States. URM program services focus on the safety, education, well-being, and self-sufficiency of youth in care. The Team coordinates placement for eligible youth referred to the URM program and provides monitoring and oversight to the state-administered URM programs working closely with states to ensure sufficient capacity to serve all URM-eligible populations. The Team develops guidance and procedures for the administration and implementation of the URM program, and provides technical assistance on a variety of administrative, case, programmatic, financial, and policy matters. The Team

also manages all data collected on youth served in the URM program.

C. The Unaccompanied Alien Children's Programs is directly responsible in providing care and services to unaccompanied alien children who are referred to ORR for care pending immigration status, or identified as victims of trafficking. The Unaccompanied Alien Children's Program consists of the Division of Unaccompanied Alien Children's Operations, the Division of Planning and Logistics, and the Division of Unaccompanied Alien Children's Health. The Program maintains statistical information and data on each child and any actions concerning the child while the child is under the Director's care. The Unaccompanied Alien Children's Programs includes compliance teams who conducts oversight of allegations of abuse, monitoring and inspections of facilities, and placement locations in which unaccompanied alien children reside. Unaccompanied Alien Children Program staff ensures that services are administered in a manner that supports child welfare standards of care and services and complete regular monitoring of service provision. The Deputy Director reports directly to the Director of ORR.

The Director of the Division of Unaccompanied Alien Children's Operations implements intake and placement decisions for all unaccompanied alien children. The Division supports specialized care through grants and contracts. The Division ensures consideration of the child's best interest in care and custody decisions. The Division coordinates all decisions related to sponsor reunification, background checks, home assessments, follow-up services, medical assessment and treatment, and repatriation. The Division administers the pro bono legal services and child advocate programs, and compiles a state-by-state list of professionals or entities qualified to provide the children with a guardian and attorney representational services. The Division also supports grants for services provided to children after their release from ORR care.

The Director leads the Division of Planning and Logistics and oversees the development of a comprehensive strategic plan to ensure that the Unaccompanied Alien Children Programs is able to anticipate and meet capacity needs. The Planning and Logistic Division will lead a continuous improvement plan. The Division prepares plans for temporary increases in shelter capacity and staffing, as well as temporary changes in ORR staffing to support continued Unaccompanied Children Program operations. The Division leads coordination with other federal agencies and work with other Unaccompanied Alien Children's divisions to support influx response. If ORR experiences an influx in referrals of unaccompanied children, the team leads influx response operations and logistics.

The Director of the Division of Unaccompanied Alien Children's Health oversees the provision of health and medical services to unaccompanied children in ORR care. The Division reviews and approves orders for complex medical procedures and reviews test results for certain medical ailments. The Division also ensures reporting of public health information to the appropriate public health authorities.

III. Continuation of Policy. Except as inconsistent with this reorganization, all statements of policy and interpretations with respect to organizational components affected by this notice within ACF, heretofore issued and in effect on this date of this reorganization are continued in full force and effect.

IV. Delegation of Authority. All delegations and re-delegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further re-delegations, provided they are consistent with this reorganization.

V. Funds, Personnel, and Equipment. Transfer of organizations and functions affected by this reorganization shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies, and other resources.

This reorganization will be effective upon date of signature.

Delegation of Authority. Directives or orders by the Assistant Secretary of the Administration of Children and Families, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

(Authority: 44 U.S.C. 3101.)

Dated: December 1, 2020.

Megan E. Steel,

Office of the Executive Secretariat, Administration for Children and Families.

[FR Doc. 2020–28706 Filed 12–28–20; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2012–N–0197; FDA–2017–N–1095; FDA–2011–N–0424; FDA–2017–N–2021 and FDA–2010–N–0493]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain*. 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.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Shortages Data Collection	0910–0491	05/31/2021
Electronic Submission of Allegations of Regulatory Misconduct Associated with Medical Devices	0910–0769	11/30/2023

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB—Continued

Title of collection	OMB control No.	Date approval expires
Temporary Marketing Permit Applications	0910–0133	12/31/2023
Channels of Trade Policy for Commodities with Residues of Pesticide Chemicals for Which Tolerances Have Been Revoked, Suspended, or Modified by the EPA	0910–0562	12/31/2023
Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded	0910–0688	12/31/2023

Dated: December 21, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–28608 Filed 12–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2246]

Fee Rates Under the Over-the-Counter Monograph Drug User Fee Program for Fiscal Year 2021

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fee rates under the Over-the-Counter (OTC) Monograph Drug user fee program for fiscal year (FY) 2021. On March 27, 2020, a new section was added to the Federal Food, Drug, and Cosmetic Act (FD&C Act) by the Coronavirus Aid, Relief, and Economic Security Act, which authorizes FDA to assess and collect user fees from qualifying manufacturers of OTC monograph drugs and submitters of OTC monograph order requests. FDA refers to the OTC Monograph Drug user fee program as ''OMUFA'' throughout this document. This notice establishes the OMUFA fee rates for FY 2021.

FOR FURTHER INFORMATION CONTACT: David Haas, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD 20705–4304, 240–402–4585.

SUPPLEMENTARY INFORMATION:

I. Background

Section 744M of the FD&C Act (21 U.S.C. 379j–72) authorizes FDA to assess and collect: (1) Facility fees from qualifying owners of OTC monograph drug facilities and (2) fees from submitters of qualifying OTC monograph order requests. These fees are to support FDA's OTC monograph drug activities, which are detailed in section 744L(6) of the FD&C Act (21 U.S.C. 379j–71(6)) and include various FDA activities associated with OTC monograph drugs and inspection of facilities associated with such products. For OMUFA purposes:

- An OTC monograph drug is a nonprescription drug without an approved new drug application which is governed by the provisions of section 505G of the FD&C Act ((21 U.S.C. 355h); see section 744L(5) of the FD&C Act);
- An OTC monograph drug facility is a foreign or domestic business or other entity that, in addition to meeting other criteria, is engaged in manufacturing or processing the finished dosage form of an OTC monograph drug (see section 744L(10) of the FD&C Act). The Agency refers to such facility as Monograph Drug Facility (MDF);
- A contract manufacturing organization (CMO) facility is an OTC monograph drug facility where neither the owner nor any affiliate of the owner or facility sells the OTC monograph drug produced at such facility directly to wholesalers, retailers, or consumers in the United States (see section 744L(2) of the FD&C Act); and
- An OTC monograph order request (OMOR) is a request for an administrative order, with respect to an OTC monograph drug, which is submitted under section 505G(b)(5) of the FD&C Act (see section 744L(7) of the FD&C Act).

FDA will assess and collect facility fees with respect to the two types of OTC monograph drug facilities—MDF and CMO facilities. A full facility fee will be assessed to each qualifying person that owns a facility identified as an MDF (see section 744M(a)(1)(A) of the FD&C Act), and a reduced facility fee of two-thirds will be assessed to each qualifying person that owns a facility identified as a CMO facility (see section 744M(a)(1)(B)(ii) of the FD&C Act). The facility fees are due 45 days after the date of publication [1] of this notice (see section 744M(a)(1)(D)(i) of the FD&C Act). As discussed below, OTC monograph drug facilities are exempt from FY 2021 facility fees if they had ceased OTC monograph drug activities, and updated their registration with FDA to that effect, prior to December 31, 2019 (see section 744M(a)(1)(B)(i) of the FD&C Act).

In addition to facility fees, the Agency will assess and collect fees from submitters of OMORs, except for OMORs which request certain safety-related changes (as discussed below). There are two levels of OMOR fees, based on whether the OMOR at issue is a Tier 1 or Tier 2 OMOR.[2]

For FY 2021, the OMUFA fee rates are as follows: Tier 1 OMOR fees ($500,000), Tier 2 OMOR fees ($100,000), MDF facility fees ($14,060), and CMO facility fees ($9,373). These fees are effective as of October 1, 2020, and will remain in effect through September 30, 2021. This document describes the calculations used to set the OMUFA facility fees and OMOR fees for FY 2021.

II. Facility Fee Revenue Amount for FY 2021

A. Base Fee Revenue Amount

Under OMUFA, FDA sets annual facility fees to generate the total facility fee revenues for each fiscal year established by section 744M(b) of the FD&C Act. The yearly base revenue amount is the starting point for setting annual facility fee rates. The base revenue amount for FY 2021 is $8,000,000 (see section 744M(b)(3)(A) of the FD&C Act).

B. Fee Revenue Adjustment for Inflation

Under OMUFA, the annual base revenue amount for facility fees is adjusted for inflation for FY 2022 and each subsequent FY (see section

[1] Although under section 744M(c)(4)(A) of the FD&C Act, FDA was to publish this notice not later than the second Monday in May of 2020, we note that under section 744M(f)(1) of the FD&C Act, OMUFA fees ''shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts''. An appropriation of FY 2021 OMUFA fees was provided under section 123 of the Continuing Appropriations Act, 2021, Division A of Public Law 116–159 (October 1, 2020).

[2] Under OMUFA, a Tier 1 OMOR is defined as any OMOR which is not a Tier 2 OMOR (see section 744L(8) of the FD&C Act). Tier 2 OMORs are detailed in section 744L(9) of the FD&C Act.

744M(c)(1) of the FD&C Act). Because the adjustment for inflation does not apply until FY 2022, the FY 2021 facility fee revenue is not subject to an inflation adjustment by FDA.

C. Fee Revenue Adjustment for Additional Direct Cost

Under OMUFA, $14,000,000 is added to the facility fee revenues for FY 2021 to account for additional direct costs (see section 744M(c)(3)(A) of the FD&C Act).

D. Fee Revenue Adjustment for Operating Reserve

Under OMUFA, FDA may further increase the FY 2021 facility fee revenue and fees if such an adjustment is necessary in order to provide up to 3 weeks of operating reserves of carryover user fees for OTC monograph drug activities (see section 744M(c)(2)(A) of the FD&C Act). However, under the statute, if the carryover balance exceeds 10 weeks of operating reserves, FDA is required to decrease fees to provide for not more than 10 weeks of operating reserves of carryover user fees (see section 744M(c)(2)(C) of the FD&C Act).

FDA is applying the operating reserve adjustment to increase the FY 2021 facility fee revenue and fees to enable the Agency to maintain 3 weeks of operating reserves of carryover user fees. To determine the 3-week operating reserve amount, the FY 2021 annual base revenue adjusted for additional direct costs (*i.e.,* $8,000,000 + $14,000,000 = $22,000,000), is divided by 52, and then multiplied by 3. The 3-week operating reserve amount for FY 2021 is $1,269,231.

As a result of the above calculations, the final FY 2021 OMUFA target facility fee revenue is $23,269,000 (rounded to the nearest thousand dollars).

III. Determination of FY 2021 OMOR Fees

Under OMUFA, the FY 2021 Tier 1 OMOR fee is $500,000 and the Tier 2 OMOR fee is $100,000 (see section 744M(a)(2)(A)(i) and (ii) of the FD&C Act, respectively). OMOR fees are not included in the OMUFA target revenue calculation, which is based on the facility fees (see section 744M(b)(1) of the FD&C Act).

An OMOR fee is generally assessed to each person who submits an OMOR (see section 744M(a)(2)(A) of the FD&C Act). OMOR fees are due on the date of the submission of the OMOR (see section 744M(a)(2)(B) of the FD&C Act). The payor should submit the OMOR fee that applies to the type of OMOR they are submitting (*i.e.,* Tier 1 or Tier 2). FDA will determine whether the requestor has submitted the appropriate OMOR fee following receipt of the OMOR and the fee.

An OMOR fee will not be assessed if the OMOR seeks to make certain safety changes with respect to an OTC monograph drug. Specifically, no fee will be assessed if FDA finds that the OMOR seeks to change the drug facts labeling of an OTC monograph drug in a way that would add to or strengthen: (1) A contraindication, warning, or precaution; (2) a statement about risk associated with misuse or abuse; or (3) an instruction about dosage and administration that is intended to increase the safe use of the OTC monograph drug (see section 744M(a)(2)(C) of the FD&C Act).

IV. Facility Fee Calculations

A. Facility Fee Revenues and Fees

For FY 2021, facility fee rates are being established to generate a total target revenue amount equal to $23,269,000 (rounded to the nearest thousand dollars). FDA used the methodology described below to determine the appropriate number of MDF and CMO facilities to be used in setting the OMUFA facility fees for FY 2021. FDA took into consideration that the CMO facility fee is equal to two-thirds of the amount of the MDF facility fee (see section 744M(a)(1)(B)(ii) of the FD&C Act).

B. Estimate of the Number of Qualifying Facilities and Setting the Facility Fees

For FY 2021, FDA utilized the Agency's Electronic Drug Registration and Listing System (eDRLS) to estimate the number of qualifying MDF or CMO facilities that engage in the manufacturing or processing of the finished dosage form of an OTC monograph drug. In setting the FY 2021 facility fees, FDA considers the fee-qualifying population of OTC monograph drug facilities to be the population of establishments coded in eDRLS with the business operation qualifier of ''manufactures human over-the-counter drug products produced under a monograph'' or ''contract manufacturing for human over-the-counter drug products produced under a monograph'' and indicating at least one of the following business operations: Finished dosage form manufacture, label, manufacture, pack, relabel, or repack. FDA estimated this population through December 30, 2020, based on information provided by facilities in eDRLS during the first three calendar quarters of 2020.

Those facilities that only manufacture the active pharmaceutical ingredient (or API) of an OTC monograph drug do not meet the definition of an OTC monograph drug facility (see section 744L(10)(A)(i)(II)) of the FD&C Act). Likewise, a facility is not considered an OTC monograph drug facility if its only manufacturing or processing activities are one or more of the following: (a) Production of clinical research supplies; (b) testing; or (c) placement of outer packaging on packages containing multiple products, for such purposes as creating multipacks, when each monograph drug product contained within the overpackaging is already in a final packaged form prior to placement in the outer overpackaging (see section 744L(10)(A)(iii) of the FD&C Act). In addition, as noted above, certain OTC monograph drug facilities are exempt from facility fees. Under the statute, a facility fee will not be assessed if the identified OTC monograph drug facility: (1) Has ceased all activities related to OTC monograph drugs prior to December 31 of the year immediately preceding the applicable fiscal year; and (2) has updated its eDRLS registration to reflect that change (see section 744M(a)(1)(B)(i) of the FD&C Act). As the applicable fiscal year for fee-setting under this notice is FY 2021, the year immediately preceding the applicable fiscal year is FY 2020. December of FY 2020 is December 2019. Thus, a FY 2021 facility fee will not be assessed with respect to an OTC monograph drug facility that, prior to December 31, 2019, had ceased all activities related to OTC monograph drugs and updated its eDRLS registration to that effect.

FDA considered a number of factors that could affect collection of the target revenue, including that FY 2021 is the first year of this new user fee program and uncertainties related to the effects of the COVID–19 public health emergency. In estimating the total number of fee-paying facilities, the Agency made certain assumptions, including that:

(1) Facilities using expired Structured Product Labeling (SPL) codes in eDRLS were no longer manufacturing and marketing OTC monograph drugs;

(2) Facilities that have deregistered in eDRLS have exited the market;

(3) Facilities that FDA believes registered incorrectly as OTC monograph drug facilities (for example, because the associated drug listings for these facilities do not include OTC monograph drugs but instead indicate such products as OTC drug products under an approved drug application or OTC animal drug products) are not engaged in manufacturing or processing the finished dosage form of an OTC monograph drug; and

(4) Facilities that registered but do not have an active OTC monograph drug product listing associated in their registration profile are not manufacturing or processing such drug products.

Each establishment paying the facility fee is counted as one fee-paying unit. The total estimate of fee-paying units is further analyzed to determine the number of respective MDF and CMO fee-paying units.

Based on the data obtained from eDRLS, FDA estimates there will be 1,712 fee-paying units. The Agency estimates that 90 percent (1,712 × .90 = 1,541, rounded) will incur the MDF fee and 10 percent (1,712 × .10 = 171, rounded) will incur the CMO fee.

To determine the number of full fee-paying equivalents (the denominator) to be used in setting the OMUFA fees, FDA assigns a value of 1 to each MDF (1,541) and a value of ⅔ to each CMO (171 × ⅔ = 114) for a full facility equivalent of 1,655 (rounded). The target fee revenue of $23,269,000 is then divided by 1,655 for an MDF fee of $14,060 and a CMO fee of $9,373.

V. Fee Schedule for FY 2021

The fee rates for FY 2021 are displayed in table 1.

TABLE 1—FEE SCHEDULE FOR FY 2021

Fee category	FY 2021 fee rates
OMOR:	
Tier 1	$500,000
Tier 2	100,000
Facility Fees:	
MDF	14,060
CMO	9,373

VI. Fee Payment Options and Procedures

The new fee rates are effective October 1, 2020, through September 30, 2021. To pay the OMOR, MDF, and CMO fees, complete an OTC Monograph User Fee Cover Sheet, available at: *https://userfees.fda.gov/OA_HTML/omufaCAcdLogin.jsp*. A user fee identification (ID) number will be generated. Payment must be made in U.S. currency by electronic check or wire transfer, payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card for payments under $25,000 (Discover, VISA, MasterCard, American Express).

FDA has partnered with the U.S. Department of the Treasury to use *Pay.gov,* a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website after completing the OTC Monograph User Fee Cover Sheet and generating the user fee ID number. Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* (*Note:* Only full payments are accepted. No partial payments can be made online). Once an invoice is located, ''Pay Now'' should be selected to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

For payments made by wire transfer, include the unique user fee ID number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID number, the payment may not be applied, which could result in FDA not filing an application and other penalties. The originating financial institution may charge a wire transfer fee. Applicable wire transfer fees must be included with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The account information for wire transfers is as follows: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

Dated: December 22, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–28714 Filed 12–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: DATA 2000 Waiver Training Payment Program Application for Payment, OMB No. 0906–xxxx—New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this Notice has closed.

DATES: Comments on this ICR should be received no later than January 28, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *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.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: DATA 2000 Waiver Training Payment Program Application for Payment, OMB No. 0906–xxxx—New.

Abstract: The Substance Use—Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115–271), section 6083, amended the Social Security Act (subsections 1834(o)(3) and 1833(bb)), authorizing the Secretary to pay Federally Qualified Health Centers (FQHC) and Rural Health Clinics (RHC) the average cost of

training to obtain DATA 2000 waivers for their physicians and practitioners to furnish opioid use disorder treatment services. To receive payment, FQHCs and RHCs must submit a formal application.

In order to be eligible for payment, as well as to provide HRSA with information necessary for validation and issuance of accurate payments, the form requires that FQHCs and RHCs provide information identifying the submitting organization and the number of practitioners who have completed training and obtained a DATA 2000 waiver. The form requires the submitting FQHC or RHC to include information regarding each claimed practitioner's name, physician or practitioner type (*e.g.,* physician, physician assistant, nurse practitioner, certified nurse midwife, clinical nurse specialist, certified registered nurse, or anesthetist), National Provider Identifier number, Drug Enforcement Administration number, state medical license number, length of training, date the training was completed, date of waiver attainment, and DATA 2000 waiver number. Additionally, the form requires signature of an attestation statement certifying that (1) each practitioner for which the entity is seeking payment under the application is employed by or working under contract for this facility; (2) it is the first time the entity is seeking payment on behalf of the listed practitioner(s); (3) the entity is eligible to seek payment under 42 U.S.C. 1395m(o)(3) or 42 U.S.C. 1395l(bb); (4) each practitioner is furnishing opioid use disorder treatment services; and (5) that the statements herein are true, complete, and accurate to the best of the applicant's knowledge. FQHCs and RHCs will need a System for Award Management account and a HRSA Electronic Handbooks account in order to apply (visit *https://sam.gov/SAM/* and *https://grants.hrsa.gov/2010/WebEPSExternal/Interface/UserRegistration/RegistrationHome.aspx?controlName=ContentTabs* for more information on how to create an account).

A 60-day notice published in the **Federal Register** on October 6, 2020, vol. 85, No. 194; pp. 63121–22. There were no public comments.

Need and Proposed Use of the Information: The Substance Use—Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act requires FQHCs and RHCs to submit to the Secretary an application for payment at such time, in such manner, and containing such information as specified by the Secretary in order to receive a payment under section 6083. This form allows FQHCs and RHCs to apply for such payments based on the average cost of training to obtain DATA 2000 waivers, as determined by the Secretary, for their physicians and practitioners to furnish opioid use disorder treatment services. HRSA intends to validate and pay $3,000 per eligible provider submitted on the form by FQHCs and RHCs. The form also provides HRSA with the requisite data to validate qualifying DATA 2000 waiver possessions for the purpose of ensuring accurate payments to FQHCs and RHCs.

The following changes were made since the publication of the 60 Day notice. The number of respondents, total respondents, and total burden hours were updated to reflect administrative costs in the agency's spend plan. The figures assume a $3,000 payment for each DATA 2000 waiver and $750,000 in administrative costs, thereby leaving $7,250,000 in funds available for payment to FQHCs and RHCs. Language was added in the ''Need and Proposed Use of the Information'' section to signal to stakeholders that HRSA intends to validate and pay $3,000 per eligible provider submitted on the form by FQHCs and RHCs. Additionally, language was added in the ''Abstract'' section notifying FQHCs and RHCs that they will need a System for Award Management account and a HRSA Electronic Handbooks account in order to apply.

Likely Respondents: Only FQHC and RHC are eligible to apply.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
DATA 2000 Waiver Training Payment Program Application for Payment	2,416	1	2,416	0.5	1,208
Total	2, 416		2,416		1,208

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Amy P. McNulty,

Deputy Director, Executive Secretariat.

[FR Doc. 2020–28767 Filed 12–28–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–New]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is announcing it has submitted to the Office of Management and Budget (OMB) for review and clearance the following collection of information. The addresses section has been corrected to reflect the correct comments email address.

DATES: Comments on the ICR must be received on or before January 28, 2021.

ADDRESSES: Submit your comments to *http://www.reginfo.gov/public/do/PRAMain* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0990-New and project title for reference.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, OS/DHHS has submitted the following proposed collection of information to OMB for review and clearance.

OMB No. 0990-New—HHS Teletracking COVID–19 Portal; OMB Control Number

Abstract: The data collected through this ICR informs the Federal Government's understanding of disease patterns and furthers the development of policies for prevention and control of disease spread and impact related to the 2019 Novel Coronavirus (COVID–19). One of the most important uses of the data collected through this ICR is to determine critical allocations of limited supplies (*e.g.,* protective equipment and medication). For instance, this collection has been used to distribute Remdesivir, a vital therapeutic that HHS distributes to the American healthcare system, via distinct data calls on regular intervals. As of July 10, HHS reduced the number requests for data from hospitals to support allocations of Remdesivir. HHS has stopped sending out one-time requests for data to aid in the distribution of Remdesivir or any other treatments or supplies. This consolidated daily reporting is the only mechanism used for the distribution calculations, and daily reports are needed to ensure accurate calculations.

Type of Respondent: We acknowledge the burden placed on many hospitals, including resource constraints, and have allowed for some flexibilities, such as back-submissions or submitting every business days, with the understanding that respondents may not have sufficient staff working over the weekend. It is our belief that collection of this information daily is the most effective way to detect outbreaks and needs for Federal assistance over time, by hospital and geographical area, and to alert the appropriate officials for action. It's requested that 5,500 hospitals, submit data daily on the number of patients tested for COVID–19, as well as information on bed capacity and requirements for other supplies.

The HHS Teletracking COVID–19 Portal (U.S. Healthcare COVID–19 Portal) includes some data that were initially submitted by hospitals to HHS through CDC's National Healthcare Safety Network (NHSN) COVID–19 Module (OMB Control No. 0920–1290, approved 03/26/2020). Over the last several month's time, the guidance for which data elements should be sent to HHS and through which method was updated at the request of the White House Coronavirus Task Force and other leaders to better inform the response.

ESTIMATED ANNUALIZED BURDEN HOURS

Number of respondents	Form name (electronic portal)	Number of responses per respondents	Total annual responses	Average burden per response (in hours)	Total burden hours
5,500	HHS Teletracking COVID–19 Portal	365	2,007,500	1.75	3,513,125

Terry Clark,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2020–28787 Filed 12–28–20; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Comprehensive and Rapid Response to NIAID Research Programs (N01), Task Area C.

Date: January 19, 2021.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G11, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Kumud Singh, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G11, Rockville, MD 20852, 301–761–7830, *kumud.singh@nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Comprehensive and Rapid Response to NIAID Research Programs, Task Area D.

Date: January 21, 2021.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G11, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Kumud Singh, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G11, Rockville, MD 20852, 301–761–7830, *kumud.singh@nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Comprehensive and Rapid Response to NIAID Research Programs, Task Area E.

Date: January 22, 2021.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G11, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Kumud Singh, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G11, Rockville, MD 20852, 301–761–7830, *kumud.singh@nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Comprehensive and Rapid Response to NIAID Research Programs, Task Area F.

Date: January 27, 2021.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G11, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Kumud Singh, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G11, Rockville, MD 20852, 301–761–7830, *kumud.singh@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 21, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–28623 Filed 12–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, National Eye Institute.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual grant applications conducted by the National Eye Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Eye Institute.

Date: January 26–27, 2021.

Time: 10:30 a.m. to 5:25 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Eye Institute, National Institutes of Health, Building 31, Room 6A22, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: David M. Schneeweis, Ph.D., Acting Scientific Director, National Eye Institute, National Institutes of Health, Building 31, Room 6A22, Bethesda, MD 20892, 301–451–6763, *David.schneeweis@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: December 22, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–28759 Filed 12–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 Allergy and Infectious Diseases Special Emphasis Panel; NIAID SBIR Phase II Clinical Trial Implementation Cooperative Agreement (U44); NIAID Clinical Trial Implementation Cooperative Agreement (U01); NIAID Clinical Trial Planning Grants (R34 Clinical Trial Not Allowed).

Date: January 19–22, 2021.

Time: 10:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E71A, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Patricia A. Gonzales Hurtado, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E71A, Rockville, MD 20852, 240–627–3556, *Patricia.Gonzales@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 21, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–28619 Filed 12–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 Allergy and Infectious Diseases Special Emphasis Panel; Emergency Awards: Rapid Investigation of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS–CoV–2) and Coronavirus Disease 2019 (COVID–19).

Date: January 21–22, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G41, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Brenda Lange-Gustafson, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G41, Rockville, MD 20852, (240) 669–5047, *bgustafson@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856,

Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 21, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–28625 Filed 12–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 on Drug Abuse.

The meeting will be held as a virtual meeting and is open to the public, as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, 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 and Podcasting website (*http://videocast.nih.gov/*).

A portion of 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 intramural programs and projects as well as the grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with intramural programs and projects as well as the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Drug Abuse.

Date: February 9, 2021.

Closed: 11:00 a.m. to 12:15 p.m.

Agenda: To review and evaluate grant applications.

Closed: 12:15 p.m. to 12:45 p.m.

Agenda: Report to Council from the BSC.

Open: 1:15 p.m. to 4:30 p.m.

Agenda: Presentations and other business of the Council.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Susan R.B. Weiss, Ph.D., Director, Division of Extramural Research, Office of the Director, National Institute on Drug Abuse, NIH, Three White Flint North, RM 09D08, 11601 Landsdown Street, Bethesda, MD 20852, 301–443–6480, *sweiss@nida.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: *www.drugabuse.gov/NACDA/NACDAHome.html,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: December 21, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–28616 Filed 12–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Comprehensive and Rapid Response to NIAID Research Programs, Task Area G.

Date: January 25, 2021.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G30, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Ron Otten, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G30, Rockville, MD 20852, 404–639–1018, *ron.otten@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 21, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–28622 Filed 12–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Cancer Institute Clinical Trials and Translational Research Advisory Committee.

The meeting will be held as a virtual meeting and is open to the public. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The meeting will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov*).

Name of Committee: National Cancer Institute Clinical Trials and Translational Research Advisory Committee Ad hoc Translational Research Strategy Subcommittee.

Date: January 14, 2021.

Time: 11:00 a.m. to 12:00 p.m.

Agenda: Group Discussion of Opportunities and Gaps in Translational Research.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850 (Virtual Meeting).

Contact Person: Peter Ujhazy, MD, Ph.D., Deputy Associate Director, Translational Research Program, Division of Cancer Treatment and Diagnosis, National Institutes of Health, National Cancer Institute, 9609 Medical Center Drive, Room 3W106, Rockville, MD 20850, 240–276–5681, *ujhazyp@mail.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: *http://deainfo.nci.nih.gov/advisory/ctac/ctac.htm,* where an agenda and any additional information for the meeting will be posted when available.

This notice is being published less than 15 days prior to the meeting due to scheduling limitations.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: December 22, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–28758 Filed 12–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 Allergy and Infectious Diseases Special Emphasis Panel; Emergency Awards: Rapid Investigation of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS–CoV–2) and Coronavirus Disease 2019 (COVID–19).

Date: January 21–22, 2021.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G22, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Inka I. Sastalla, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G22, Rockville, MD 20852, 301–761–6431, *inka.sastalla@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 21, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–28621 Filed 12–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 Allergy and Infectious Diseases Special Emphasis Panel; NIAID Resource Related Research Projects (R24 Clinical Trial Not Allowed).

Date: January 22, 2021.

Time: 11:30 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F52, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Jennifer Hartt Meyers, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F52, Rockville, MD 20852, 301–761–6602, *jennifer.meyers@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 21, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–28618 Filed 12–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4559–DR; Docket ID FEMA–2020–0001]

Louisiana; Amendment No. 9 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Louisiana (FEMA–4559–DR), dated August 28, 2020, and related determinations.

DATES: This amendment was issued September 14, 2020.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Louisiana is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of August 28, 2020.

Bossier, Evangeline, and Webster Parishes for debris removal [Category A] (already designated for emergency protective measures [Category B], including direct federal assistance, under the Public Assistance program).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2020–28725 Filed 12–28–20; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4558–DR; Docket ID FEMA–2020–0001]

California; Amendment No. 4 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of California (FEMA–4558–DR), dated August 22, 2020, and related determinations.

DATES: This amendment was issued September 13, 2020.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of California is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of August 22, 2020.

Butte County for Individual Assistance and assistance for debris removal [Category A] (already designated for emergency protective measures [Category B], including direct federal assistance, under the Public Assistance program).

San Mateo County for debris removal [Category A] and permanent work [Categories C–G] (already designated for Individual Assistance and assistance for emergency protective measures [Category B], including direct federal assistance, under the Public Assistance program).

Monterey, Napa, Santa Cruz, Solano, and Sonoma Counties for permanent work [Categories C–G](already designated for Individual Assistance and assistance for debris removal and emergency protective measures [Categories A and B], including direct federal assistance, under the Public Assistance program).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2020–28740 Filed 12–28–20; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4561–DR; Docket ID FEMA–2020–0001]

Sac & Fox Tribe of the Mississippi in Iowa; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the Sac & Fox Tribe of the Mississippi in Iowa (FEMA–4561–DR), dated September 10, 2020, and related determinations.

DATES: The declaration was issued September 10, 2020.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.C

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 10, 2020, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage to the lands associated with the Sac & Fox Tribe of the Mississippi in Iowa resulting from severe storms and straight-line winds on August 10, 2020, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists for the Sac & Fox Tribe of the Mississippi in Iowa.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance and Hazard Mitigation for the Sac & Fox Tribe of the Mississippi in Iowa. Direct Federal assistance is authorized. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Public Assistance and Hazard Mitigation will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, DuWayne Tewes, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The Sac & Fox Tribe of the Mississippi in Iowa for Public Assistance.

The Sac & Fox Tribe of the Mississippi in Iowa is eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2020–28730 Filed 12–28–20; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4559–DR; Docket ID FEMA–2020–0001]

Louisiana; Amendment No. 5 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Louisiana (FEMA–4559–DR), dated August 28, 2020, and related determinations.

DATES: This amendment was issued September 7, 2020.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Louisiana is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of August 28, 2020.

Acadia, Grant, Natchitoches, Vermilion, and Winn Parishes for Public Assistance [Category A] (already designated for Individual Assistance and assistance for emergency protective measures [Category B], including direct federal assistance, under the Public Assistance program.)

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2020–28729 Filed 12–28–20; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4559–DR; Docket ID FEMA–2020–0001]

Louisiana; Amendment No. 4 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Louisiana (FEMA–4559–DR), dated August 28, 2020, and related determinations.

DATES: This amendment was issued September 5, 2020.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Louisiana is hereby amended to include permanent work under the Public Assistance program for those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of August 28, 2020.

Allen, Beauregard, Calcasieu, Cameron, Jefferson Davis, and Vernon Parishes for Public Assistance [Categories C–G](already designated for Individual Assistance and assistance for debris removal and emergency protective measures [Categories A and B], including direct federal assistance, under the Public Assistance program.)

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2020–28735 Filed 12–28–20; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4560–DR; Docket ID FEMA–2020–0001]

Puerto Rico; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the Commonwealth of Puerto Rico (FEMA–4560–DR), dated September 9, 2020, and related determinations.

DATES: The declaration was issued September 9, 2020.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 9, 2020, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the Commonwealth of Puerto Rico resulting from Tropical Storm Isaias during the period of July 29 to July 31, 2020, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the Commonwealth of Puerto Rico.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance in the designated areas and Hazard Mitigation throughout the Commonwealth. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation and Other Needs Assistance under section 408 will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Alexis Amparo, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the Commonwealth of Puerto Rico have been designated as adversely affected by this major disaster:

The municipalities of Aguada, Hormigueros, Mayaguez, and Rincon for Individual Assistance.

All areas within the Commonwealth of Puerto Rico are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2020–28736 Filed 12–28–20; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4559–DR; Docket ID FEMA–2020–0001]

Louisiana; Amendment No. 10 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Louisiana (FEMA–4559–DR), dated August 28, 2020, and related determinations.

DATES: This amendment was issued September 16, 2020.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Louisiana is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of August 28, 2020.

Claiborne Parish for debris removal [Category A] (already designated for emergency protective measures [Category B], including direct federal assistance, under the Public Assistance program).

La Salle and Ouachita Parishes for debris removal [Category A] (already designated for Individual Assistance and assistance for emergency protective measures [Category B], including direct federal assistance, under the Public Assistance program).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2020–28741 Filed 12–28–20; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3541–EM; Docket ID FEMA–2020–0001]

Arkansas; Amendment No. 1 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the State of Arkansas (FEMA–3541–EM), dated August 27, 2020, and related determinations.

DATES: This amendment was issued September 11, 2020.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this emergency is closed effective August 28, 2020.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2020–28728 Filed 12–28–20; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4473–DR; Docket ID FEMA–2020–0001]

Puerto Rico; Amendment No. 8 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the Commonwealth of Puerto Rico (FEMA–4473–DR), dated January 16, 2020, and related determinations.

DATES: This amendment was issued September 10, 2020.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this disaster is closed effective July 3, 2020.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2020–28722 Filed 12–28–20; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4558–DR; Docket ID FEMA–2020–0001]

California; Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of California (FEMA–4558–DR), dated August 22, 2020, and related determinations.

DATES: This amendment was issued September 10, 2020.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of California is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of August 22, 2020.

Butte, Plumas, and Yuba Counties for emergency protective measures (Category B), including direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2020–28724 Filed 12–28–20; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4557–DR; Docket ID FEMA–2020–0001]

Iowa; Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Iowa (FEMA–4557–DR), dated August 17, 2020, and related determinations.

DATES: This amendment was issued September 8, 2020.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Iowa is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of August 17, 2020.

Greene, Grundy, Guthrie, Hardin, Iowa, Jackson, and Washington Counties for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2020–28726 Filed 12–28–20; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4559–DR; Docket ID FEMA–2020–0001]

Louisiana; Amendment No. 6 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Louisiana (FEMA–4559–DR), dated August 28, 2020, and related determinations.

DATES: This amendment was issued September 9, 2020.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Louisiana is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of August 28, 2020.

Morehouse and Union Parishes for Individual Assistance (already designated for emergency protective measures [Category B], including direct federal assistance, under the Public Assistance program.)

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2020–28733 Filed 12–28–20; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3538–EM; Docket ID FEMA–2020–0001]

Louisiana; Amendment No. 3 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the State of Louisiana (FEMA–3538–EM), dated August 23, 2020, and related determinations.

DATES: This amendment was issued September 11, 2020.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this emergency is closed effective August 27, 2020.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2020–28739 Filed 12–28–20; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4559–DR; Docket ID FEMA–2020–0001]

Louisiana; Amendment No. 7 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Louisiana (FEMA–4559–DR), dated August 28, 2020, and related determinations.

DATES: This amendment was issued September 11, 2020.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Louisiana is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of August 28, 2020.

Bienville, Catahoula, and Sabine Parishes for debris removal [Category A] (already designated for emergency protective measures [Category B], including direct federal assistance, under the Public Assistance program).

Jackson, Lincoln, and Rapides Parishes for debris removal [Category A] (already designated for Individual Assistance and emergency protective measures [Category B], including direct federal assistance, under the Public Assistance program).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2020–28723 Filed 12–28–20; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4559–DR; Docket ID FEMA–2020–0001]

Louisiana; Amendment No. 8 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Louisiana (FEMA–4559–DR), dated August 28, 2020, and related determinations.

DATES: This amendment was issued September 12, 2020.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Louisiana is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of August 28, 2020.

Caddo, La Salle, and St. Landry Parishes for Individual Assistance (already designated for emergency protective measures [Category B], including direct federal assistance, under the Public Assistance program).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2020–28727 Filed 12–28–20; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3540–EM; Docket ID FEMA–2020–0001]

Texas; Amendment No. 4 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the State of Texas (FEMA–3540–EM), dated August 24, 2020, and related determinations.

DATES: This amendment was issued September 11, 2020.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this emergency is closed effective August 27, 2020.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2020–28734 Filed 12–28–20; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3546–EM; Docket ID FEMA–2020–0001]

Florida; Amendment No. 1 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the State of Florida (FEMA–3546–EM), dated September 15, 2020, and related determinations.

DATES: This amendment was issued September 18, 2020.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of an emergency declaration for the State of Florida is hereby amended to include reimbursement for eligible emergency protective measures for the following areas among those areas determined to have been adversely affected by the event declared an emergency by the President in his declaration of September 15, 2020.

Calhoun, Franklin, Gadsden, Gulf, Jackson, and Liberty Counties for reimbursement for eligible emergency protective measures (already designated for emergency protective measures [Category B], limited to direct Federal assistance, under the Public Assistance program).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Pete Gaynor,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2020–28732 Filed 12–28–20; 8:45 am]

BILLING CODE 9111–23–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1235]

Certain Vehicle Control Systems, Vehicles Containing the Same, and Components Thereof; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on November 19, 2020, under section 337 of the Tariff Act of 1930, as amended, on behalf of Jaguar Land Rover Limited of the United Kingdom and Jaguar Land Rover North America, LLC of Mahwah, New Jersey. A supplement was filed on December 10, 2020. The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain vehicle control systems, vehicles containing the same, and components thereof by reason of infringement of certain claims of U.S. Patent No. RE46,828 (''the '828 patent''). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute. The complainants request that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: Katherine Hiner, Office of the Secretary, Docket Services Division, U.S. International Trade Commission, telephone (202) 205–1802.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2020).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on December 21, 2020, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a

violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 21, 25–37, 39, and 41–47 of the '828 patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is ''automobile driving-mode control systems, components thereof, and automobiles containing those automobile driving-mode systems'';

(3) Notwithstanding any Commission Rules to the contrary, which are hereby waived, the respondents shall, and complainants may, present evidence and arguments concerning the ease or difficulty (in terms of, *e.g.,* time, cost and technological requirements), of removing, replacing, or altering the accused automobile driving-mode control systems, and the presiding administrative law judge shall, as part of any recommended determination issued pursuant to Commission Rule 210.42(a)(1)(ii), make findings and issue a recommendation concerning the impact of this issue on any remedy or concerning the potential tailoring of any remedy based on this issue;

(4) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

Jaguar Land Rover Limited, Abbey Road, Whitley, Coventry CV3 4LF, United Kingdom

Jaguar Land Rover North America, LLC, 100 Jaguar Land Rover Way, Mahwah, NJ 07495

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Dr. Ing. h.c. F. Porsche AG, d/b/a Porsche AG, Porscheplatz 1, D–70435 Stuttgart, Germany

Porsche Cars North America, Inc., One Porsche Drive, Atlanta, GA 30354

Automobili Lamborghini S.p.A., Via Modena 12, 40091 Sant'Agata Bolognese (BO), Italy

Automobili Lamborghini America, LLC, 2200 Ferdinand Porsche Drive, Herndon, VA 20171

Volkswagen AG, Berliner Ring 2, 38440 Wolfsburg, Germany

Volkswagen Group of America, Inc., 2200 Ferdinand Porsche Drive, Herndon, VA 20171

Audi AG, Auto-Union-Straße 1, 85057 Ingolstadt, Germany

Audi of America, LLC, 2200 Ferdinand Porsche Drive, Herndon, VA 20171

(5) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations will not be named as a party to this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), as amended in 85 FR 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainants of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: December 21, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–28675 Filed 12–28–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1234]

Certain Radio Frequency Identification (''RFID'') Products, Components Thereof, and Products Containing the Same Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on November 13, 2020, under section 337 of the Tariff Act of 1930, as amended, on behalf of Amtech Systems LLC of Albuquerque, New Mexico. Supplements to the complaint were filed on November 16, 2020 and December 9, 2020. The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain radio frequency identification (''RFID'') products, components thereof, and products containing the same by reason of infringement of certain claims of U.S. Patent No. 7,518,532 (''the '532 Patent''); U.S. Patent No. 7,772,977 (''the '977 Patent''); U.S. Patent No. 8,237,565 (''the '565 Patent''); U.S. Patent No. 7,548,153 (''the '153 Patent''); U.S. Patent No. 8,427,279 (''the '279 Patent''); and U.S. Patent No. 10,083,329 (''the '329 Patent''). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute. The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: Pathenia M. Proctor, The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2020).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on December 21, 2020, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1–12 of the '532 Patent; claims 1–3 of the '977 Patent; claims 1–7 of the '565 Patent; claim 25 of the '153 Patent; claims 1, 3–5, 13–14, and 17–30 of the '279 Patent; and claims 1–5, 7, 9–15, 17, and 19 of the '329 Patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is ''RFID products that are used as toll collection systems on highways and roads'';

(3) Pursuant to Commission Rule 210.50(b)(1), 19 CFR 210.50(b)(1), the presiding administrative law judge shall take evidence or other information and hear arguments from the parties and other interested persons with respect to the public interest in this investigation, as appropriate, and provide the Commission with findings of fact and a recommended determination on this issue, which shall be limited to the statutory public interest factors set forth in 19 U.S.C. 1337(d)(1) and (f)(1);

(4) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is: Amtech Systems LLC, 8600 Jefferson Street NE, Albuquerque, NM 87113–1629.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Kapsch TrafficCom AG, AM Europlatz 2, 1120, Vienna, Austria
Kapsch TrafficCom B.V., Verlengde Poolseweg 14, Breda Noord-Brabant, 4818CL, Netherlands
Kapsch TrafficCom Canada, Inc., 6020 Ambler Drive, Mississauga, ON L4W 2P1, Canada
Kapsch TrafficCom Holding Corp., 8201 Greensboro Drive, Suite 1002, McLean, VA 22102
Kapsch TrafficCom Holding II US Corp., 8201 Greensboro Drive, Suite 1002, McLean, VA 22102
Kapsch TrafficCom IVHS, Inc., 8201 Greensboro Drive, Suite 1002, McLean, VA 22102
Kapsch TrafficCom USA, Inc., 8201 Greensboro Drive, Suite 1002, McLean, VA 22102
Kapsch TrafficCom Inc., 8201 Greensboro Drive, Suite 1002, McLean, VA 22102
Kapsch TrafficCom Services USA, Inc., 8201 Greensboro Drive, Suite 1002, McLean, VA 22102

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW, Suite 401, Washington, DC 20436; and

(5) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondent in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), as amended in 85 FR 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainant of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of the respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: December 21, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–28651 Filed 12–28–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1236]

Certain Polycrystalline Diamond Compacts and Articles Containing Same; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on November 23, 2020, under section 337 of the Tariff Act of 1930, as amended, on behalf of US Synthetic Corporation of Orem, Utah. A supplement was filed on December 11, 2020. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain polycrystalline diamond compacts and articles containing same by reason of infringement of certain claims of U.S. Patent Nos. 9,932,274 (''the '274 Patent''); 10,508,502 (''the '502 Patent''); 9,315,881 (''the '881 Patent''); 10,507,565 (''the '565 Patent''); and 8,616,306 (''the '306 Patent''). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the

Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: Katherine Hiner, Office of Docket Services, U.S. International Trade Commission, telephone (202) 205–1802.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2020).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on December 21, 2020, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 34, 38, and 39 of the '274 patent; claims 1, 2, 4, 8–11, 15–17, and 19–21 of the '502 patent; claims 1, 2, 4–8, and 15–17 of the '881 patent; claims 1–11, 13–15, 18–20, and 22–24 of the '565 patent; and claims 15, 20, and 21 of the '306 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is ''polycrystalline diamond compacts (PDC), PDC cutters, drill bits including PDC cutters, and PDC bearings and bearing elements'';

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is: US Synthetic Corporation, 1260 South 1600 West, Orem, UT 84058.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

SF Diamond Co., Ltd., No. 109, No. 10 Ave., Economic Development Zone, Zhengzhou, Henan, 450016, China
SF Diamond USA, Inc., 25519 Oakhurst Drive, Spring, TX 77386
Element Six Abrasives Holdings Ltd., 20 Carlton House Terrace, London, SW1Y 5AN, United Kingdom
Element Six Global Innovation Centre, Fermi Ave., Harwell Oxford, Didcot, Oxfordshire, OX11 0QR, United Kingdom
Element Six GmbH, Städeweg 18, 36151 Burghaun, Germany
Element Six Limited, 1 Debid Rd., Nuffield, Springs 1559, South Africa
Element Six Production (Pty) Limited, Shannon Airport, Shannon, County Clare, V14 E803, Ireland
Element Six Hard Materials (Wuxi) Co. Limited, No. 105–1, Xinjin Rd., Meicun, Wuxi New District, 214112, China
Element Six Trading (Shanghai) Co. Limited, Unit 3201, Century Link Tower 1, No. 1198 Century Ave., Pudong New District, Shanghai, 200122, China
Element Six Technologies US Corporation, 3901 Burton Drive, Santa Clara, CA 95054
Element Six US Corporation, 24900 Pitkin Road, Suite 250, Spring, TX 77386
ServSix US, 554 East 1400 South, Orem, UT 84097
Synergy Materials Technology Limited, Room 301, 3/F Kai Wong Commercial Building, 222 Queen's Road Central, Hong Kong, SAR of China
Iljin Diamond Co., Ltd. Iljin Building, 45, Mapo-daero, Mapo-gu, Seoul, KOREA, 04167, Republic of Korea
Iljin Holdings Co., Ltd., Iljin Building, 45, Mapo-daero, Mapo-gu, Seoul, KOREA, 04167, Republic of Korea
Iljin USA Inc., 15995 N Barkers Landing Rd., #310, Houston TX 77079
Iljin Europe GmbH, Kölner Str. 3, 65760 Eschborn, Germany
Iljin Japan Co., Ltd., Hamamatsucho General B/L 7F, 2–2–15, Hamamatsu-cho, Minato-ku, Tokyo, 105–0013, Japan
Iljin China Co., Ltd., 3F–C, BaoNa B/D (LP Tower), NC.25, Xianfeng St., Minhang District, Shanghai, 201103, China
Henan Jingrui New Material Technology Co., Ltd., West Side of Xingang Road, Zhengzhou City Airport, Henan, 451171, China
Zhengzhou New Asia Superhard Materials Composite Co., Ltd., No. 22, Chunlan Road, Zhengzhou, Henan, 450001, China
International Diamond Services, Inc., 283 Lockhaven Drive, Suite 300, Houston, TX 77073
CR Gems Superabrasives Co., Ltd., No. 3802 Shengang Road, Songjiang District, Shanghai 201611, China
FIDC Beijing Fortune International Diamond, Room 1010, Building 3, West International Center, No. 99 Beisanhuan West Road, Haidian District, Beijing, 100086, China
Fujian Wanlong Superhard Material Technology Co., Ltd., No. 13 Zhitai Road, Quangzhou Economic and Technology Development Zone, Fujian, 362000, China
Zhuhai Juxin Technology, No. 157, West Pinggong Road, Nanping Technology Park, Zhuhai, Guangdong Province, 519060, China
Shenzhen Haimingrun Superhard Materials Co., Ltd., 102, Building A7, Zhihui Innovation Park, Meiying (Phoenix), No. 3, Fengxing Xingye Third Road, Fuyong, Shenzhen City, Guangdong, 518128, China

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations will not participate as a party to this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), as amended in 85 FR 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainant of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: December 21, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–28669 Filed 12–28–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1218]

Notice of a Commission Determination Not To Review an Initial Determination Granting Leave To Amend the Complaint and Notice of Investigation; Certain Variable Speed Wind Turbine Generators and Components Thereof

AGENCY: International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the International Trade Commission (''Commission'') has determined not to review an initial determination (''ID'') (Order No. 10) of the presiding administrative law judge (''ALJ''), granting leave to amend the complaint and notice of investigation.

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 September 8, 2020. 85 FR 55492–93 (Sep. 8, 2020). The complaint, as supplemented, was filed by General Electric Company (''GE'') and 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 variable speed wind turbine generators and components thereof by reason of infringement of certain claims of United States Patent Nos. 6,921,985 (''the '985 patent'') and 7,629,705 (''the '705 patent''). *Id.* at 55492. The complaint further alleges that a domestic industry exists. *Id.* The Commission's notice of investigation named Siemens Gamesa Renewable Energy Inc. of Orlando, Florida; Siemens Gamesa Renewable Energy A/S of Brande, Denmark; and Gamesa Electric, S.A.U. of Zamudio, Spain (collectively ''SGRE''). *Id.* at 55493. The Office of Unfair Import Investigations is not participating in this investigation. *Id.*

On November 13, 2020, GE moved for leave to amend the complaint and notice of investigation to add independent claim 15 and dependent claims 16 and 21–24 to the asserted claims of the '985 patent and dependent claim 2 for the '705 patent. On November 25, 2020, SGRE filed a brief opposing the motion.

On December 2, 2020, the presiding administrative law judge (''ALJ'') issued the subject ID granting the motion and allowing GE leave to amend the complaint and notice of investigation to add the requested claims. The ALJ reached that conclusion by finding that the record supported the conclusion that GE did not obtain information supporting allegations of infringement as to the additional claims until after it filed the complaint in this investigation. The ALJ also found that granting the motion would not prejudice the parties' rights in the investigation because the additional claims would not expand the scope of accused products at issue in the investigation, and adequate time remains in fact discovery, scheduled to close on March 5, 2021. No petitions for review of the ID were received.

The Commission vote for this determination took place on December 18, 2020. The following claims have been added to the investigation: claims 15–16 and 21–24 of the '985 patent and claim 2 of the '705 patent.

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: December 21, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–28673 Filed 12–28–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1202]

Certain Synthetic Roofing Underlayment Products and Components Thereof; Commission Determination Not To Review an Initial Determination Terminating the Investigation as to All Respondents Based on Withdrawal of the Complaint; 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'') granting complainant's unopposed motion to terminate the above-captioned investigation as to all respondents based on withdrawal of the complaint.

FOR FURTHER INFORMATION CONTACT: Richard P. Hadorn, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3179. 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, telephone (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on June 1, 2020, based on a complaint filed by Kirsch Research and Development, LLC (''Kirsch'') of Simi Valley, California. 85 FR 33198–99 (June 1, 2020). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), based on the importation into the United States, the sale for importation, or the sale within the United States after importation of certain synthetic roofing underlayment products and components thereof by reason of infringement of certain claims of U.S. Patent No. 8,765,251. *Id.* at 33198. The complaint further alleges that a domestic industry exists. *Id.* The notice of investigation names eleven respondents: Atlas Roofing Corporation of Atlanta, Georgia;

CertainTeed Corporation of Malvern, Pennsylvania; Dupont De Nemours, Inc. and E.I. Du Pont De Nemours and Company, both of Wilmington, Delaware; Epilay, Inc. of Carson, California; GAF Corporation of Parsippany, New Jersey; Owens Corning, Owens Corning Roofing & Asphalt, LLC, and InterWrap Corp., each of Toledo, Ohio; SCC of Issaquah, Washington; and TAMKO Building Products, LLC of Joplin, Missouri. *Id.* The Office of Unfair Import Investigations is not named as a party. *Id.*

On August 4, 2020, the Commission determined to amend the complaint and notice of investigation by substituting CertainTeed LLC for respondent CertainTeed Corporation and GAF Materials LLC for respondent GAF Corporation. Order No. 6 (July 14, 2020), *unreviewed by* 85 FR 47988 (Aug. 7, 2020). That same day, the Commission also determined to terminate the investigation as to CertainTeed Corporation and GAF Corporation based on good cause. Order No. 7 (July 14, 2020), *unreviewed by* Comm'n Notice (Aug. 4, 2020). On November 18, 2020, the Commission determined to terminate the investigation as to SCC based on settlement. Order No. 18 (Oct. 22, 2020), *unreviewed by* Comm'n Notice (Nov. 18, 2020).

On December 7, 2020, Kirsch filed an unopposed motion to terminate the investigation as to all respondents based on withdrawal of the complaint under Commission Rule 210.21(a)(1) (19 CFR 210.21(a)(1)). Kirsch's motion included a request to stay the procedural schedule pending termination of the investigation. Mot. at 3–4. No party responded to the motion.

On December 9, 2020, the ALJ issued the subject ID granting the unopposed motion. The ID finds that the motion complies with the requirements of Commission Rule 210.21(a)(1) (19 CFR 210.21(a)(1)); that the parties ''appear to agree that there are no extraordinary circumstances'' that would prevent termination; and that terminating the investigation ''is in the public interest.'' ID at 2–3. No petitions for review of the subject ID were filed.

The Commission has determined not to review the subject ID. This investigation is terminated in its entirety.

The Commission vote for this determination took place on December 21, 2020.

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: December 22, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–28778 Filed 12–28–20; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Advanced Media Workflow Association, Inc.

Notice is hereby given that, on December 15, 2020, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Advanced Media Workflow Association, Inc. has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Alpha Video, Eden Prairie, MN; Aperi, Camarillo, CA; NTT Electronics Europe sr, Milano, ITALY; NVIDIA Corporate, Santa Clara, CA; SynaMedia, Lawrenceville, GA; and Telestream, LLC, Nevada City, CA, have been added as parties to this venture.

Also, AXON Digital Design BV, Gilze, NETHERLANDS; Embrionex Design Inc., Laval Quebec, CANADA; Fox NE&O Technology Group, Los Angeles, CA; IML, Seoul, SOUTH KOREA; Mellanox Technologies Inc., Sunnyvale, CA; Nevion Limited, Theale, UNITED KINGDOM; UNIVISION Communications Inc., Miami, FL; and Vidispine, Kista, SWEDEN, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Advanced Media Workflow Association, Inc. intends to file additional written notifications disclosing all changes in membership.

On March 28, 2000, Advanced Media Workflow Association, Inc. filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on June 29, 2000 (65 FR 40127).

The last notification was filed with the Department on September 15, 2020. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on September 29, 2020 (85 FR 61031).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2020–28696 Filed 12–28–20; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Brian M. Manjarres, M.D.; Decision and Order

On September 28, 2020, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, Government), issued an Order to Show Cause (hereinafter, OSC) to Brian M. Manjarres, M.D. (hereinafter, Registrant). OSC, at 1. The OSC proposed the revocation of Registrant's Certificate of Registration No. FM0288363. *Id.* It alleged that Registrant is without ''authority to handle controlled substances in the State of California, the state in which [Registrant is] registered with the DEA.'' *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that on January 1, 2020, Registrant surrendered his medical license ''after the Medical Board of California filed an Accusation against [him] alleging gross negligence, repeated negligent acts, incompetence, and failure to maintain adequate and accurate records in [his] care and treatment of numerous patients, and additionally alleging that [he] self-prescribed controlled substances and engaged in general unprofessional conduct.'' *Id.* at 1–2. The OSC further alleged that because Registrant surrendered his medical license, Registrant lacks the authority to handle controlled substances in the State of California. *Id.* at 2.

The OSC notified Registrant of the right to either request a hearing on the allegations or submit a written statement in lieu of exercising the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* (citing 21 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan. *Id.* at 2–3 (citing 21 U.S.C. 824(c)(2)(C)).

A DEA Diversion Investigator personally served Registrant with the OSC on October 21, 2020, and Registrant signed a DEA Form 12,

Receipt for Cash or Other Items, to acknowledge his receipt of the OSC. Request for Final Agency Action (hereinafter, RFAA) Exhibit (hereinafter, RFAAX) 4, at 1–2 (Declaration of Diversion Investigator), 8 (DEA Form 12 signed by Registrant). I find that more than thirty days have now passed since the Government accomplished service of the OSC. Further, based on the Government's written representations, I find that neither Registrant, nor anyone purporting to represent Registrant, requested a hearing, submitted a written statement while waiving Registrant's right to a hearing ''or otherwise corresponded or communicated with DEA regarding the Order served on him.'' RFAA, at 1. Accordingly, I find that Registrant has waived the right to a hearing and the right to submit a written statement and corrective action plan. 21 CFR 1301.43(d) and 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.46.

I. Findings of Fact

a. Registrant's DEA Registration

Registrant is the holder of DEA Certificate of Registration No. FM0288363 at the registered address of Namaste Medical Group Inc., 1357 7th Avenue, Suite A, San Diego, California, 92101–4381. RFAAX 1 (Certification of Registration Status). Pursuant to this registration, Registrant is authorized to dispense controlled substances in schedules II through V as a practitioner-DW/30. *Id.* Registrant's registration expires on January 31, 2022, and ''is in an active pending status until the resolution of administrative proceedings.'' *Id.*

b. The Status of Registrant's State License

Registrant and the Medical Board of California entered into a Stipulated Surrender of License and Order, whereby Registrant surrendered his California medical license. RFAAX 3. The accusations surrounding the surrender included gross negligence involving the prescribing of controlled substances and self-prescribing controlled substances. *Id.* at 14–60. On December 12, 2019, the Medical Board of California entered an Order adopting the Stipulated Surrender with an effective date of January 1, 2020. *Id.* at 1. The Medical Board of California's online records, of which I take official notice, document that Registrant's license is still surrendered.[1] Medical Board of California License Verification, *https://www.mbc.ca.gov/Breeze/License_Verification.aspx* (last visited date of signature of this Order).

Accordingly, I find that Registrant currently is not licensed to engage in the practice of medicine in California, the state in which Registrant is registered with the DEA.

II. Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the CSA ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71,371 (2011), *pet. for rev. denied,* 481 Fed. Appx. 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27,616, 27,617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper,* 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.,* 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton,* 43 FR at 27,617.

According to California statute, ''[n]o person other than a physician . . . shall write or issue a prescription.'' Cal. Health & Safety Code § 11150 (West 2020). Further, ''physician,'' as defined by California statute, is a person who is ''licensed to practice'' in California. *Id.* at § 11024.

Here, the undisputed evidence in the record is that Registrant currently lacks authority to practice medicine in California. As already discussed, a physician must be a licensed practitioner to dispense a controlled substance in California. Thus, because Registrant lacks authority to practice medicine in California and, therefore, is not authorized to handle controlled substances in California, Registrant is not eligible to maintain a DEA registration. Accordingly, I will order that Registrant's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. FM0288363 issued to Brian M. Manjarres, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. § 823(f), I hereby deny any pending application of Brian M. Manjarres, M.D. to renew or modify this registration or for any other registrations in the State of California. This Order is effective January 28, 2021.

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–28677 Filed 12–28–20; 8:45 am]

BILLING CODE 4410–09–P

[1] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Registrant may dispute my finding by filing a properly supported motion for reconsideration within fifteen calendar days of the date of this Order. Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the Government. In the event Registrant files a motion, the Government shall have fifteen calendar days to file a response. Any such motion and response may be filed and served by email (*dea.addo.attorneys@dea.usdoj.gov*).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Irene G. Gurvits, M.D.; Decision and Order

On August 19, 2020, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, Government), issued an Order to Show Cause (hereinafter, OSC) to Irene G. Gurvits, M.D. (hereinafter, Registrant). OSC, at 1. The OSC proposed the revocation of Registrant's Certificate of Registration No. BG6075875. *Id.* It alleged that Registrant is without ''authority to handle controlled substances in the State of New York, the state in which [Registrant is] registered with the DEA.'' *Id.* at 2 (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that on May 26, 2020, ''the New York State Board for Professional Medical Conduct issued a Determination and Order revoking [Registrant's] license to practice medicine in the State of New York.'' *Id.* The OSC further alleged that because Registrant's medical license was revoked, Registrant lacks the authority to handle controlled substances in the State of New York. *Id.*

The OSC notified Registrant of the right to either request a hearing on the allegations or submit a written statement in lieu of exercising the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* (citing 21 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan. *Id.* at 3 (citing 21 U.S.C. 824(c)(2)(C)).

A DEA Diversion Investigator (hereinafter, DI) personally served Registrant with the OSC on August 31, 2020, at her home address, which is also the mail address on her registration. Request for Final Agency Action (hereinafter, RFAA) Exhibit (hereinafter, RFAAX) 4, at 1–2 (Declaration of DI). The DI stated that after the DI explained the purpose of the Order, Registrant ''refused to accept the Order and slammed the door shut.'' *Id.* The DI slipped the envelope with the Order under Registrant's door and ''Registrant then opened the door and [the DI] again explained the purpose of the Order. Registrant took the envelope containing the signed Order from underneath the door and immediately closed the door.'' *Id.*

I find that more than thirty days have now passed since the Government accomplished service of the OSC. Further, based on the Government's written representations, I find that neither Registrant, nor anyone purporting to represent Registrant, requested a hearing, submitted a written statement while waiving Registrant's right to a hearing ''or otherwise corresponded or communicated with DEA regarding the Order served on her.'' RFAA, at 1. Accordingly, I find that Registrant has waived the right to a hearing and the right to submit a written statement and corrective action plan. 21 CFR 1301.43(d) and 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.46.

I. Findings of Fact

a. Registrant's DEA Registration

Registrant is the holder of DEA Certificate of Registration No. BG6075875 at the registered address of 102 West 75 St., Suite 107, New York, NY 10023. RFAAX 1 (Certification of Registration Status). Pursuant to this registration, Registrant is authorized to dispense controlled substances in schedules II through V as a practitioner-DW/30. *Id.* Registrant's registration expires on September 30, 2022, and ''is in an active pending status until the resolution of administrative proceedings.'' *Id.*

b. The Status of Registrant's State License

The State of New York Department of Health State Board for Professional Conduct (hereinafter, the Board) entered a Determination and Order on May 26, 2020, revoking Registrant's medical license effective upon service on Registrant. RFAAX 3 (Board Order), at 8. The State of New York's online records, of which I take official notice, document Registrant's license status as ''license revoked.'' [1] New York Office of the Professions, Verification Searches, *http://www.op.nysed.gov/opsearches.htm#* (last visited date of signature of this Order).

Accordingly, I find that Registrant currently is not licensed to engage in the practice of medicine in New York, the state in which Registrant is registered with the DEA.

II. Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the CSA ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71,371 (2011), *pet. for rev. denied,* 481 Fed. Appx. 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27,616, 27,617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper,* 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.,* 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton,* 43 FR at 27,617.

[1] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Registrant may dispute my finding by filing a properly supported motion for reconsideration within fifteen calendar days of the date of this Order. Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the Government. In the event Registrant files a motion, the Government shall have fifteen calendar days to file a response. Any such motion and response may be filed and served by email (*dea.addo.attorneys@dea.usdoj.gov*).

According to the New York Controlled Substances Act (hereinafter, the Act), ''[i]t shall be unlawful for any person to manufacture, sell, prescribe, distribute, dispense, administer, possess, have under his control, abandon, or transport a controlled substance except as expressly allowed by this article.'' N.Y. Pub. Health Law § 3304 (West 2020). The Act defines ''practitioner,'' as ''a physician . . . or other person licensed, or otherwise permitted to dispense, administer, or conduct research with respect to a controlled substance in the course of a licensed professional practice. . . .'' *Id.* at § 3302(29). Finally, New York regulations state that ''[a] prescription for a controlled substance may be issued only by a practitioner who is . . . authorized to prescribe controlled substances pursuant to his licensed professional practice . . .'' N.Y. Comp. Codes R. & Regs. Tit. 10, § 80.64 (West 2020).

Here, the undisputed evidence in the record is that Registrant currently lacks authority to practice medicine in New York. As already discussed, a physician must be a licensed practitioner to dispense a controlled substance in New York. Thus, because Registrant lacks authority to practice medicine in New York and, therefore, is not authorized to handle controlled substances in New York, Registrant is not eligible to maintain a DEA registration. Accordingly, I will order that Registrant's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. BG6075875 issued to Irene G. Gurvits, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Irene G. Gurvits, M.D. to renew or modify this registration or for any other registrations in the State of New York. This Order is effective January 28, 2021.

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–28683 Filed 12–28–20; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 18–33]

Steven M. Kotsonis, M.D.; Order

On May 3, 2018, the Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (hereinafter, DEA or Government) issued an Order to Show Cause (hereinafter, OSC) to Steven M. Kotsonis, M.D. (hereinafter, Respondent), which sought to revoke Respondent's DEA Certificate of Registration FK1584336 and to deny any pending applications for renewals or modifications of such registration, based on its contention that his continued registration is inconsistent with the public interest. Administrative Law Judge Exhibit (ALJX) 1 (OSC). In response to the OSC, Respondent submitted a timely request for a hearing, which was held from August 14–17, 2018. On October 23, 2018, Chief Administrative Law Judge John J. Mulrooney, II issued a Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter, Recommended Decision), which recommended that I revoke Respondent's registration and that I deny any pending application for renewal. Respondent filed Exceptions to the Recommended Decision, and the record was forwarded to me for final Agency action on November 26, 2018.

After reviewing the record, I learned that Respondent had surrendered his DEA registration on December 23, 2019. I issued an Order on September 25, 2020, requiring the Government to produce documentation of Respondent's surrender of his registration. The Order further instructed the parties to file a Request for Dismissal ''if it is the intent of [the] party to rely on Respondent's voluntary surrender of his registration to terminate this proceeding'' or a brief on the issue ''if [the] party opposes the dismissal of this proceeding prior to the issuance of my Decision on the Government's allegation in the OSC.'' Both parties filed timely responses.

Respondent filed a Request for Dismissal on October 15, 2020. As grounds for the dismissal, Respondent stated that, ''upon DEA request, he voluntarily surrendered his DEA registration on December 23, 2019.'' Respondent Request for Dismissal.

The Government submitted a response to my September 25 Order on October 23, 2020 (hereinafter, the Government Response). As required by my September 25 Order, the Government submitted a copy of the Voluntary Surrender of Controlled Substances Privileges form, DEA–104, signed by Respondent surrendering DEA Registration No. FK1584336. The Government stated that Respondent voluntarily surrendered his DEA registration following a guilty plea to felony criminal drug charges in a criminal matter concurrent to the instant matter. Government Response at 2. The Government Response neither requested that I dismiss this matter nor that I file a final Decision on the allegations it made in the OSC. Rather, the Government provided legal arguments regarding why Respondent's voluntary surrender of his registration did not preclude me from issuing a final Decision. *Id.* at 2–3. The Government then concluded its Response stating that I ''should issue whatever order is appropriate in light of the administrative record presented.'' *Id.* at 3.

Based upon my review of the parties' submissions, the record, and public documents from Respondent's criminal case, I am granting Respondent's Request for Dismissal.

Facts

Respondent was registered with DEA as a practitioner in schedules II through V under Certificate of Registration No. FK1584336, at the registered address of 347 Park Ave., Pewaukee, Wisconsin 53702. OSC at 1. In its OSC, the Government contended that Respondent's registration was inconsistent with the public interest and should be revoked because Respondent failed to comply with applicable federal law relating to controlled substances. *Id.* at 1–2. Specifically, the OSC alleged that Respondent issued prescriptions for controlled substances outside the usual course of professional practice and not for a legitimate medical purpose, in violation of 21 CFR 1306.04(a). *Id.* at 2.

On December 23, 2019, Respondent voluntarily surrendered his DEA registration. Government Response, Attachment 1 (DEA Form 104 signed by Respondent). In his surrender form, Respondent affirmed that he was voluntarily surrendering his registration for cause ''[i]n view of [his] alleged failure to comply with the Federal requirements pertaining to controlled substances.'' *Id.* Respondent also acknowledged that submitting the form to DEA would result in the immediate termination of his registration. *Id.*

The Government stated in its Response that Respondent surrendered his DEA registration ''following a guilty plea to felony criminal drug charges in [a] concurrent criminal matter.''

Government Response, at 1–2. According to the publicly available records from the Respondent's concurrent criminal matter, *U.S.* v. *Steven M. Kotsonis,* No. 2:16–CR–92 (E.D. Wis. filed July 21, 2016), Respondent was criminally indicted on June 21, 2016, on twenty counts alleging violations of the Controlled Substances Act, specifically 21 U.S.C. 841(a)(1), (b)(1)(C), and 846.[1] Respondent pled guilty to one count, Count 17, of the indictment for ''dispensing unlawfully a controlled substance outside a professional medical practice and not for a legitimate medical purpose'' in violation of 21 U.S.C. 841(a)(1) and (b)(1)(C). Judgment, at 1, *Kotsonis,* No. 2:16–cr–92.

Attachment A of the Plea Agreement, which I have attached to this Order, provides a narrative of the factual basis for Respondent's guilty plea.[2] Plea Agreement, at 13–15, *Kotsonis,* No. 2:16–cr–92. In brief summary, Respondent admitted that the clinic he co-owned, and at which he was the exclusive health care provider, only accepted cash, that individuals payed $200 to $350 in cash to obtain a prescription, that ''[p]rescriptions were written for large quantities of Oxycodone, particularly Oxycodone 30 mg (average of 150–180 tablets per month), along with other narcotic medications commonly prescribed for pain relief such as amphetamine and morphine,''[3] and that ''[i]ndividuals frequently obtaine[ed] prescriptions at [his clinic] without being examined or having their vitals (height, weight, blood pressure) taken during the visit.'' *Id.* at 13. Respondent also admitted to signing controlled substance prescriptions prepared by his office manager, who was not a licensed health care provider, without examining the patients or reviewing the patients' files. *Id.* at 13 and 15. In regard to the specific count to which Respondent pled guilty, Count 17 of the indictment, Respondent admitted that on January 31, 2013, he signed a prescription for 90 tablets of Oxycodone 30 mg for ''Patient D'' that the clinic's office manager prepared and that he did so without seeing Patient D. *Id.* at 14. When Patient D was interviewed regarding Respondent's clinic, she stated that, despite having visited the clinic and received prescriptions for Oxycodone on four prior occasions, ''she did not see [Respondent], did not have vitals taken, did not receive any type of medical exam, and did not submit a urine screening.'' *Id.* at 13.

Discussion

DEA regulations promulgated pursuant to the authority delegated by the Controlled Substances Act (CSA) provide that ''the registration of any person . . . shall terminate, without any further action by the Administration, if and when such person . . . surrenders a registration.'' 21 CFR 1301.52. As Respondent surrendered his DEA registration on December 23, 2019, pursuant to the regulation, his registration terminated on the day of his surrender, and Respondent is no longer authorized to dispense controlled substances under federal law.

The termination of Respondent's registration, however, does not automatically terminate this proceeding. Although factually distinct from registrations terminated through a voluntary surrender, DEA has issued final decisions revoking registrations subsequent to their expirations, and the legal reasoning for the Agency's ability to issue decisions in those matters is applicable here. As my predecessor explained in *Jeffrey Olsen, M.D.,* in which he ordered the revocation of an expired registration, ''mootness does not play the same role in administrative agency adjudications as it plays in Article III court proceedings'' and '' '[t]he agency, with like effect as in the case of other orders, and in its sound discretion, may issue a declaratory order to terminate a controversy or remove uncertainty.' '' 84 FR 68,474, 68,478 (2019) (quoting *Tennessee Gas Pipeline* v. *Federal Power Comm'n,* 606 F.2d 1373, 1380 (D.C. Cir. 1979); 5 U.S.C. 554(e)); *see also Climax Molybdenum Co.* v. *Sec'y of Labor, Mine Safety and Health Admin.,* 703 F.2d 447, 451 (10th Cir. 1983) (''At the outset, we note that an administrative agency is not bound by the constitutional requirement of a 'case or controversy' that limits the authority of [A]rticle III courts to rule on moot issues.''). DEA is therefore not precluded from issuing a final decision revoking a registration that was voluntarily surrendered even though that registration is terminated.

As my predecessor identified in *Olsen,*

> [F]inal adjudications are particularly helpful in supporting the purposes of the CSA and my responsibilities to enforce the CSA because nothing in the CSA prohibits an individual or an entity from applying for a registration even when there is a history of being denied a registration, or a history of having a registration suspended or revoked. As such, having a final, official record of allegations, evidence, and the Administrator's decisions regarding those allegations and evidence, assists and supports future interactions between the Agency and the registrant or applicant.

84 FR at 68,479. As additionally noted in *Olsen,* ''a final adjudication is a public record of the Agency's expectations for current and prospective members of that community.'' *Id.* Final adjudications also provide continuing education for all DEA personnel and help coordinate law enforcement efforts. *Id.* Finally, final adjudications inform stakeholders, such as legislators and the public, about the Agency's work and allows them to provide feedback to the Agency, thereby helping shape how the Agency carries out its responsibilities under the CSA. *Id.*

Since *Olsen* was decided, the Agency has universally issued final adjudications in cases where a registration expired while a proceeding to revoke the registration was pending before the Administrator. *See, e.g., Salvatore Cavaliere,* D.O., 85 FR 45,657 (2020); *Jaime C. David,* M.D., 85 FR 10,462 (2020); *Jeanne E. Germeil, M.D.,* 85 FR 73,786 (2020). I recognize, however, that a voluntary surrender for cause of a registration that is executed while the matter is pending before the Administrator can be distinct from the expiration of a registration, depending on the circumstances particular to a matter, and that the aforementioned benefits obtained by a final Agency adjudication could be diminished by those circumstances. I also recognize that the voluntary surrender for cause is an essential tool in preserving Agency enforcement resources and in preventing the misuse of a registration during the pending enforcement action. However, it would be contrary to my duties under the CSA to allow the usurpation of the Agency's enforcement mission by permitting the unilateral

[1] I am taking official notice of the docket and two documents from Respondent's criminal matter, the Plea Agreement and the Judgment. *Kotsonis,* No. 2:16–cr–92. Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Respondent may dispute my finding by filing a properly supported motion for reconsideration of finding of fact within fifteen calendar days of the date of this Order. Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the Government. In the event Respondent files a motion, the Government shall have fifteen calendar days to file a response. Any such motion and response may be filed and served by email (*dea.addo.attorneys@dea.usdoj.gov*).

[2] Respondent admitted that the facts in Attachment A are true and ''establish his guilt beyond a reasonable doubt.'' Plea Agreement, at 2, *Kotsonis,* No. 2:16–cr–92.

[3] Oxycodone is a schedule II controlled substance. 21 CFR 1308.12(1).

execution of a voluntary surrender for cause by a registrant after the registrant has availed himself of the hearing process and, particularly where he obtained an unfavorable recommendation from an Administrative Law Judge; and therefore, I find that it is most reasonable to assess whether to adjudicate particular matters to finality based on the particular circumstances presented by the matters.

Based on my evaluation of the record in this matter, I have decided that the benefits to issuing a final adjudication in this matter are diminished by the particular circumstances, and as such, I am dismissing this matter. Here, Respondent voluntarily surrendered his registration for cause concurrent with his guilty plea to a felony, thereby acknowledging that the surrender was ''[i]n view of [his] alleged failure to comply with the Federal requirements pertaining to controlled substances.'' Government Response, Attach. 1. The Judgment from Respondent's concurrent criminal case provides a record of Respondent's criminal violation of the CSA for issuing a prescription for a controlled substance outside the usual course of professional practice and without a legitimate medical purpose, and the Plea Agreement provides an official record of the details of Respondent's criminal violation. I find that these records provide many of the same benefits that a final Decision would provide in this matter—they will assist and support any future interactions between the Agency and Respondent including by providing the Agency with facts that may be relevant should Respondent re-apply for a registration in the future; they provide a public record regarding the Agency's expectations of registrants; they inform stakeholders about the Agency's work; and they enable me to allocate Agency resources efficiently and effectively. Accordingly, I find that it is in the Agency's interest to dismiss this matter without my issuing a final Decision on the Government's request to revoke Respondent's registration, and I will grant Respondent's Request for Dismissal.

My decision to dismiss this matter should not be interpreted as applying unilaterally to all matters seeking revocation of a registration in which a registrant surrenders their license while the matter is pending before me. The Agency expends considerable resources investigating and adjudicating these matters, not every matter will have such a robust record absent a final adjudication, and each matter is unique. I will, therefore, continue to evaluate such matters on a case-by-case basis to determine if a final adjudication is warranted.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824, I hereby dismiss the Order to Show Cause issued to Steven M. Kotsonis, M.D. This Order is effective immediately.

Timothy J. Shea,

Acting Administrator.

Attachment A

This investigation began in 2012 and arose in connection with the investigation of Dr. Beaver who operated Beaver Medical Clinic. In April of 2012, Dr. Beaver voluntarily surrendered his DEA registration for cause based upon allegations of improper prescribing of controlled substances and Dr. Beaver's Wisconsin medical license was limited to preclude him from prescribing controlled substances. In May of 2012, Dr. Kotsonis began working at Beaver Medical Clinic and DEA Investigators met with Kotsonis to notify him of DEA's concerns that narcotics prescribed at Beaver Medical Clinic were frequently being sold by patients. During this meeting, Kotsonis acknowledged that Moyer, who was the office manager at Beaver Medical Clinic at the time, sometimes prepared prescriptions for him, and he agreed with Investigators when they suggested that Kotsonis himself should prepare the prescriptions.

Sometime prior to December of 2012, Kotsonis relocated his practice to 10721 W Capitol Drive, Office G103, Wauwatosa, Wisconsin, and changed the name of the practice to Compassionate Care Clinic. Moyer continued to work for Kotsonis as the officer manager of the Compassionate Care Clinic (''Compassionate'') and also, at some point, became the co-owner of Compassionate. Moyer is not a licensed health care provider and there are no other licensed physicians, nurses, or other health care providers working at Compassionate aside from Kotsonis.

The investigation of Compassionate has revealed that only cash is accepted and individuals pay $200 to $350 in cash to obtain a prescription. Prescriptions are written for large quantities of Oxycodone, particularly Oxycodone 30mg (average of 150–180 tablets per month), along with other narcotic medications commonly prescribed for pain relief such as amphetamine and morphine. Moyer typically fills out the prescriptions and has Kotsonis sign the prescriptions without Kotsonis actually seeing the individual patient. Individuals frequently obtain prescriptions at Compassionate without being examined or having their vitals (height, weight, blood pressure) taken during their visit.

For example, in January 2013, CS #1 a/k/a Patient ''D,'' was interviewed regarding Compassionate. CS #1 stated that she was brought to Compassionate by her friend, who was addicted to Oxycodone, and CS #1 was introduced to Moyer by her friend as a new patient. CS #1 stated that she visited Compassionate on approximately 4 occasions and CS #1's friend went with her on every occasion but one. CS #1's friend paid for the appointment fee and in return received a portion of CS #1's pills. CS #1's friend also brought other individuals to Compassionate to obtain Oxycodone prescriptions. CS #1 provided MRI's regarding back issues from 2006 to 2008 to Moyer and was accepted as a patient. CS #1 stated that she received prescriptions ranging from 150–210 tablets of Oxycodone 30 mg at each of her visits to Compassionate. During the visits CS #1 did not see Kotsonis, did not have vitals taken, did not receive any type of medical exam, and did not submit a urine screening. CS #1 received prescriptions from Moyer, who prepared the prescriptions and took the prescriptions to Kotsonis for signature. During the visits, Moyer asked CS #1 a few questions about pain and CS #1 stated she had back pain. CS #1 filled out a form regarding pain during each visit. On one occasion CS #1 and her friend went to a visit early and said they were driving to Florida. Moyer asked what they were prescribed last time and CS #1 said 180 tablets of Oxycodone 30mg. Moyer told CS #1 that she would write the prescription for 210 tablets because of the long drive to Florida. Moyer wrote the prescriptions out in the waiting room because they were already signed by Kotsonis. CS #1 stated that during the visits she witnessed Moyer take the patient sign-in sheet, write the individuals' names and dates of birth on the prescriptions (sometimes written in the waiting room) and take the stack of prescriptions to Kotsonis's office for signature. Moyer then saw the individuals and wrote the quantities on the prescription. The waiting room was always full with approximately 15 individuals in the waiting room and approximately 5 individuals waiting outside the waiting room in the hallway.

Count Seventeen: On January 31, 2013, CS #1 and an undercover agent (UC #1) visited Compassionate and this visit is audio and video recorded.

During the visit, CS #1 filled out a two-page pain form and CS #1 and UC #1 signed in on the patient sign-in sheet. During the visit, Moyer stood next to the patient sign-in sheet and wrote down names on a prescription pad from the sign-in sheet and she asked some of the individuals for their date of birth and which drug they were prescribed. Moyer entered Kotsonis's office carrying the handwritten prescriptions and exited minutes later. The individuals were provided prescriptions and many did not see Kotsonis. During the visit, Moyer called CS #1 and UC #1 into her office. UC #1 did not see any medical equipment in the office. Moyer asked CS #1 to tell the truth about her current criminal charges. Moyer said she would have to cut CS #1 loose but would give CS #1 a prescription. Moyer said DEA would say what kind of people CS #1 was hanging out with and then ''bye bye clinic, bye bye license, bye bye Dr. Steve's career'' because DEA would go after the doctor. Moyer said if CS #1's criminal charges were dropped she could come back to the clinic. Moyer said CS #1's friend (who referred CS #1 to the clinic) was dumb because he sold pills to an undercover cop. Moyer asked CS #1 for her name and date of birth and wrote CS #1 a prescription for 90 tablets of Oxycodone 30mg, which Moyer took to Kotsonis to sign. CS #1 paid Moyer $200 cash for the visit. Moyer asked CS #1 if she knew what people called Moyer. CS #1 said no and Moyer responded ''The Oxy Czar.'' ''They call me the gestapo because if you screw up the world will stop, so don't screw up.'' Moyer then continued to fill out additional prescriptions.

CS #1 asked Moyer if UC #1 could be accepted as a patient and she said everyone who came with CS #1 would have to be rescreened (because of CS #1's criminal charges). Moyer then looked over the MRIs provided by UC #1 and said the second MRI looked a little better than the first. Moyer said she would show the MRIs to the doctor. Moyer opened her desk drawer and pulled out a handful of prescriptions, papers, and cash, then put everything back in the drawer and said ''This is a nasty little business we're in.'' Moyer then said ''I own this clinic now, and I don't have to be nice. I don't have to let just anybody in neither. It's my clinic, me and the doctor's clinic, I don't have to let anybody in. And I won't, if I think they're a problem. No way, why would I? Are you kidding? This is a big business here.'' She told UC #1 that the first office visit was $350 and UC #1 could come alone next time and asked him/her to bring prescription records. UC #1 was given a longer version of the pain form provided to CS #1 earlier in the visit to bring back with her to the next visit. Moyer exited her office, called out CS #1's name along with five other names and said she would get the prescriptions signed. Moyer then entered Kotsonis's office and approximately four minutes later she exited Kotsonis's office and handed out the prescriptions. CS #1 and UC #1 then made their next appointment with the receptionist.

On July 23, 2013, a search warrant was executed at Compassionate Care Clinic and Kotsonis' patient files were seized along with other evidence. Patient files, computers, Moyer's cellphone and pre-signed prescriptions (containing the doctor's signature only), filled out prescriptions without signature and ripped up prescriptions were recovered from Moyer's office. Agents also recovered a letter from Costco refusing to fill Dr. Kotsonis' prescriptions and an Express Scripts letter regarding excessive medication prescribed to a patient as well as prefilled out monthly evaluation notes. Agents observed minimal medical equipment in the clinic. During the execution of the search warrant Kotsonis agreed to be interviewed and was advised he was not under arrest. Kotosnis admitted to allowing Moyer to prepare prescriptions that he subsequently signs and said she brings in prescriptions 3–4 patients at a time and that he trusts Moyer's advice on what medication should be prescribed and generally agrees with her. Kotsonis stated most of the time he verifies what prescription the patient is receiving. He stated that if Moyer does not bring the patient file to his office with the prescription to verify he trusts what she says the patient is receiving. Kotsonis estimated 20–25 patients per day are follow up patients and Moyer brings 10–12 patient charts to Kotsonis a day and Kotsonis actually sees and examines 1–2 patients per day. Moyer was also interviewed and stated the she and Kotsonis discuss patients but he determines what to prescribe. She stated she writes out prescriptions before the patients are seen based upon their last prescription but does not write down a quantity.

[FR Doc. 2020–28676 Filed 12–28–20; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Annamalai Ashokan, M.D.; Decision and Order

On June 1, 2020, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, Government), issued an Order to Show Cause (hereinafter, OSC) to Annamalai Ashokan, M.D. (hereinafter, Registrant). OSC, at 1. The OSC proposed the revocation of Registrant's Certificate of Registration No. BA0859174. *Id.* It alleged that Registrant is without ''authority to handle controlled substances in the State of California, the state in which [Registrant is] registered with the DEA.'' *Id.* at 1–2 (citing 21 U.S.C. 824(a)(3)).

Specifically, the OSC alleged that Registrant surrendered his medical license pursuant to an agreement he entered into with the Medical Board of California on November 12, 2019, and that his license remains surrendered. *Id.* at 1–2. The OSC further alleged that because Registrant surrendered his medical license, Registrant lacks the authority to handle controlled substances in the State of California. *Id.* at 2.

The OSC notified Registrant of the right to either request a hearing on the allegations or submit a written statement in lieu of exercising the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* (citing 21 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan. *Id.* at 3 (citing 21 U.S.C. 824(c)(2)(C)).

On June 4, 2020, a DEA Diversion Investigator placed a copy of the OSC addressed to the Registrant in his ''office's outgoing mail pickup box for pickup by DEA mailroom staff that day. The letter would have been placed in the United States mail by DEA's mailroom staff no later than the following day, June 5, 2020.'' Request for Final Agency Action (hereinafter, RFAA) Exhibit (hereinafter, RFAAX) 4, at 1 (Declaration of Diversion Investigator). Registrant's attorney sent a letter, dated July 22, 2020, to the Assistant Administrator, Diversion Control Division, stating that Registrant had surrendered his medical license and that ''he hereby waives his right to a hearing on this matter.'' RFAAX 5 (Letter from Registrant's Attorney), at 1. I find that more than thirty days have now passed since the Government accomplished service of the OSC.

Further, based on the Government's written representations, I find that neither Registrant, nor anyone purporting to represent Registrant, requested a hearing, submitted a written statement while waiving Registrant's right to a hearing, or submitted a corrective action plan. Further, I find that Registrant, through counsel, explicitly waived his right to a hearing. RFAA, at 2; RFAAX 5. Accordingly, I find that Registrant has waived the right to a hearing and the right to submit a written statement and corrective action plan. 21 CFR 1301.43(d) and 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.46.

I. Findings of Fact

a. Registrant's DEA Registration

Registrant is the holder of DEA Certificate of Registration No. BA0859174 at the registered address of 581 McCray Street, Suite E, Hollister, CA 95023. RFAAX 1 (Certification of Registration Status). Pursuant to this registration, Registrant is authorized to dispense controlled substances in schedules II through V as a practitioner-DW/30. *Id.* Registrant's registration will expire on June 30, 2021. *Id.*

b. The Status of Registrant's State License

On November 12, 2019, Registrant and the Medical Board of California entered into a Stipulated Surrender of License and Order, whereby Registrant surrendered his California medical license. RFAAX 3. The accusations surrounding the surrender included unprofessional conduct involving the prescription of controlled substances. *Id.* at 12–14. On November 20, 2019, the Medical Board of California entered an Order adopting the Stipulated Surrender with an effective date of November 27, 2019. *Id.* at 1. The Medical Board of California's online records, of which I take official notice, document that Registrant's license is still surrendered.[1] Medical Board of California License Verification, *https://www.mbc.ca.gov/Breeze/License_Verification.aspx* (last visited date of signature of this Order).

Accordingly, I find that Registrant currently is not licensed to engage in the practice of medicine in California, the state in which Registrant is registered with the DEA.

II. Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the CSA ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71371 (2011), *pet. for rev. denied,* 481 Fed. Appx. 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27616, 27617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper,* 76 FR at 71371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39130, 39131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51104, 51105 (1993); *Bobby Watts, M.D.,* 53 FR 11919, 11920 (1988); *Frederick Marsh Blanton,* 43 FR at 27617.

According to California statute, ''[n]o person other than a physician . . . shall write or issue a prescription.'' Cal. Health & Safety Code § 11150 (West 2020). Further, ''physician,'' as defined by California statute, is a person who is ''licensed to practice'' in California. *Id.* at § 11024.

Here, the undisputed evidence in the record is that Registrant currently lacks authority to practice medicine in California. As already discussed, a physician must be a licensed practitioner to dispense a controlled substance in California. Thus, because Registrant lacks authority to practice medicine in California and, therefore, is not authorized to handle controlled substances in California, Registrant is not eligible to maintain a DEA registration. Accordingly, I will order that Registrant's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. BA0859174 issued to Annamalai Ashokan, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. § 823(f), I hereby deny any pending application of Annamalai Ashokan, M.D. to renew or modify this registration or for any other registrations in the State of California. This Order is effective January 28, 2021.

Timothy J. Shea,

Acting Administrator.

[FR Doc. 2020–28678 Filed 12–28–20; 8:45 am]

BILLING CODE 4410–09–P

[1] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Registrant may dispute my finding by filing a properly supported motion for reconsideration within fifteen calendar days of the date of this Order. Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the Government. In the event Registrant files a motion, the Government shall have fifteen calendar days to file a response. Any such motion and response may be filed and served by email (*dea.addo.attorneys@dea.usdoj.gov*).

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation and Liability Act

On December 18, 2020, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Southern of Texas in the lawsuit entitled *United States* v. *Allied Transportation Company, et al.,* Civil Action No. 3:20–cv–382.

The United States filed a Complaint against the defendants pursuant to Sections 106 and 107 of the Comprehensive Environmental

Response, Compensation and Liability Act (''CERCLA''), 42 U.S.C. ¶ 9606, 9607. The Complaint seeks, *inter alia,* injunctive relief to perform a cleanup at the Gulfco Marine Maintenance NPL site (''Site''), an inactive barge facility located in Freeport, Brazoria County, Texas, and recovery of costs incurred by the United States in responding to the release of hazardous substances at the Site. Under the proposed Consent Decree, the Defendants will implement a remedy for ground water contamination that was selected by EPA on September 29, 2011. The Defendants will also pay past response costs in the amount of $1.2 million and reimburse the United States for future response costs.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Allied Transportation Company, et al.,* D.J. Ref. No. 90–11–2–09587. 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 Consent Decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Consent Decree 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 or money order for $111.50 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy without the exhibits and signature pages, the cost is $19.75.

Karen Dworkin,

Deputy Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2020–28744 Filed 12–28–20; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Affirmative Action Program Verification Interface

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Office of Federal Contract Compliance Programs (OFCCP)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before January 28, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Anthony May by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: OFCCP administers and enforces three equal employment opportunity laws:

- Executive Order 11246, as amended (E.O. 11246);
- Section 503 of the Rehabilitation Act of 1973, as amended (Section 503);
- Vietnam Era Veterans' Readjustment Assistance Act of 1974, as amended (VEVRAA).

These authorities prohibit employment discrimination by covered federal contractors and subcontractors and require that they provide equal employment opportunities regardless of race, color, religion, sex, sexual orientation, gender identity, national origin, disability, or status as a protected veteran. Additionally, federal contractors and subcontractors are prohibited from discriminating against applicants and employees for inquiring about, discussing, or disclosing information about their pay or the pay of their co-workers, subject to certain limitations. E.O. 11246's basic coverage applies to federal contractors and subcontractors and to federally assisted construction contractors holding a government contract in excess of $10,000, or government contracts that have, or can reasonably be expected to have, an aggregate total value exceeding $10,000 in a 12-month period. E.O. 11246 also applies to government bills of lading, depositories of federal funds in any amount, and to financial institutions that are issuing and paying agents for U.S. Savings Bonds. E.O. 11246's Affirmative Action Program (AAP) requirements apply to federal contractors and subcontractors with 50 or more employees and a contract of $50,000 or more. Section 503 prohibits employment discrimination against applicants and employees because of physical or mental disability and requires affirmative action to ensure that persons are treated without regard to disability. Section 503 applies to federal contractors and subcontractors with contracts in excess of $15,000, and its AAP coverage applies to federal contractors and subcontractors with 50 or more employees and a contract of $50,000 or more. VEVRAA prohibits employment discrimination against protected veterans and requires affirmative action to ensure that persons are treated without regard to their status as a protected veteran. VEVRAA applies to federal contractors and subcontractors with contracts of $150,000 or more, and its AAP coverage applies to federal contractors and subcontractors with 50 or more employees and a contract of $150,000 or more. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on September 14, 2020 (85 FR 56635).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition,

notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–OFCCP.

Title of Collection: Affirmative Action Program Verification Interface.

OMB Control Number: 1250–0NEW.

Affected Public: Private Sector—Businesses or other for-profits.

Total Estimated Number of Respondents: 116,898.

Total Estimated Number of Responses: 116,898.

Total Estimated Annual Time Burden: 48,509 hours (first year); 13,791 (subsequent/ongoing years).

Total Estimated Annual Other Costs Burden: $0.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: December 18, 2020.

Anthony May,

Management and Program Analyst.

[FR Doc. 2020–28679 Filed 12–28–20; 8:45 am]

BILLING CODE 4510–CM–P

OFFICE OF MANAGEMENT AND BUDGET

Discount Rates for Cost-Effectiveness Analysis of Federal Programs

AGENCY: Office of Management and Budget

ACTION: Revisions to Appendix C of OMB Circular A–94

SUMMARY: The Office of Management and Budget (OMB) revised Circular A–94 in 1992. With this action, OMB has revised the Circular and specified certain discount rates to be updated annually when the interest rate and inflation assumptions used to prepare the Budget of the United States Government were changed. These updated discount rates are found in Appendix C of the revised Circular and are to be used for cost-effectiveness analysis, including lease-purchase analysis, as specified in the revised Circular. These rates do not apply to regulatory analysis.

The revised Circular can be accessed at *https://www.whitehouse.gov/wp-content/uploads/2020/12/Appendix-C.pdf.*

DATES: The revised discount rates will be in effect through December 2021.

FOR FURTHER INFORMATION CONTACT: Rachel Hernández, Office of Economic Policy, Office of Management and Budget, (202) 395–3585.

Gideon Lukens,

Deputy Associate Director for Economic Policy.

[FR Doc. 2020–28650 Filed 12–28–20; 8:45 am]

BILLING CODE 3110–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2020–0162]

Information Collection: Voluntary Reporting of Planned New Reactor Applications

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, ''Voluntary Reporting of Planned New Reactor Applications.''

DATES: Submit comments by March 1, 2021. 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–2020–0162. Address questions about Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@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. Nuclear Regulatory Commission, 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–2020–0162 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–2020–0162. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2020–0162 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 collection of information and related instructions may be obtained without charge by accessing ADAMS Accession No. ML20198M495. The supporting statement is available in ADAMS under Accession No. ML20198M418.
- *Attention:* The PDR, where you may examine and order copies of public documents is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), 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–2020–0162 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:* Voluntary Reporting of Planned New Reactor Applications.
2. *OMB approval number:* 3150–0228.
3. *Type of submission:* Extension.
4. *The form number, if applicable:* N/A.
5. *How often the collection is required or requested:* Annually.
6. *Who will be required or asked to respond:* Applicants, licensees, and potential applicants report this information on a strictly voluntary basis.
7. *The estimated number of annual responses:* 20.
8. *The estimated number of annual respondents:* 20.
9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 610.
10. *Abstract:* This voluntary information collection assists the NRC in determining resource and budget needs as well as aligning the proper allocation and utilization of resources to support applicant submittals, future construction-related activities, and other anticipated part 50 and/or part 52 of title 10 of the *Code of Federal Regulations* (10 CFR) licensing and design certification rulemaking actions. In addition, information provided to the NRC staff is intended to promote early communications between the NRC and the respective addressees about potential 10 CFR part 50 and/or part 52 licensing actions and related activities, submission dates, and plans for construction and inspection activities. The overarching goal of this information collection is to assist the NRC staff more effectively and efficiently plan, schedule, and implement activities and reviews in a timely manner.

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?
2. Is the estimate of the burden of the information collection accurate?
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: December 22, 2020.

For the Nuclear Regulatory Commission.

Kristen E. Benney,

Acting NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2020–28707 Filed 12–28–20; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2020–0275]

Monthly Notice; Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations

AGENCY: Nuclear Regulatory Commission.

ACTION: Monthly notice.

SUMMARY: Pursuant to section 189.a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular monthly notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration (NSHC), notwithstanding the pendency before the Commission of a request for a hearing from any person. This monthly notice includes all amendments issued, or proposed to be issued, from November 13, 2020, to December 10, 2020. The last monthly notice was published on December 1, 2020.

DATES: Comments must be filed by January 28, 2021. A request for a hearing or petitions for leave to intervene must be filed by March 1, 2021.

ADDRESSES: You may submit comments by any of the following method; 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–2020–0275. Address questions about NRC Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

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: Kay Goldstein, Office of Nuclear Reactor Regulation, telephone: 301–415–1506, email: *kay.goldstein@nrc.gov,* U.S. Nuclear Regulatory Commission, Washington DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2020–0275, facility name, unit number(s), docket number(s), application date, and subject 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–2020–0275.
- *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 reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

- Attention: The PDR, where you may examine and order copies of public documents is currently closed. You may submit your request to the PDR via email at *PDR.Resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal Rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2020–0275, facility name, unit number(s), docket number(s), application date, and subject in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, 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 the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Proposed No Significant Hazards Consideration Determination

For the facility-specific amendment requests shown below, the Commission finds that the licensees' analyses provided, consistent with title 10 of *the Code of Federal Regulations* (10 CFR) section 50.91, are sufficient to support the proposed determinations that these amendment requests involve NSHC. Under the Commission's regulations in 10 CFR 50.92, operation of the facilities in accordance with the proposed amendments would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The Commission is seeking public comments on these proposed determinations. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determinations.

Normally, the Commission will not issue the amendments until the expiration of 60 days after the date of publication of this notice. The Commission may issue any of these license amendments before expiration of the 60-day period provided that its final determination is that the amendment involves NSHC. In addition, the Commission may issue any of these amendments prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility. If the Commission takes action on any of these amendments prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. If the Commission makes a final NSHC determination for any of these amendments, any hearing will take place after issuance. The Commission expects that the need to take action on any amendment before 60 days have elapsed will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by any of these actions may file a request for a hearing and petition for leave to intervene (petition) with respect to that action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC's regulations are accessible electronically from the NRC Library on the NRC's website at *https://www.nrc.gov/reading-rm/doc-collections/cfr/.* Alternatively, a copy of the regulations is available at the NRC's Public Document Room, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d) the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) The name, address, and telephone number of the petitioner; (2) the nature of the petitioner's right to be made a party to the proceeding; (3) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions that the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion that support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one that, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer

that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document.

If a hearing is requested, and the Commission has not made a final determination on the issue of NSHC, the Commission will make a final determination on the issue of NSHC. The final determination will serve to establish when the hearing is held. If the final determination is that the amendment request involves NSHC, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission no later than 60 days from the date of publication of this notice. The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document, and should meet the requirements for petitions set forth in this section, except that under 10 CFR 2.309(h)(2) a State, local governmental body, or Federally recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. Alternatively, a State, local governmental body, Federally recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a petition is submitted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities that request to participate under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC website at *https://www.nrc.gov/site-help/e-submittals.html.* Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals/getting-started.html.* Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public website at *https://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public website at *https://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory

documents in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *https://adams.nrc.gov/ehd,* unless excluded pursuant to an order of the Commission or the presiding officer. If you do not have an NRC issued digital ID certificate as described above, click ''cancel'' when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

The table below provides the plant name, docket number, date of application, ADAMS accession number, and location in the application of the licensees' proposed NSHC determinations. For further details with respect to these license amendment applications, see the applications for amendment, which are available for public inspection in ADAMS. For additional direction on accessing information related to this document, see the ''Obtaining Information and Submitting Comments'' section of this document.

LICENSE AMENDMENT REQUEST(S)

Dominion Nuclear Connecticut, Inc.; Millstone Power Station, Unit No. 3; New London County, CT	
Docket No(s)	50–423.
Application date	November 5, 2020.
ADAMS Accession No	ML20310A324.
Location in Application of NSHC	Pages 8 and 9 of Attachment 1.
Brief Description of Amendment(s)	The proposed amendment would update the list of approved methodologies for the Core Operating Limits Report in Millstone Power Station, Unit No. 3 (Millstone 3), Technical Specification 6.9.1.6.b to reflect Westinghouse Topical Report (TR) WCAP–16996–P–A, Revision 1, ''Realistic LOCA [Loss-of-Coolant Accident] Evaluation Methodology Applied to the Full Spectrum of Break Sizes (FULL SPECTRUM LOCA Methodology).'' The reference would replace the existing reference for TR WCAP–12945–P–A, ''Code Qualification Document for Best Estimate LOCA Analysis,'' which is a legacy code qualification document for large-break LOCA that is no longer used at Millstone 3.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Lillian M. Cuoco, Esq., Senior Counsel, Dominion Energy, Inc., 120 Tredegar Street, RS–2, Richmond, VA 23219.
NRC Project Manager, Telephone Number	Richard Guzman, 301–415–1030.

Duke Energy Carolinas, LLC; Catawba Nuclear Station, Units 1 and 2; York County, SC; Duke Energy Carolinas, LLC; McGuire Nuclear Station, Units 1 and 2; Mecklenburg County, NC	
Docket No(s)	50–413, 50–414, 50–369, 50–370.
Application date	August 19, 2020.
ADAMS Accession No	ML20233A258.
Location in Application of NSHC	Page 6 of the Enclosure.
Brief Description of Amendment(s)	The amendments would revise the Catawba Nuclear Station, Units 1 and 2 and McGuire Nuclear Station, Units 1 and 2 Technical Specification 3.8.1 regarding the Emergency Diesel Generators to reduce the maximum steady state voltage specified in the associated surveillances.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Kathryn B. Nolan, Deputy General Counsel, Duke Energy Corporation, 550 South Tryon Street (DEC45A), Charlotte, NC 28202; Kathryn B. Nolan, Deputy General Counsel, Duke Energy Corporation, 550 South Tryon Street (DEC45A), Charlotte, NC 28202; Michelle Spak, General Counsel, Duke Energy Corporation, 550 South Tryon St.—DEC45A, Charlotte, NC 28202.
NRC Project Manager, Telephone Number	John Klos, 301–415–5136.

Energy Harbor Nuclear Corp. and Energy Harbor Nuclear Generation LLC; Beaver Valley Power Station, Units 1 and 2; Beaver County, PA	
Docket No(s)	50–334, 50–412.
Application date	October 30, 2020.
ADAMS Accession No	ML20304A215.
Location in Application of NSHC	Pages 9 through 11 of Enclosure A.
Brief Description of Amendment(s)	The proposed amendments would replace the currently referenced analytical methods in the technical specifications with more recent NRC-acceptable analytical methods for calculating reactor vessel neutron fluence and reactor coolant system pressure and temperature limits when updating the reactor coolant system Pressure and Temperature Limits Report.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Rick Giannantonio, General Counsel, Energy Harbor Nuclear Corp., Mail Stop A–GO–15, 76 South Main Street, Akron, OH 44308.
NRC Project Manager, Telephone Number	Jennifer Tobin, 301–415–2328.

Exelon Generation Company, LLC; Byron Station, Unit Nos. 1 and 2; Ogle County, IL	
Docket No(s)	50–455, 50–454.
Application date	October 29, 2020.
ADAMS Accession No	ML20304A147.
Location in Application of NSHC	Pages 75 through 78 of Attachment 1.

LICENSE AMENDMENT REQUEST(S)—Continued

Brief Description of Amendment(s)	The proposed amendments would revise the Renewed Facility Operating Licenses and Appendix A, Technical Specifications, to be consistent with the permanent cessation of operation and defueling of the reactors.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Tamra Domeyer, Associate General Counsel, Exelon Generation Company, LLC, 4300 Winfield Road, Warrenville, IL 60555.
NRC Project Manager, Telephone Number	Joel Wiebe, 301–415–6606.
Exelon Generation Company, LLC; Byron Station, Unit Nos. 1 and 2; Ogle County, IL	
Docket No(s)	50–454, 50–455.
Application date	November 2, 2020.
ADAMS Accession No	ML20307A333.
Location in Application of NSHC	Pages 39 and 40 of Attachment 1.
Brief Description of Amendment(s)	The proposed amendment would revise the Site Emergency Plan for the post-shutdown and permanently defueled condition.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Tamra Domeyer, Associate General Counsel, Exelon Generation Company, LLC, 4300 Winfield Road, Warrenville, IL 60555.
NRC Project Manager, Telephone Number	Joel Wiebe, 301–415–6606.
Southern Nuclear Operating Company, Inc.; Edwin I Hatch Nuclear Plant, Units 1 and 2; Appling County, GA; Southern Nuclear Operating Company, Inc.; Joseph M Farley Nuclear Plant, Units 1 and 2; Houston County, AL; Southern Nuclear Operating Company, Inc.; Vogtle Electric Generating Plant, Units 1 and 2; Burke County, GA	
Docket No(s)	50–321, 50–348, 50–364, 50–366, 50–424, 50–425.
Application date	October 30, 2020.
ADAMS Accession No	ML20304A232.
Location in Application of NSHC	Pages E1–4 through E1–6 of Enclosure 1.
Brief Description of Amendment(s)	The amendments would revise certain Surveillance Requirements (SRs) in the Technical Specifications (TSs) by adding an exception to the SR for automatic valves or dampers that are locked, sealed, or otherwise secured in the actuated position. The proposed amendments are based on Technical Specifications Task Force (TSTF) Traveler TSTF–541, Revision 2, ''Add Exceptions to Surveillance Requirements for Valves and Dampers Locked in the Actuated Position,'' dated August 28, 2019 (ADAMS Accession No. ML19240A315). The NRC approved TSTF–541, Revision 2, by letter dated December 10, 2019.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Millicent Ronnlund, Vice President and General Counsel, Southern Nuclear Operating Co., Inc., P.O. Box 1295, Birmingham, AL 35201–1295.
NRC Project Manager, Telephone Number	John Lamb, 301–415–3100.
Virginia Electric and Power Company; Surry Power Station, Unit Nos. 1 and 2; Surry County, VA	
Docket No(s)	50–280, 50–281.
Application date	September 30, 2020.
ADAMS Accession No	ML20274A329.
Location in Application of NSHC	Pages 5 through 7 of Attachment 1.
Brief Description of Amendment(s)	The proposed amendments would revise Technical Specifications 2.1.A.1.b, ''Safety Limit Reactor Core,'' to reflect the peak fuel centerline melt temperature specified in WCAP–17642–P–A, Revision 1, ''Westinghouse Performance Analysis and Design Model (PAD5).''
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	W. S. Blair, Senior Counsel, Dominion Resource Services, Inc., 120 Tredegar St., RS–2, Richmond, VA 23219.
NRC Project Manager, Telephone Number	Vaughn Thomas, 301–415–5897.
Vistra Operations Company LLC; Comanche Peak Nuclear Power Plant, Unit Nos. 1 and 2; Somervell County, TX	
Docket No(s)	50–445, 50–446.
Application date	November 19, 2020.
ADAMS Accession No	ML20324A627.
Location in Application of NSHC	Pages 35 and 36 of the Enclosure.
Brief Description of Amendment(s)	The amendments would revise Technical Specification (TS) 3.7.8, ''Station Service Water System (SSWS),'' and TS 3.8.1, ''AC [Alternating Current] Sources—Operating,'' to extend the completion time for one SSWS train and one diesel generator inoperable from 72 hours to 8 days on a one-time basis to allow the replacement of Comanche Peak Nuclear Power Plant Unit 2 SSWS Pump 2–02 (Train B) during Unit 2 Cycle 19. The proposed revised TSs include a regulatory commitment that identifies compensatory measures to be implemented during the extended completion time.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Timothy P. Matthews, Esq., Morgan, Lewis and Bockius, 1111 Pennsylvania Avenue, NW, Washington, DC 20004.
NRC Project Manager, Telephone Number	Dennis Galvin, 301–415–6256.

III. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses

During the period since publication of the last monthly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed NSHC determination, and opportunity for a hearing in connection with these

actions, was published in the **Federal Register** as indicated in the safety evaluation for each amendment.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that assessment, it is so indicated in the safety evaluation for the amendment.

For further details with respect to each action, see the amendment and associated documents such as the Commission's letter and safety evaluation, which may be obtained using the ADAMS accession numbers indicated in the table below. The safety evaluation will provide the ADAMS accession numbers for the application for amendment and the **Federal Register** citation for any environmental assessment. All of these items can be accessed as described in the ''Obtaining Information and Submitting Comments'' section of this document.

LICENSE AMENDMENT ISSUANCE(S)

Duke Energy Carolinas, LLC; Oconee Nuclear Station, Units 1, 2, and 3; Oconee County, SC	
Docket No(s)	50–269, 50–270, 50–287.
Amendment Date	November 25, 2020.
ADAMS Accession No	ML20296A281.
Amendment No(s)	418 (Unit 1), 420 (Unit 2), and 419 (Unit 3).
Brief Description of Amendment(s)	The amendments revised Technical Specification (TS) 5.5.8, ''Reactor Coolant Pump [RCP] Flywheel Inspection Program,'' by modifying RCP flywheel inspection methods and extending the inspection frequency for the RCP motor flywheel. These changes are consistent with the NRC-approved Technical Specifications Task Force (TSTF) Traveler TSTF–421,''Revision to RCP Flywheel Inspection Program (WCAP–15666).''.
Public Comments Received as to proposed NSHC (Yes/No).	No.
Energy Harbor Nuclear Corp. and Energy Harbor Nuclear Generation LLC; Perry Nuclear Power Plant, Unit 1; Lake County, OH	
Docket No(s)	50–440.
Amendment Date	October 8, 2020.
ADAMS Accession No	ML20216A354.
Amendment No(s)	191.
Brief Description of Amendment(s)	The amendment revised the expiration date of the Perry Nuclear Power Plant full-power operating license such that it expires 40 years from the date of issuance (November 7, 2026).
Public Comments Received as to Proposed NSHC (Yes/No).	No.
Exelon Generation Company, LLC; Limerick Generating Station, Units 1 and 2; Montgomery County, PA	
Docket No(s)	50–352, 50–353.
Amendment Date	November 30, 2020.
ADAMS Accession No	ML20239A725.
Amendment No(s)	249 (Unit 1) and 211 (Unit 2).
Brief Description of Amendment(s)	The amendments revised Technical Specification (TS) 3/4.10.8, ''Inservice Leak and Hydrostatic Testing,'' by adopting Technical Specifications Task Force (TSTF) Traveler TSTF–484, Revision 0, ''Use of TS 3.10.1 for Scram Time Testing Activities.'' Specifically, Limiting Condition for Operation 3.10.8 is expanded in scope to include provisions for temperature excursions greater than 212 °F as a consequence of inservice leak and hydrostatic testing, and as a consequence of scram time testing initiated in conjunction with an inservice leak or hydrostatic test, while considering operational conditions to be in Operational Condition 4.
Public Comments Received as to Proposed NSHC (Yes/No).	No.
Exelon Generation Company, LLC; Limerick Generating Station, Units 1 and 2; Montgomery County, PA	
Docket No(s)	50–352, 50–353.
Amendment Date	December 1, 2020.
ADAMS Accession No	ML20255A063.
Amendment No(s)	250 (Unit 1) and 212 (Unit 2).
Brief Description of Amendment(s)	The amendments revised technical specification surveillance requirements for testing of the safety relief valves to retain the frequency and certain testing requirements only in the inservice testing program, consistent with NUREG–1433, Revision 4.
Public Comments Received as to Proposed NSHC (Yes/No).	No.
Exelon Generation Company, LLC; Three Mile Island Nuclear Station, Unit 1; Dauphin County, PA	
Docket No(s)	50–289, 50–320.
Amendment Date	December 2, 2020.
ADAMS Accession No	ML20261H925.
Amendment No(s)	299.
Brief Description of Amendment(s)	The amendment revised the site emergency plan for the Three Mile Island site and the emergency action level scheme to reflect the permanently shutdown and defueled condition for Unit 1.
Public Comments Received as to Proposed NSHC (Yes/No).	Yes.
Exelon Generation Company, LLC; Three Mile Island Nuclear Station, Unit 1; Dauphin County, PA	
Docket No(s)	50–289.
Amendment Date	December 3, 2020.
ADAMS Accession No	ML20297A635.

LICENSE AMENDMENT ISSUANCE(S)—Continued

Amendment No(s)	300.
Brief Description of Amendment(s)	The amendment deleted permanently defueled Technical Specification 3/4.1.4, ''Handling of Irradiated Fuel with Fuel Handling Building Crane,'' since the crane necessitating this requirement is being replaced with one that does not need these additional requirements.
Public Comments Received as to Proposed NSHC (Yes/No).	No.
Exelon Generation Company, LLC; Three Mile Island Nuclear Station, Unit 1; Dauphin County, PA	
Docket No(s)	50–289.
Amendment Date	December 4, 2020.
ADAMS Accession No	ML20297A627.
Amendment No(s)	301.
Brief Description of Amendment(s)	The amendment removed the requirement for a Cyber Security Plan from the license.
Public Comments Received as to Proposed NSHC (Yes/No).	No.
Florida Power & Light Company, et al.; St. Lucie Plant, Unit No. 2; St. Lucie County, FL	
Docket No(s)	50–389.
Amendment Date	November 18, 2020.
ADAMS Accession No	ML20259A298.
Amendment No(s)	205.
Brief Description of Amendment(s)	The amendment modified the St. Lucie Plant, Unit No. 2, Technical Specifications by revising the Reactor Coolant Pump Flywheel Inspection Program requirements to be consistent with the conclusions and limitations specified in the NRC safety evaluation of Topical Report SIR–94–080, ''Relaxation of Reactor Coolant Pump Flywheel Inspection Requirements,'' dated May 21, 1997.
Public Comments Received as to Proposed NSHC (Yes/No).	No.
Florida Power & Light Company; Turkey Point Nuclear Generating Unit Nos. 3 and 4; Miami-Dade County, FL	
Docket No(s)	50–250, 50–251.
Amendment Date	October 20, 2020.
ADAMS Accession No	ML20237F385.
Amendment No(s)	293 (Unit 3) and 286 (Unit 4).
Brief Description of Amendment(s)	The amendments revised the Turkey Point Emergency Plan by adopting the methodology for developing an emergency action level scheme as described in Nuclear Energy Institute (NEI) 99–01, Revision 6, ''Development of Emergency Action Levels for Non-Passive Reactors.'' The amendments revised certain technical specification (TS) containment atmospheric radioactivity and containment ventilation isolation instrument setpoints, modified the TS limiting condition for operation with the TS action and completion times related to the inoperability of reactor coolant system radioactivity monitors, adjusted the frequency of reactor coolant system water inventory balances, changed the TS limiting condition for operation related to isolation of the containment purge supply and exhaust isolation valves, and approved the relocation of the purge valve leakage rate criteria out of the TSs to licensee administrative control within the constraints of 10 CFR 50.59.
Public Comments Received as to Proposed NSHC (Yes/No).	No.
Holtec Pilgrim, LLC and Holtec Decommissioning International; Pilgrim Nuclear Power Station; Plymouth County, MA	
Docket No(s)	50–293.
Amendment Date	December 1, 2020.
ADAMS Accession No	ML20328A297.
Amendment No(s)	253.
Brief Description of Amendment(s)	The amendment revised the Pilgrim Physical Security Plan (PSP) and revised License Condition 3.G, ''Physical Protection.'' The revised PSP integrates the existing PSP's Appendix D. Appendix D of the revised PSP provides the security requirements for the new Independent Spent Fuel Storage Installation (ISFSI) (referred to as ISFSI II) that is currently being built in the Owner Controlled Area outside of the existing Protected Area.
Public Comments Received as to Proposed NSHC (Yes/No).	No.
Nebraska Public Power District; Cooper Nuclear Station; Nemaha County, NE	
Docket No(s)	50–298.
Amendment Date	December 2, 2020.
ADAMS Accession No	ML20314A235.
Amendment No(s)	268.
Brief Description of Amendment(s)	The amendment revised technical specification actions for inoperable residual heat removal (RHR) shutdown cooling subsystems in the RHR shutdown cooling system limiting conditions for operation for Cooper Nuclear Station. The changes are based on Technical Specifications Task Force (TSTF) Traveler TSTF–566, Revision 0, ''Revise Actions for Inoperable RHR Shutdown Cooling Subsystems,'' dated January 19, 2018, using the consolidated line item improvement process.
Public Comments Received as to Proposed NSHC (Yes/No).	No.
NextEra Energy Seabrook, LLC; Seabrook Station, Unit No. 1; Rockingham County, NH	
Docket No(s)	50–443.
Amendment Date	November 24, 2020.
ADAMS Accession No	ML20298A253.
Amendment No(s)	166.

LICENSE AMENDMENT ISSUANCE(S)—Continued

Brief Description of Amendment(s)	The amendment revised Technical Specification 3/4.8.1, ''A.C. [Alternating Current]—Operating,'' to allow for a one-time extension of the allowed outage time for one emergency diesel generator inoperable from 14 days to 30 days. The change allows the licensee to perform planned maintenance on the B emergency diesel generator while at power.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Northern States Power Company—Minnesota; Prairie Island Nuclear Generating Plant, Unit Nos. 1 and 2; Goodhue County, MN

Docket No(s)	50–282, 50–306.
Amendment Date	November 18, 2020.
ADAMS Accession No	ML20283A342.
Amendment No(s)	233 (Unit 1) and 221 (Unit 2).
Brief Description of Amendment(s)	The amendments revised the Prairie Island Nuclear Generating Plant, Units 1 and 2, technical specifications to adopt Technical Specifications Task Force (TSTF) Traveler TSTF–547, ''Clarification of Rod Position Requirements,'' with site-specific variations.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Southern Nuclear Operating Company, Inc.; Edwin I Hatch Nuclear Plant, Units 1 and 2; Appling County, GA

Docket No(s)	50–321, 50–366.
Amendment Date	December 7, 2020.
ADAMS Accession No	ML20294A076.
Amendment No(s)	308 (Unit 1) and 253 (Unit 2).
Brief Description of Amendment(s)	The amendments revised the technical specifications (TSs) related to reactor pressure vessel (RPV) water inventory control (WIC) based on Technical Specifications Task Force (TSTF) Traveler TSTF–582, Revision 0, ''RPV WIC Enhancements,'' and the associated NRC staff safety evaluation of TSTF–582.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Tennessee Valley Authority; Browns Ferry Nuclear Plant, Units 1, 2, and 3; Limestone County, AL; Tennessee Valley Authority; Sequoyah Nuclear Plant, Units 1 and 2; Hamilton County, TN; Tennessee Valley Authority; Watts Bar Nuclear Plant, Units 1 and 2; Rhea County, TN

Docket No(s)	50–259, 50–260, 50–296, 50–327, 50–328, 50–390, 50–391.
Amendment Date	November 19, 2020.
ADAMS Accession No	ML20282A345.
Amendment No(s)	Browns Ferry—313 (Unit 1), 336 (Unit 2) and 296 (Unit 3); Sequoyah—350 (Unit 1) and 344 (Unit 2); Watts Bar—138 (Unit 1) and 44 (Unit 2).
Brief Description of Amendment(s)	The amendments revised the Tennessee Valley Authority Fleet Radiological Emergency Plan to change the requirement from having an on-shift emergency medical technician to a requirement for an on-shift emergency medical professional. Additionally, the amendments removed the requirement for an onsite ambulance at each site.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Tennessee Valley Authority; Sequoyah Nuclear Plant, Units 1 and 2; Hamilton County, TN

Docket No(s)	50–327, 50–328.
Amendment Date	November 12, 2020.
ADAMS Accession No	ML20262H026.
Amendment No(s)	349 (Unit 1) and 343 (Unit 2).
Brief Description of Amendment(s)	The amendments revised Technical Specification 3.3.1, Table 3.3.1–1, ''Reactor Trip System Instrumentation,'' Function 14.a. ''Turbine Trip—Low Fluid Oil Pressure,'' to increase the nominal trip setpoint from 45 pounds per square inch gauge (psig) to 800 psig, and the allowable value from greater than or equal to 39.5 psig to greater than or equal to 710 psig.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Virginia Electric and Power Company; Surry Power Station, Unit Nos. 1 and 2; Surry County, VA

Docket No(s)	50–280, 50–281.
Amendment Date	December 8, 2020.
ADAMS Accession No.	ML20148M359.
Amendment No(s)	302 (Unit 1) and 302 (Unit 2).
Brief Description of Amendment(s)	The amendments revised Technical Specifications (TS) Figure 3.1–1, ''Surry Units 1 and 2 Reactor Coolant System Heatup Limitations,'' and Figure 3.1–2, ''Surry Units 1 and 2 Reactor Coolant System Cooldown Limitations,'' to update the cumulative core burnup applicability limit and to revise and relocate the limiting material property basis from the TS figures to the TS basis.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Virginia Electric and Power Company; Surry Power Station, Unit Nos. 1 and 2; Surry County, VA

Docket No(s)	50–280, 50–281.
Amendment Date.	December 8, 2020.
ADAMS Accession No	ML20293A160.
Amendment No(s)	301 (Unit 1) and 301 (Unit 2).
Brief Description of Amendment(s)	The amendments modified the Surry licensing basis by the addition of a license condition to allow for the implementation of the provisions of 10 CFR Section 50.69, ''Risk informed categorization and treatment of structures, systems and components for nuclear power reactors.''.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

LICENSE AMENDMENT ISSUANCE(S)—Continued

Vistra Operations Company LLC; Comanche Peak Nuclear Power Plant, Unit Nos. 1 and 2; Somervell County, TX	
Docket No(s)	50–445, 50–446.
Amendment Date	November 16, 2020.
ADAMS Accession No	ML20168A924.
Amendment No(s)	176 (Unit 1) and 176 (Unit 2).
Brief Description of Amendment(s)	The amendments revised Technical Specification 3.4.15, ''RCS [Reactor Coolant System] Leakage Detection Instrumentation,'' to align with the Standard Technical Specifications for Westinghouse Plants and incorporated the changes made by Technical Specifications Task Force (TSTF) Traveler TSTF–513, Revision 3, ''Revise PWR [Pressurized-Water Reactor] Operability Requirements and Actions for RCS Leakage Instrumentation.''.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Wolf Creek Nuclear Operating Corporation; Wolf Creek Generating Station, Unit 1; Coffey County, KS	
Docket No(s)	50–482.
Amendment Date	December 7, 2020.
ADAMS Accession No.	ML20276A149.
Amendment No(s)	226.
Brief Description of Amendment(s)	The amendment revised Technical Specification 5.5.16, ''Containment Leakage Rate Testing Program,'' to extend the Type A and Type C leak rate test frequencies. Specifically, the change allows the extension of the Type A integrated leakage rate test containment test interval to 15 years and the extension of the Type C local leakage rate test interval to 75 months.
Public Comments Received as to Proposed NSHC (Yes/No).	No.

Dated: December 18, 2020.

For the Nuclear Regulatory Commission.

Caroline L. Carusone,

Deputy Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2020–28442 Filed 12–28–20; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2012–0110]

Acceptability of Probabilistic Risk Assessment Results for Risk-Informed Activities

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory guide; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Revision 3 to Regulatory Guide (RG) 1.200, ''Acceptability of Probabilistic Risk Assessment Results for Risk-Informed Activities.'' Revision 3 describes one acceptable approach for determining whether a base probabilistic risk assessment (PRA), in total or the portions that are used to support an application, is acceptable to provide confidence in the results, such that the PRA can be used in regulatory decisionmaking for light-water reactors (LWRs). When used in support of an application, the use of this RG will obviate the need for an in-depth review of the base PRA by NRC reviewers, allowing them to focus their review on key assumptions and areas identified by peer reviewers.

DATES: Revision 3 to RG 1.200 is available on December 29, 2020.

ADDRESSES: Please refer to Docket ID NRC–2012–0110 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2012–0110. Address questions about Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *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 ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *Attention:* The PDR, where you may examine and order copies of public documents is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them.

FOR FURTHER INFORMATION CONTACT: Anders Gilbertson, telephone: 301–415–1541, email: *Anders.Gilbertson@nrc.gov,* and Harriet Karagiannis, telephone: 301–415–2493, email: *Harriet.Karagiannis@nrc.gov.* Both are staff of the Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Discussion

The NRC is issuing a revision to an existing guide in the NRC's ''Regulatory Guide'' series. This series was developed to describe and make available to the public information regarding methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, techniques that the NRC staff uses in evaluating specific issues or postulated events, and data that the NRC staff needs in its review of applications for permits and licenses. Regulatory guides are not NRC regulations and compliance with them is not required. Methods and solutions that differ from those set forth in RGs are acceptable if supported by a basis for the issuance or continuance of a permit or license by the Commission.

Revision 3 to RG 1.200 was issued with a temporary identification of Draft Regulatory Guide, DG–1362 (ADAMS Accession No. ML19308B636). RG 1.200 (Revision 3) describes one acceptable approach for determining whether the base PRA, in total or the portions that are used to support an application, is

sufficient to provide confidence in the results, such that the PRA can be used in regulatory decisionmaking for LWRs. Also, it addresses new industry guidance and enhancements identified since the last revision was issued in March 2009. Specifically, this revision endorses, with staff clarifications and exceptions, the American Society of Mechanical Engineers (ASME) and American Nuclear Society (ANS) Standard ASME/ANS RA–Sa–2009, ''Standard for Level 1/Large Early Release Frequency Probabilistic Risk Assessment for Nuclear Power Plant Applications''; the ASME/ANS standard ASME/ANS RA–S Case 1 for seismic PRA, ''Case for ASME/ANS RA–Sb–2013 Standard for Level 1/Large Early Release Frequency Probabilistic Risk Assessment of Nuclear Power Plant Applications''; Nuclear Energy Institute (NEI) 17–07, Revision 2, ''Performance of PRA Peer Reviews Using the ASME/ANS PRA Standard'' (ADAMS Accession No. ML19241A615); and Pressurized Water Reactor Owners Group (PWROG) report PWROG–19027–NP, Revision 2, ''Newly Developed Method Requirements and Peer Review'' (ADAMS Accession No. ML20213C660). This revision of the RG further provides for a peer review of newly developed methods, clarifies the process for determining how to classify changes to a PRA, provides definitions related to newly developed methods and other PRA terms, and enhances guidance related to key assumptions and sources of uncertainty.

II. Additional Information

The NRC published a notice of the availability of DG–1362 in the **Federal Register** on July 1, 2020 (85 FR 39599) for a 30-day public comment period. The public comment period closed on July 31, 2020. Public comments on DG–1362 and the staff responses to the public comments are available in ADAMS under Accession No. ML20238B873. Revision 3 to RG 1.200 may be found in ADAMS under Accession No. ML20238B871.

III. Congressional Review Act

This RG is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

IV. Backfitting, Forward Fitting, and Issue Finality

This RG provides one acceptable approach for determining whether the base PRA, in total or the portions that are used to support an application, is sufficient to provide confidence in the results, such that the PRA can be used in regulatory decisionmaking for LWRs. Issuance of this RG does not constitute backfitting as defined in section 50.109 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Backfitting,'' and as described in NRC Management Directive 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests'' (ADAMS Accession No. ML18093B087); does not constitute forward fitting as that term is defined and described in Management Directive 8.4; and does not affect the issue finality of any approval issued under 10 CFR part 52, ''Licenses, Certificates, and Approvals for Nuclear Power Plants.'' As explained in this RG, applicants and licensees are not required to comply with the positions set forth in this RG.

Dated: December 21, 2020.

For the Nuclear Regulatory Commission.

Robert G. Roche-Rivera,

Acting Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2020–28632 Filed 12–28–20; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–338–SLR and 50–339–SLR; ASLBP No. 21–970–01–SLR–01]

Virginia Electric and Power Company; Establishment of Atomic Safety and Licensing Board

Pursuant to delegation by the Commission, *see* 37 FR 28,710 (Dec. 29, 1972), and the Commission's regulations, *see, e.g.,* 10 CFR 2.104, 2.105, 2.300, 2.309, 2.313, 2.318, 2.321, notice is hereby given that an Atomic Safety and Licensing Board (Board) is being established to preside over the following proceeding:

Virginia Electric and Power Company (North Anna Power Station, Units 1 and 2)

This proceeding involves an application seeking a twenty-year subsequent license renewal of Renewed Facility Operating License Nos. NPF–4 and NPF–7, which currently authorize Virginia Electric and Power Company to operate the North Anna Power Company, Units 1 and 2, located in Louisa, Virginia, until, respectively, April 1, 2038 and August 21, 2040. In response to a notice published in the **Federal Register** announcing the opportunity to request a hearing, *see* 85 FR 65,438 (Oct. 15, 2020), a hearing request was filed on December 14, 2020 on behalf of Beyond Nuclear, Sierra Club, and Alliance for Progressive Virginia.

The Board is comprised of the following Administrative Judges:

G. Paul Bollwerk, III, Chairman, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001

Nicholas G. Trikouros, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001

Dr. Gary S. Arnold, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001

All correspondence, documents, and other materials shall be filed in accordance with the NRC E-Filing rule. *See* 10 CFR 2.302.

Rockville, Maryland. December 21, 2020.

Edward R. Hawkens,

Chief Administrative Judge, Atomic Safety and Licensing Board Panel.

[FR Doc. 2020–28634 Filed 12–28–20; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2020–0237]

Considerations for Estimating Site-Specific Probable Maximum Precipitation at Nuclear Power Plants in the United States of America

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft NUREG; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment a draft NUREG, knowledge management NUREG, NUREG/KM–0015, ''Considerations for Estimating Site-Specific Probable Maximum Precipitation at Nuclear Power Plants in the United States of America.'' The NRC Staff and Oak Ridge National Laboratory have prepared a reference document summarizing recent lessons-learned in connection with a review of the site-specific probable maximum precipitation (SSPMP) estimates used by some nuclear power plant owners and operators in connection with a recent re-evaluation of external flooding at their respective project sites.

DATES: Submit comments by March 1, 2021. 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 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–2020–0237. Address questions about Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

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: Kevin Quinlan, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6809, email: *Kevin.Quinlan@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2020–0237 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–2020–0237.

• *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, at 301–415–4737, or by email to *pdr.resource@nrc.gov.* NUREG/KM–0015, ''Considerations for Estimating Site-Specific Probable Maximum Precipitation at Nuclear Power Plants in the United States of America'' is available in ADAMS under Accession No. ML20356A293.

• *Attention:* The PDR, where you may examine and order copies of public documents is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal Rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2020–0237 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, 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 the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

By letter dated March 12, 2012, the NRC issued a request for information to all power reactor licensees and holders of construction permits in active or deferred status licensees to reevaluate seismic and external flooding for their sites against current Commission requirements and guidance. This request was made consistent with section 50.54(f)—''Conditions of Licenses''—of the Commission's regulations found at part 50 of title of the *Code of Federal Regulations* (10 CFR). The request was issued in connection with implementing lessons-learned identified by the staff, and described in their Near-Term Task Force Report, following the 2011 accident at the Fukushima Dai-ichi nuclear power plant. In connection with this request, owners and operators were to re-evaluate flood hazards at their respective sites using present-day methods and regulatory guidance used by the NRC staff when reviewing 10 CFR part 52 applications for Early Site Permits and Combined Operating Licenses.

In response to the staff's 2012 § 50.54(f) information request, owners and licensees submitted about 60 external flood hazard re-evaluation reports (FHRRs) corresponding to the operating fleet of power reactors. In the matter of the probable maximum precipitation (PMP) value used for some of the flood-hazard re-evaluations (primarily the estimation of local intense precipitation and riverine-based floods), current NRC guidance documents recommend the use of the PMP estimation methods described in a series of Hydrometeorological Reports (HMRs) developed by the National Oceanographic and Atmospheric Administration (NOAA). The PMP event itself is generally defined as the greatest depth of precipitation for a given duration meteorologically possible for a design watershed or a given storm area at a particular time of year. The estimated PMP over a particular watershed or basin results in a flood magnitude for which there is virtually no risk of exceeding. The challenge, however, is that HMR-derived PMP estimates are based on methodologies and data which have not been updated with rainfall and storm events which have occurred in the decades since the HMRs were last published.

Upon review of the FHRRs, the staff found that about 26 project sites responding to the § 50.54(f) information request submitted PMP estimates that were not based on NOAA HMRs but were developed by a commercial interest. As part of the FHRR process, the staff conducted an audit of the commercial vendor who developed the site-specific PMP estimates to better-understand the technical basis underlying the approach. In all cases, these SSPMP estimates were less than those obtained from the applicable HMR. Although the development and estimation of the SSPMP studies reviewed by the staff generally followed processes similar to those described in the existing guidance, several different methods, data sources, assumptions, and procedures were used to obtain site specific results other than those found using the HMR methodology.

Based on the staff's § 50.54(f) review experience and in anticipation of its continued use, this NUREG summarizes the lessons-learned concerning the review and application of a SSPMP. To that end, this NUREG addresses the following topics:

- Storm Selection
- Storm Reconstruction
- Storm Transposition
- Storm Representative Dew Point Selection

- Precipitable Water Estimation
- Dew Point Climatology, Moisture Maximization, and Moisture Transposition
- Terrain Adjustment
- Envelopment and Probable Maximum Precipitation Determination
- Spatial and Temporal Distributions for SSPMP Applications

This reference document describes the technical theory, data sources, and analysis methodology that could be used to derive a SSPMP estimate. Certain new terms are also introduced and defined. This reference document also identifies key technical (meteorological) considerations when reviewing a SSPMP estimate.

To date, there is no clear NRC guidance on this topic or a commonly agreed-to approach on the estimation of SSPMP. As the staff may be reviewing additional SSPMP estimates in the future in connection with its regulatory responsibilities, it was decided to elicit stakeholder views on the matters and approaches discussed in this draft document.

This document contains no regulatory guidance or regulatory positions.

III. Knowledge Management

Since its inception, the Atomic Energy Commission and its successor, the NRC, have focused on preserving the (explicit) documentary record of its decision-making in the form of NUREGs, SECY Papers, Regulatory Guides, and other documents. However, in 2006, the agency recognized that there was a need to engage in a more-formal program of knowledge management that also reflects the less-tangible (implicit) human capital aspect of the agencies' knowledge base. This feature was particularly important as the agency enters its fifth decade of operation—a period characterized by an increasing number of retirements among long-serving staff involved in many of the agencies' early regulatory programs and associated licensing actions. Staff efforts thus far in preserving this legacy of experience that describe important historical events, facts, and research that were instrumental in shaping NRC's regulatory programs, can be found at *https://www.nrc.gov/reading-rm/doc-collections/nuregs/knowledge/.*

The purpose of this knowledge management NUREG (or NUREG/KM) is intended to satisfy an NRC goal of maintaining and preserving knowledge concerning the lessons-learned from the recent flood hazard re-evaluations at current and planned nuclear power plant sites performed most recently in connection with the staff 2012 § 50.54(f) reviews.

Dated: December 22, 2020.

For the Nuclear Regulatory Commission.

Luissette Candelario,

Project Manager, External Hazards Branch, Division of Engineering and External Hazards, Office of Nuclear Reactor Regulation.

[FR Doc. 2020–28708 Filed 12–28–20; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–266 and 50–301; NRC–2020–0248]

NextEra Energy Point Beach, LLC; Point Beach Nuclear Plant, Units 1 and 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Subsequent license renewal application; receipt.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has received an application for the subsequent renewal of Renewed Facility Operating License Nos. DPR–24 and DPR–27, which authorize NextEra Energy Point Beach, LLC (NextEra, the applicant), to operate Point Beach Nuclear Plant, Units 1 and 2 (Point Beach). The subsequent renewed licenses would authorize the applicant to operate Point Beach for an additional 20 years beyond the period specified in each of the current renewed licenses. The current renewed operating licenses for Point Beach expire as follows: Unit 1 on October 5, 2030, and Unit 2 on March 8, 2033.

DATES: The subsequent license renewal application referenced in this document is available on December 29, 2020.

ADDRESSES: Please refer to Docket ID NRC–2020–0248 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0248. Address questions about Docket IDs to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *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 ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *Public Library:* A copy of the subsequent license renewal application for Point Beach can be accessed at the following public library (however, the library is currently closed due to the Coronavirus Disease 2019 public health emergency and, accordingly, access will be available once the library has reopened): Lester Public Library, 1001 Adams St., Two Rivers, Wisconsin 54211.
- *Attention:* The PDR, where you may examine and purchase copies of public documents, is currently closed. You may submit your request to the PDR via email at *PDR.Resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Bill Rogers, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2945, email: *Bill.Rogers@nrc.gov.*

SUPPLEMENTARY INFORMATION: The NRC has received an application (ADAMS Package Accession No. ML20329A292) from NextEra, dated November 16, 2020, filed pursuant to Section 103 of the Atomic Energy Act of 1954, as amended, and part 54 of title 10 of the *Code of Federal Regulations,* for subsequent renewal of the renewed operating licenses for Point Beach. Subsequent renewal of the licenses would authorize the applicant to operate the facility for an additional 20-year period beyond the current renewed operating license expiration dates of October 5, 2030, and March 8, 2033, for Units 1 and 2, respectively. The Point Beach units are pressurized-water reactors located near Manitowoc, Wisconsin. The acceptability of the tendered application for docketing and other matters, including an opportunity to request a hearing, will be the subject of subsequent **Federal Register** notices.

Dated: December 21, 2020.

For the Nuclear Regulatory Commission.

Lauren K. Gibson,

Chief, License Renewal Project Branch, Division of New and Renewed Licenses, Office of Nuclear Reactor Regulation.

[FR Doc. 2020–28626 Filed 12–28–20; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2021–51 and CP2021–53; Docket Nos. MC2021–52 and CP2021–54; Docket Nos. MC2021–53 and CP2021–55]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 31, 2020.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov*. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2021–51 and CP2021–53; *Filing Title:* USPS Request to Add Parcel Select Contract 45 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 21, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Curtis E. Kidd; *Comments Due:* December 31, 2020.

2. *Docket No(s).:* MC2021–52 and CP2021–54; *Filing Title:* USPS Request to Add Priority Mail & First-Class Package Service Contract 184 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 21, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Curtis E. Kidd; *Comments Due:* December 31, 2020.

3. *Docket No(s).:* MC2021–53 and CP2021–55; *Filing Title:* USPS Request to Add Priority Mail & First-Class Package Service Contract 185 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* December 21, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Curtis E. Kidd; *Comments Due:* December 31, 2020.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2020–28721 Filed 12–28–20; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90765; File No. S7–16–20]

Order Granting Conditional Substituted Compliance in Connection With Certain Requirements Applicable to Non-U.S. Security-Based Swap Dealers and Major Security-Based Swap Participants Subject to Regulation in the Federal Republic of Germany

December 22, 2020.

I. Overview

The Bundesanstalt für Finanzdienstleistungsaufsicht (''BaFin''), the German financial authority, has submitted a ''substituted compliance'' application requesting that the Commission determine, pursuant to the Securities Exchange Act of 1934 (''Exchange Act'') rule 3a71–6, that security-based swap dealers and major-security based swap participants (''SBS Entities'') subject to regulation in Germany conditionally may satisfy requirements under the Exchange Act by complying with comparable German and European Union (''EU'') requirements.[1] BaFin's request particularly sought substituted compliance in connection with certain Exchange Act requirements related to risk control (but not including nonbank capital and margin requirements), internal supervision and compliance, counterparty protection, and books and records. The application incorporated comparability analyses regarding applicable German and EU law, as well as information regarding German supervisory and enforcement frameworks.

On November 13, 2020, the Commission published a notice of BaFin's completed application, accompanied by a proposed Order to conditionally grant substituted compliance in connection with the application.[2] The proposal incorporated a number of conditions to tailor the scope of substituted compliance consistent with the prerequisite that relevant German and EU requirements produce regulatory outcomes that are

[1] *See* Letter from Elisabeth Roegele, Chief Executive Director of Securities Supervision and Deputy President, BaFin, to Vanessa Countryman, Secretary, Commission, dated Nov. 6, 2020 (''BaFin Application''). The application is available on the Commission's website at: *https://www.sec.gov/files/germany-BaFin-complete-application-substituted-compliance-11062020.pdf.*

[2] Exchange Act Release No. 90378 (Nov. 9, 2020), 85 FR 72726 (Nov. 13, 2020) (''German Substituted Compliance Notice and Proposed Order'').

comparable to relevant requirements under the Exchange Act.

This Order has been modified from the proposal in certain respects to address commenter concerns or to make clarifying changes, as discussed below. In making these substituted compliance determinations, the Commission continues to recognize that other regulatory regimes will have exclusions, exceptions and exemptions that may not align perfectly with the corresponding requirements under the Exchange Act. Where the German regime produces comparable outcomes notwithstanding those particular differences, the Commission has made a positive substituted compliance determination. Conversely, where those exclusions, exemptions and exceptions lead to outcomes that are not comparable, the Commission has not made a positive substituted compliance determination.

Under the substituted compliance framework, failure to comply with the applicable foreign requirements and other conditions to the Order would lead to a violation of the applicable requirements under the Exchange Act and potential enforcement action by the Commission (as opposed to automatic revocation of the substituted compliance order).

II. Substituted Compliance Framework and Prerequisites

A. Substituted Compliance Availability and Purpose

As discussed in the German Substituted Compliance Notice and Proposed Order, rule 3a71–6 provides a framework whereby non-U.S. SBS Entities may satisfy certain requirements under Exchange Act section 15F by complying with comparable regulatory requirements of a foreign jurisdiction. Because substituted compliance does not constitute exemptive relief, but instead provides an alternative method by which non-U.S. SBS Entities may comply with applicable Exchange Act requirements, the non-U.S. SBS Entities would remain subject to the relevant requirements under section 15F. The Commission accordingly will retain the authority to inspect, examine and supervise those SBS Entities' compliance and take enforcement action as appropriate.[3]

Under rule 3a71–6, substituted compliance potentially is available in connection with section 15F requirements regarding: Business conduct and supervision; chief compliance officers; trade acknowledgment and verification; capital; margin; recordkeeping and reporting; and portfolio reconciliation, portfolio compression and trading relationship documentation.[4]

Substituted compliance is not available in connection with antifraud prohibitions and certain other requirements under the Federal securities laws, however.[5] SBS Entities in Germany accordingly must comply directly with those requirements notwithstanding the availability of substituted compliance for other requirements.

The substituted compliance framework reflects the cross-border nature of the security-based swap market, and is intended to promote efficiency and competition by helping to address potential duplication and inconsistency between relevant U.S. and foreign requirements.[6] In practice, substituted compliance may be expected to help achieve those goals by making it possible for SBS Entities to leverage their existing systems and practices to comply with relevant Exchange Act requirements in conjunction with their compliance with relevant foreign requirements. The registration compliance date for SBS Entities is October 6, 2021,[7] and substituted compliance should assist relevant non-U.S. security-based swap market participants in preparing for registration.

B. Specific Prerequisites

1. Comparability of Regulatory Outcomes

As provided by rule 3a71–6, substituted compliance in part is conditioned on the Commission determining the analogous foreign requirements are ''comparable'' to applicable requirements under the Exchange Act, after accounting for factors such as ''the scope and objectives of the relevant foreign regulatory requirements'' and ''the effectiveness of the supervisory compliance program administered, and the enforcement authority exercised'' by the foreign authority. The comparability assessments are to be based on a ''holistic approach'' that ''will focus on the comparability of regulatory outcomes rather than predicating substituted compliance on requirement-by-requirement similarity.''[8]

2. Memorandum of Understanding

Exchange Act rule 3a71–6(a)(2)(ii) further predicates the availability of substituted compliance on the Commission and the foreign financial regulatory authority having entered into a supervisory and enforcement memorandum of understanding and/or other arrangement with the relevant foreign financial regulatory authority ''addressing supervisory and enforcement cooperation and other matters arising under the substituted compliance determination.'' The Commission and BaFin recently entered into the relevant memorandum of understanding, thus satisfying this prerequisite.[9]

[3] *Id.* at 72727.

[4] *Id.*

[5] *Id.* (addressing unavailability of substituted compliance in connection with antifraud provisions, as well as provisions related to transactions with counterparties that are not eligible contract participants (''ECPs''), segregation of customer assets, required clearing upon counterparty election, regulatory reporting and public dissemination, and registration of offerings).

[6] *See generally* Exchange Act Release No. 77617 (Apr. 14, 2016), 81 FR 29960, 30073 (May 13, 2016) (''Business Conduct Adopting Release'') (noting that the cross-border nature of the security-based swap market poses special regulatory challenges, in that relevant U.S. requirements ''have the potential to lead to requirements that are duplicative of or in conflict with applicable foreign business conduct requirements, even when the two sets of requirements implement similar goals and lead to similar results'').

[7] *See* ''Key Dates for Registration of Security-Based Swap Dealers and Major Security-Based Swap Participants,'' available at *https://www.sec.gov/page/key-dates-registration-security-based-swap-dealers-and-major-security-based-swap-participants.*

[8] *See* German Substituted Compliance Notice and Proposed Order, 85 FR at 72727. In the German Substituted Compliance Notice and Proposed Order, the Commission preliminarily concluded that this comparability prerequisite was met in connection with a number of requirements under the Exchange Act, in some cases with the addition of conditions to help ensure the comparability of regulatory outcomes.

[9] The Commission and BaFin have entered into a memorandum of understanding to address substituted compliance cooperation, a copy of which the Commission expects to publish on its website at *www.sec.gov* under the ''Substituted Compliance'' tab, which is located on the ''Security-Based Swap Markets'' page in the Division of Trading and Markets section of the site. BaFin and the ECB share responsibility for supervising compliance with certain provisions of EU and German law. The MOU contemplates that there may be books and records and information related to Covered Entities that are in the possession of the ECB's single supervisory mechanism (''SSM'') or otherwise cannot be shared by BaFin without the consent of the ECB/SSM (''ECB Information''). The MOU provides that upon the SEC's request BaFin will use its best efforts to assist the SEC in obtaining ECB information in a prompt manner. This arrangement addresses BaFin's cooperation with respect to ECB information in connection with the current application, which does not include capital and margin requirements. *Compare with* Exchange Act Release No. 34–90766 (December 22, 2020) (''French Substituted Compliance Notice and Proposed Order''). As discussed below, under the Order reliance on substituted compliance is conditioned in part on the applicable MOU remaining in force. *See* part III.B, *infra.*

III. General Availability of Substituted Compliance Under the Order

A. Covered Entities

1. Proposed Approach

Under the proposal, the definition of ''Covered Entity'' specified which entities could make use of substituted compliance. Consistent with the availability of substituted compliance under Exchange Act rule 3a71–6, the proposed definition in part would limit the availability of substituted compliance to SBS Entities that are not U.S. persons. In addition, to help ensure that firms that rely on substituted compliance are subject to relevant German and EU requirements and oversight, the proposed definition would require that Covered Entities be investment firms or credit institutions that BaFin has authorized to provide investment services or perform investment activities in Germany.[10]

2. Final Provisions

Commenters did not address the proposed ''Covered Entity'' definition, and the Commission is issuing the definition as proposed.[11] Substituted compliance accordingly is available only to non-U.S. firms, and requires relevant German and EU requirements and oversight.

B. Additional General Conditions

1. Proposed Approach

The proposal also incorporated a number of additional general conditions intended to predicate a positive substituted compliance determination on the applicability of relevant German and EU requirements needed to establish comparability:

- ''Subject to and Complies with'' applicability condition—For each relevant section of the proposed Order, a positive substituted compliance determination would be predicated on the entity being subject to and complying with the applicable German and EU requirements needed to establish comparability.[12]
- MiFID ''investment services or activities''—The Covered Entity's security-based swap activities would have to constitute ''investment services or activities'' for purposes of applicable provisions[13] under MiFID, WpHG and related EU and German requirements, and must fall within the scope of the firm's authorization from BaFin.[14]
- MiFID ''clients''—The Covered Entity's counterparties (or potential counterparties) would have to be ''clients'' (or potential ''clients'') for purposes of MiFID, WpHG and related EU and German requirements.[15]
- MiFID ''financial instruments''—The relevant security-based swaps would have to be ''financial instruments'' for purposes of [applicable provisions under] MiFID, WpHG and related EU and German requirements.[16]
- CRD ''institutions''—The Covered Entity would have to be an ''institution'' for purposes of applicable provisions under CRD, KWG and CRR and related EU and German requirements.[17]

In addition, consistent with the requirements of rule 3a71–6 and the Commission's need for access to information regarding registered entities, substituted compliance under the proposal further would be conditioned on the Commission and BaFin having an applicable memorandum of understanding or other arrangement addressing cooperation with respect to the substituted compliance Order at the time the Covered Entity makes use of substituted compliance.[18]

Also, to assist the Commission's oversight over firms that avail themselves of substituted compliance, a Covered Entity relying on the substituted compliance order must provide notice of its intent to rely on the order by notifying the Commission in writing.[19]

2. Final Provisions

Commenters did not address the proposed general conditions, and the Commission is issuing those general conditions largely as proposed.[20] The Commission is making two technical changes to the introductory paragraph and definitions section of the Order, however.[21] In the Commission's view, the conditions are structured appropriately to predicate a positive substituted compliance determination on the applicability of relevant German and EU requirements needed to establish comparability, as well as on the continued effectiveness of the requisite MOU, and the provision of notice to the Commission regarding the Covered Entity's intent to rely on substituted compliance.

C. European Union Cross-Border Matters

1. Proposed Approach

The proposal also included general conditions addressing the cross-border

[10] German Substituted Compliance Notice and Proposed Order, 85 FR at 72729.

[11] *See* paragraph (f)(1) to the Order.

[12] The Commission noted, as an example, that this proposed condition would not be satisfied when the comparable German or EU requirements would not apply to the security-based swap activities of a third-country branch of a German SBS Entity. German Substituted Compliance Notice and Proposed Order, 85 FR at 72730.

[13] Under this condition, a Covered Entity's security-based swap activities must constitute ''investment services or activities'' only to the extent that the relevant part of the Order requires the Covered Entity to be subject to and comply with a provision of MiFID, WpHG and related EU and German requirements. If the relevant part of the Order does not require the Covered Entity to be subject to and comply with one of those provisions, then the Covered Entity's security-based swap activities do not have to constitute ''investment services or activities'' to be able to use substituted compliance under that part of the Order.

[14] German Substituted Compliance Notice and Proposed Order, 85 FR at 72730. The EU's Markets in Financial Instruments Directive (''MiFID''), Directive 2014/65/EU, has been implemented in Germany via amendments to the Securities Trading Act—Wertpapierhandelsgesetz (''WpHG''). MiFID and WgHG address, *inter alia,* organizational, compliance and conduct requirements applicable to nonbank ''investment firms.'' In significant part, those requirements also apply to credit institutions that provide investment services or perform investment activities. Commission Delegated Regulation (EU) 2017/565 (''MiFID Org Reg'') in part supplements MiFID with respect to organizational requirements for firms. The Markets in Financial Instruments Regulation (''MiFIR''), Regulation (EU) 648/2012, generally addresses trading venues and transparency. Commission Delegated Directive (EU) 2017/593 (''MiFID Delegated Directive'') in part supplements MiFID with regard to safeguarding client property, and in Germany is implemented in relevant part by the WpHG. Directive (EU) 2015/849 (''MLD'') addresses requirements on the prevention of the use of the financial system for the purposes of money laundering or terrorist financing, and in Germany has been implemented by the Money Laundering Act—Geldwäschegesetz (''GwG'').

[15] German Substituted Compliance Notice and Proposed Order, 85 FR at 72730.

[16] *Id.*

[17] *Id.* The EU's Capital Requirements Directive IV (''CRD''), Directive 2013/36/EU has been adopted in Germany via amendments to the Banking Act—Kreditwesengesetz (''KWG''). CRD and KWG set forth prudential requirements and certain related requirements applicable to credit institutions and certain nonbank investment firms. Certain CRD requirements regarding reporting obligations have been incorporated into German law by the Finanzdienstleistungsaufsichtsgesetz (''FinDAG''). The Capital Requirements Regulation (''CRR''), Regulation (EU) 575/2013 further addresses prudential requirements and related recordkeeping requirements for credit institutions and certain investment firms. Commission Implementing Regulation (EU) 680/2014 (''CRR Reporting ITS'') sets forth implementing technical standard regarding supervisory reporting.

[18] *Id.* at 72730. The Commission and BaFin have entered into a memorandum of understanding to address substituted compliance cooperation. *See* note 9, *supra.* Consistent with the final Order, Covered Entities must ensure that this memorandum of understanding remains in place at the time the Covered Entity relies on substituted compliance.

[19] *Id.*

[20] *See* paragraphs (a)(1) through (6) to the Order.

[21] The introductory paragraph of the Order adds ''as may be amended or superseded from time to time'' to clarify that the Order, including the Order's conditions, may be amended or superseded from time to time. Similarly, the EU and German laws defined in the Order clarify that the EU and German laws referenced therein may be ''amended or superseded from time to time.''

application of MiFID, MAR and EU and German requirements adopted pursuant to MiFID or MAR. For some requirements under MiFID (and other EU and Member State requirements adopted pursuant to MiFID), EU law allocates the responsibility for supervising and enforcing those requirements to authorities of the Member State where an entity provides certain services. Similarly, for some requirements under MAR (and other EU and Member State requirements adopted pursuant to MAR), EU law allocates the responsibility for supervising and enforcing those requirements to authorities of potentially multiple Member States. To help ensure that the prerequisites to substituted compliance with respect to supervision and enforcement are satisfied in fact, the proposal provided substituted compliance only if BaFin is responsible for supervision and enforcement of those requirements.[22]

2. Commenter Views and Final Provisions

As noted above, commenters did not address the general conditions, including those related to EU cross-border matters. The Commission is issuing as proposed the general conditions related to EU cross-border matters.[23] In the Commission's view, these conditions are structured appropriately to permit the use of substituted compliance only when BaFin is the entity responsible for supervising a Covered Entity's compliance with a relevant provision of MiFID, MAR or related EU or German requirements.

IV. Substituted Compliance for Risk Control Requirements

A. Proposed Approach

BaFin's application in part requested substituted compliance in connection with risk control requirements relating to:

- Risk management systems—Internal risk management system requirements that address the obligation of registered entities to follow policies and procedures reasonably designed to help manage the risks associated with their business activities.
- Trade acknowledgment and verification—Trade acknowledgment and verification requirements intended to help avoid legal and operational risks by requiring definitive written records of transactions and procedures to avoid disagreements regarding the meaning of transaction terms.
- Portfolio reconciliation and dispute reporting—Portfolio reconciliation and dispute reporting provisions that require that counterparties engage in portfolio reconciliation and resolve discrepancies in connection with uncleared security-based swaps, and to provide prompt notification to the Commission and applicable prudential regulators regarding certain valuation disputes.
- Portfolio compression—Portfolio compression provisions that require that SBS Entities have procedures addressing bilateral offset, bilateral compression and multilateral compression in connection with uncleared security-based swaps.
- Trading relationship documentation—Trading relationship documentation provisions that require SBS Entities to have procedures to execute written security-based swap trading relationship documentation with their counterparties prior to, or contemporaneously with, executing certain security-based swaps.[24]

Taken as a whole, these risk control requirements help to promote market stability by mandating that registered entities follow practices that are appropriate to manage the market, counterparty, operational and legal risks associated with their security-based swap businesses.

In proposing to provide conditional substituted compliance in connection with this part of BaFin's application, the Commission preliminarily concluded that the relevant German and EU requirements in general would produce regulatory outcomes that are comparable to those associated with those risk control requirements, by subjecting German entities to financial responsibility, risk mitigation and documentation practices that are appropriate to the risks associated with their security-based swap businesses.[25] Substituted compliance under the proposal was to be conditioned in part on Covered Entities being subject to the specified German and EU provisions that in the aggregate produce regulatory outcomes that are comparable to those associated with the risk control requirements under the Exchange Act.[26]

Substituted compliance under the proposal further would be subject to certain additional conditions to help ensure the comparability of outcomes. First, substituted compliance in connection with the trading relationship documentation provisions would be conditioned on the requirement that the Covered Entity not treat its counterparties as ''eligible counterparties'' for purposes of relevant MiFID provisions.[27] In addition, substituted compliance related to trading relationship documentation under the proposal would not extend to certain disclosures regarding legal and bankruptcy status.[28] Finally, substituted compliance in connection with dispute reporting requirements would be conditioned on the Covered Entity having to provide the Commission with reports regarding disputes between counterparties on the same basis as they provide those reports to competent authorities pursuant to EU law.[29]

B. Commenter Views and Final Provisions

Commenters expressed general support for the proposed approach toward substituted compliance for the risk control provisions, but requested that the Commission modify aspects of the proposal related to risk management systems, trade acknowledgement and verification, and trading relationship documentation.[30] After considering

[22] *See* German Substituted Compliance Notice and Proposed Order, 85 FR at 72730, 72743–44.

[23] *See* paragraphs (a)(7)(i) and (ii) to the Order.

[24] German Substituted Compliance Notice and Proposed Order, 85 FR at 72730–31.

[25] *Id.* at 72731.

[26] *Id.* at 72731 n.48. Those proposed conditions in part addressed compliance with certain requirements arising under the European Market Infrastructure Regulation (''EMIR''), Regulation (EU) 648/2012. EMIR in part imposes certain risk-mitigation requirements on counterparties in connection with uncleared OTC transactions. Delegated Regulation (EU) 149/2013 (''EMIR RTS'') supplements EMIR with various regulatory technical standards, including standards addressing confirmations, portfolio reconciliation, portfolio compression and dispute resolution. Delegated Regulation (EU) 2016/2251 (''EMIR Margin RTS'') further supplements EMIR with regulatory technical standards related to risk mitigation techniques.

[27] *Id.* at 72731. Certain relevant German and EU requirements that provide for this type of documentation do not apply to investment firms' transactions with ''eligible counterparties.''

[28] *Id.* The trading relationship documentation provisions of rule 15F(b)(5) requires certain disclosures regarding the status of the SBS Entity or its counterparty as an insured depository institution or financial counterparty, and regarding the possible application of the insolvency regime set forth under Title II of the Dodd-Frank Act or the Federal Deposit Insurance Act. Documentation requirements under applicable German and EU law would not be expected to address the disclosure of information related to insolvency procedures under U.S. law.

[29] *Id.* Under the Exchange Act requirement, SBS Entities must promptly report, to the Commission, valuation disputes in excess of $20 million that have been outstanding for three or five business days (depending on counterparty types). EU requirements provide that firms must report at least monthly, to competent authorities, disputes between counterparties in excess of €15 million and outstanding for at least 15 business days.

[30] *See* Letter from Kyle Brandon, Managing Director, Head of Derivative Policy, SIFMA (Dec. 8, 2020) (''SIFMA Letter''). The other comments expressed generally concurrence with the SIFMA Letter, but did not otherwise comment specifically on the risk control requirements. *See* Letter from

Continued

commenter views, the Commission is providing for substituted compliance in connection with the risk control requirements largely as provided by the proposal, with certain discrete changes discussed below.

The Commission continues to conclude that, taken as a whole, applicable requirements under German and EU law subject German entities to financial responsibility, risk mitigation and documentation practices that are appropriate to the risks associated with their security-based swap businesses, and thus produce regulatory outcomes that are comparable to the outcomes associated with the relevant risk control requirements under the Exchange Act. Although the Commission recognizes that there are differences between the approaches taken by the relevant risk control requirements under the Exchange Act and relevant German and EU requirements, the Commission continues to believe that those differences on balance should not preclude substituted compliance for these requirements, as the relevant German and EU requirements taken as a whole produce comparable regulatory outcomes.

Substituted compliance for risk management system requirements is conditioned on Covered Entities complying with specified German and EU requirements that promote risk management within those entities, consistent with the proposal.[31] The Commission has considered commenter views recommending that those underlying German and EU requirements be targeted in certain respects, but concludes that those requirements as a whole are crafted to produce a regulatory outcome comparable to requirements under the Exchange Act and to avoid ambiguity in application.[32]

For trade acknowledgment and verification requirements, substituted compliance is conditioned on Covered Entities complying with confirmation requirements pursuant to EMIR and MiFID, consistent with the proposal.[33] The Commission has considered commenter views recommending that substituted compliance should only be conditioned on compliance with the EMIR confirmation requirements, but concludes that both sets of requirements contribute to the conclusion that German and EU law produces a comparable regulatory outcome to the trade acknowledgement and verification requirements under the Exchange Act.[34]

Substituted compliance for trading relationship documentation requirements has been modified from the proposal after taking into account issues raised by commenters.[35] In contrast to the proposal—which would not have provided substituted compliance in connection with the rule 15Fi–5(b)(5) disclosures regarding the status of the entity or its counterparty as an insured depository institution or financial counterparty (on the grounds that the relevant German and EU provisions do not address the disclosure of that type of information)—the Order will provide for substituted compliance in connection with that disclosure unless the counterparty to the Covered Entity is a U.S. person.[36] Also, the portion of the Order that conditions substituted compliance on the Covered Entity not treating its counterparties as ''eligible counterparties'' for purposes of relevant MiFID provisions has been modified from the proposal to better clarify the targeted nature of that condition.[37] The Order also has been modified to better target the German and

Jan Ford, Head of Compliance, Americas and Co-Head of SBS Council, Deutsche Bank, and Gary Kane, Co-Head Institutional Client Group, Americas and Co-Head of SBS Council, Deutsche Bank (Dec. 8, 2020) (''Deutsche Bank Letter'') at 2 (''strongly endorse the comments and recommendations'' in the SIFMA Letter); Letter from Wim Mijs, Chief Executive Officer, European Banking Federation (Dec. 8, 2020) (''EBF Letter'') at 1 (''strongly support'' the SIFMA Letter). Comments may be found on the Commission's website at: *https://www.sec.gov/comments/s7-16-20/s71620.htm.*

[31] Substituted compliance for the risk management system requirements particularly is conditioned on Covered Entities being subject to and complying with: MiFID art. 16(4)–(5) and WpHG sec. 80 (addressing administrative and accounting procedures, internal control mechanisms, risk assessment procedures and information processing system safeguards); MiFID Org Reg art. 21–24 (addressing risk management and internal audit); CRD art. 74, 76 and 79–87 and KWG sections 25a, 25b, 25c (other than 25c(2)), 25d (other than 25d(3) and 25d(11)) (addressing internal governance and the treatment of various categories of risk); and EMIR Margin RTS art. 2 (addressing required risk management procedures for the exchange of collateral for non-centrally cleared over-the-counter derivatives contracts); CRR art. 286–88 and 293 (addressing counterparty credit risk management and risk management systems); EMIR Margin RTS art. 2 (addressing general provisions for risk management procedures). *See* paragraph (b)(1) to the Order.

[32] SIFMA recommended that the predicates to substituted compliance not include MiFID Org Reg article 22 (related to compliance), or the CRD, KWG and CRR provisions noted above. In the Commission's view, removal of those compliance, risk management, audit, governance and related conditional would fail to promote risk management consistent with the requisite regulatory outcome. SIFMA also recommended the addition of an ''in each case relating to risk management'' limitation to those prerequisites, on the grounds that not all of the applicable provisions are limited in scope to internal risk management. In the Commision's view, however, this type of limitation would be expected to lead to ambiguity, resulting in uncertainty regarding the availability and application of substituted compliance.

[33] Substituted compliance for the trade acknowledgement and verification requirements particularly is conditioned on the Covered Entity being subject to and complying with: MiFID art. 25(6) and WpHG sec. 63(12) (addressing reports on services), MiFID Org Reg art. 59–61 (addressing essential information regarding executed orders and portfolio management), EMIR art. 11(1)(a) (addressing required bilateral confirmations for uncleared over-the-counter derivatives) and EMIR RTS art. 12 (addressing timeliness of confirmations). *See* para (b)(2) to the Order.

[34] SIFMA recommended that substituted compliance for trade acknowledgement and verification need only be conditioned on compliance with EMIR confirmation requirements, consistent with the CFTC's approach to substituted compliance. The MiFID confirmation requirement specifies data elements that are not directly addressed by the EMIR confirmation requirement, and in the Commission's view the holistic approach for comparing regulatory outcomes should seek to reflect the whole of a jurisdiction's relevant requirements, rather than select subsets of those requirements.

[35] Substituted compliance in connection with trading relationship documentation requirements is conditioned on Covered Entities being subject to and complying with: MiFID art. 25(5) and WpHG sec. 83(2) (addressing required records of documents regarding parties' rights and obligations and other terms on which the investment firm will provide services); MiFID Org Reg art. 24, 58, 73 and applicable parts of Annex I (addressing audit requirements, records related to appropriateness assessments, client agreements and parties' rights and obligations); and EMIR Margin RTS art. 2 (addressing general provisions for risk management procedures, including procedures providing for or specifying the terms of agreements). *See* para. (b)(5)(i) to the Order. Those EMIR requirements apply only to ''OTC derivatives contracts,'' which are defined as derivatives contracts not executed on certain ''regulated markets'' or equivalent ''third-country markets.'' *See* EMIR art. 2(7). The EMIR-related conditions accordingly will not impede substituted compliance in connection with exchange-traded or market-traded security-based swaps that do not constitute ''OTC derivatives contracts.''

[36] *See* paragraph (b)(5) to the Order. After considering commenter views, the Commission concludes that the absence of such disclosure would not preclude a comparable regulatory outcome when the counterparty is not a U.S. person, as the insolvency-related consequences that are the subject of the disclosure would not be applicable to non-U.S. counterparties in most cases. *In this respect the Commission notes that the requirements of EMIR Margin art. 2 in part address procedures providing for or specifying the terms of agreements entered into by the counterparties, including applicable governing law for non-cleared derivatives. EMIR Margin RTS art. 2 further provides that counterparties which enter into a netting or collateral exchange agreement must perform an independent legal review regarding enforceability.*

[37] In particular, the Order condition that does not allow for application of the MiFID ''eligible counterparty'' exception has been modified from the proposal by including ''in relation to the MiFID and WpHG provisions specified in paragraph (b)(5)(i)'' language. This technical change clarifies that the condition does not address a Covered Entity's use of the ''eligible counterparty'' exception in unrelated circumstances (such as when the Covered Entity's relies on the exception in connection with its non-SBS business, or in connection with activities and business for which the Covered Entity does not seek substituted compliance).

EU law prerequisites to substituted compliance for those requirements.[38]

The Commission received no comments related to substituted compliance in connection with portfolio reconciliation and dispute reporting requirements, and the Commission is providing for substituted compliance in connection with those requirements as proposed.[39] Substituted compliance in connection with the dispute reporting requirements is conditioned in part on the Covered Entities providing the Commission with reports regarding disputes between counterparties on the same basis as the entities provide those reports to competent authorities pursuant to EU law, to allow the Commission to obtain notice regarding key information in a manner that makes use of existing obligations under EU law.[40]

Finally, the Commission received no comments related to substituted compliance in connection with portfolio compression requirements, and the Commission is providing for substituted compliance in connection with those requirements as proposed.[41]

V. Substituted Compliance for Internal Supervision and Compliance Requirements

A. Proposed Approach

BaFin's application further requested substituted compliance in connection with requirements relating to:

- Internal supervision—Diligent supervision and conflict of interest provisions that generally require SBS Entities to establish, maintain and enforce supervisory policies and procedures that reasonably are designed to prevent violations of applicable law, and implement certain systems and interest.
- Chief compliance officers—Chief compliance officer provisions that generally require SBS Entities to designate individuals with the responsibility and authority to establish, administer and review compliance policies and procedures, to resolve conflicts of interest, and to prepare and certify annual compliance reports to the Commission.
- Additional Exchange Act section 15F(j) requirements—Certain additional requirements related to information-gathering, and antitrust prohibitions.[42]

Taken as a whole, those requirements generally help to advance SBS Entities' use of structures, processes and responsible personnel reasonably designed to promote compliance with applicable law, identify and cure instances of noncompliance, and manage conflicts of interest.

In proposing to provide conditional substituted compliance in connection with this part of BaFin's application, the Commission preliminarily concluded that the relevant German and EU requirements in general would produce comparable regulatory outcomes by providing that German SBS Entities have structures and processes that reasonably are designed to promote compliance with applicable law and to identify and cure instances of non-compliance and manage conflicts of interest. Substituted compliance under the proposal was to be conditioned in part on SBS Entities being subject to and complying with specified German and EU provisions that in the aggregate produce regulatory outcomes that are comparable to those associated with those internal supervision, compliance and related requirements under the Exchange Act.[43]

Under the proposal, substituted compliance would be subject to certain additional conditions to help ensure the comparability of outcomes. First, substituted compliance in connection with the internal supervision requirements would be conditioned on the SBS Entities complying with applicable German and EU supervisory and compliance provisions *as if* those provisions also require the entities to comply with applicable requirements under the Exchange Act and the other conditions to the Order. This condition was intended to reflect that, even with substituted compliance, SBS Entities still directly would be subject to a number of requirements under the Exchange Act and conditions to the final Order that fall outside the ambit of German and EU internal supervision and compliance requirements.[44]

For similar reasons, the proposal would condition substituted compliance in connection with compliance report requirements on the Covered Entity annually providing the Commission with certain compliance reports required pursuant to regulations under MiFID. Those reports must be in English, be accompanied by a certification under penalty of law that the report is accurate and complete, and would have to address the SBS Entity's compliance with other conditions to the substituted compliance order.[45] In addition, substituted compliance under the proposal would not extend to antitrust provisions under the Exchange Act, based on the preliminary conclusion that allowing an alternative means of compliance would not lead to comparable regulatory outcomes.[46]

B. Commenter Views and Final Provisions

Commenters expressed general support for the proposed approach toward substituted compliance, but requested that the Commission modify aspects of the proposed order. After considering commenter views, the Commission is providing for substituted compliance that generally is consistent with the proposal, with certain clarifying changes discussed below.[47]

The Commission continues to conclude that, taken as a whole, applicable requirements under German and EU law require that SBS Entities have structures and processes that reasonably are designed to promote

[38] In particular, the Order has been modified from the proposal by removing MiFID Org Reg article 56, related to records of appropriateness assessments, as those records do not advance the purposes behind the trading relationship documentation requirement to the same extent as the other relevant provisions. The Order, however, does not incorporate the suggested addition of ''in each case relating to written agreements with security-based swap counterparties'' language that may be expected to be ambiguous in application.

[39] *See* paragraph (b)(3) to the Order. Substituted compliance in connection with those requirements is conditioned in part on Covered Entities being subject to and complying with EMIR art. 11(1)(b) (addressing required portfolio reconciliation and dispute resolution for uncleared over-the-counter derivatives) and EMIR RTS art. 13 and 15 (addressing further requirements related to portfolio reconciliation and dispute resolution). *See* para. (b)(3)(i) to the proposed Order.

[40] *See* paragraph (b)(3)(ii) to the Order. The Commission recognizes the differences between the two sets of requirements—under which Exchange Act rule 15Fi–3 requires SBS Entities to report valuation disputes in excess of $20 million that have been outstanding for three or five business days (depending on counterparty types), while EMIR RTS art. 15(2) requires firms to report disputes between counterparties in excess of €15 million and outstanding for at least 15 business days. In the Commission's view, the two requirements produce comparable regulatory outcomes notwithstanding those differences.

[41] *See* paragraph (b)(4) to the Order. Substituted compliance in connection with portfolio compression requirements is conditioned on Covered Entities being subject to and complying with EMIR RTS art. 14 (also addressing portfolio protection).

[42] German Substituted Compliance Notice and Proposed Order, 85 FR at 72732.

[43] *Id.* at 72733 n.62.

[44] *Id.* at 72733. The condition was intended to allow Covered Entities to use their existing internal supervision and compliance frameworks to comply with the relevant Exchange Act requirements and order conditions, rather than having to establish separate special-purpose supervision and compliance frameworks.

[45] *Id.* at 72733–34.

[46] *Id.* at 72734.

[47] *See* paragraph (c) to the Order.

compliance with applicable law and to identify and cure instances of non-compliance and manage conflicts of interest, and thus produce regulatory outcomes that are comparable to those associated with the above-described internal supervision, chief compliance officer, conflict of interest and information-related requirements. Although there are differences between the approaches taken by the relevant risk control requirements under the Exchange Act and relevant German and EU requirements, the Commission continues to believe that the relevant German and EU requirements taken as a whole produce comparable regulatory outcomes.

Substituted compliance in connection with those requirements is conditioned in part on Covered Entities being subject to and complying with specified German and EU provisions that promote compliance and address conflicts of interest.[48] The Commission has considered commenter views regarding those prerequisites, but concludes that those German and EU provisions as a whole are appropriate to produce comparable regulatory outcomes.[49]

The Order retains, with clarifications, proposed provisions to target substituted compliance as needed to promote the consistency of regulatory outcomes. Accordingly, substituted compliance in connection with internal supervision is conditioned on the Covered Entity complying with applicable German and EU supervisory and compliance provisions *as if* those provisions also require SBS Entities to comply with applicable requirements under the Exchange Act and the other applicable conditions to the Order.[50] Similarly, substituted compliance in connection with the chief compliance officer requirements is conditioned on the Covered Entity annually providing certain compliance reports to the Commission, in English, with a certification under penalty of law that the report is accurate and complete, and with the report addressing the SBS Entity's compliance with other applicable conditions to the order.[51] For the reasons discussed in the proposal, moreover, the substituted compliance Order does not extend to antitrust provisions under the Exchange Act.

VI. Substituted Compliance for Counterparty Protection Requirements

A. Proposed Approach

BaFin's application in part requested substituted compliance in connection with counterparty protection requirements relating to:

- Disclosure of material risks and characteristics and material incentives or conflicts of interest—Requirements that an SBS Entity disclose to certain security-based swap counterparties certain information about the material risks and characteristics of the security-based swap, as well as material incentives or conflicts of interest that the SBS Entity may have in connection with the security-based swap.
- Daily mark disclosure—Requirements that an SBS Entity provide daily mark information to certain security-based swap counterparties.
- Fair and balanced communications—Requirements that an SBS Entity communicate with security-based swap counterparties in a fair and balanced manner based on principles of fair dealing and good faith.
- Clearing rights disclosure—Requirements that an SBS Entity provide certain counterparties with information regarding clearing rights under the Exchange Act.
- ''Know your counterparty''—Requirements that an SBS Entity establish, maintain and enforce written policies and procedures to obtain and retain certain information regarding a security-based swap counterparty that is necessary for conducting business with that counterparty.
- Suitability—Requirements for a security-based swap dealer to undertake reasonable diligence to understand the potential risks and rewards of any recommendation of a security-based swap or trading strategy involving a security-based swap that it makes to certain counterparties and to have a reasonable basis to believe that the recommendation is suitable for the counterparty.

Taken as a whole, these counterparty protection requirements help to ''bring professional standards of conduct to, and increase transparency in, the security-based swap market and to require registered [entities] to treat parties to these transactions fairly.'' [52]

The proposal provided for substituted compliance in connection with fair and balanced communications, disclosure of material risks and characteristics, disclosure of material incentives or conflicts of interest, ''know your counterparty,'' suitability and daily mark disclosure requirements. In proposing to provide conditional substituted compliance for these requirements, the Commission preliminarily concluded that the relevant German and EU requirements in general would produce regulatory outcomes that are comparable to requirements under the Exchange Act, by subjecting German Covered Entities to obligations that promote standards of professional conduct, transparency and the fair treatment of parties.

As proposed, substituted compliance for these requirements would be subject to certain conditions to help ensure the comparability of outcomes. First, under the proposal, substituted compliance for fair and balanced communications, disclosure of material risks and characteristics, disclosure of material incentives or conflicts of interest, ''know your counterparty'' and suitability requirements would be conditioned on Covered Entities being subject to, and complying with, relevant

[48] In connection with the internal supervision, chief compliance officer and conflict of interest and information-gathering provisions, Covered Entities particularly must comply with: MiFID art. 16 and 23 and WpHG sec. 63, 80 and 83–84 (addressing organizational requirements and conflicts of interest); MiFID Org Reg art. 21–37 (addressing organizational requirements, compliance, risk management, internal audit, senior management responsibility, complaints handling, remuneration policies and practices, personal transaction restrictions, outsourcing, conflicts of interest and investment research and marketing); MiFID Org Reg 72–76 and Annex IV (addressing recordkeeping, including records of orders, transactions and communications); and CRD articles 74, 76, 79–87, 88(1) and 91(1)–(2), 91(7)–(9), 92–95 and KWG sections 25a, 25b, 25c (other than 25c(2)), 25d (other than 25d(3) and 25d(11)), 25e and 25f (addressing internal governance, recovery and resolution plans, risk management policies, and management body and remuneration policies). *See* paragraph (c)(3).

[49] SIFMA in part recommended removal of certain risk-related and record-related provisions from the conditions. The Commission, however, does not believe that excluding those provisions would promote supervisory and compliance goals consistent with the necessary regulatory outcome. The Commission also is not incorporating additional suggested language to focus the application of underlying German and EU provisions (by requiring compliance with German and EU requirements only to the extent they ''relate to'' oversight arrangements, compliance and conflict of interest management), as that type of limitation may cause ambiguity.

[50] *See* paragraph (c)(4) to the Order. For clarity, the Order has been modified from the proposal to provide that the Covered Entity must comply with relevant German and EU provisions as if those provisions address ''applicable'' conditions to the Order connected to requirements for which the Covered Entity is relying on substituted compliance. That part of the condition does not apply to parts of the Order for which the Covered Entity does not rely on substituted compliance.

[51] *See* paragraph (c)(3)(ii) to the Order. Here too, the Order has been modified from the proposal to clarify that the compliance report need only address other applicable conditions to the Order. This condition is not intended to create an independent requirement that the Covered Entity provide the relevant compliance reports to German or EU authorities, and does not address the ability of German or EU authorities to obtain and review such records.

[52] *See* Business Conduct Adopting Release, 81 FR at 30065.

German and EU requirements.[53] Second, the proposal would additionally condition substituted compliance for suitability requirements on the counterparty being a per se ''professional client'' as defined in MiFID (rather than a ''retail client'' or an elective ''professional client'' [54]) and not a ''special entity'' as defined in Exchange Act section 15F(h)(2)(C) and Exchange Act rule 15Fh–2(d).[55] Finally, in the proposal the Commission preliminarily viewed EU daily portfolio reconciliation requirements as comparable to Exchange Act daily mark disclosure requirements.[56] These daily portfolio reconciliation requirements apply to portfolios of a financial counterparty or a non-financial counterparty subject to the clearing obligation in EMIR in which the counterparties have 500 or more OTC derivatives contracts outstanding with each other.[57] The Commission preliminarily viewed EU portfolio reconciliation requirements for other types of portfolios, which may be reconciled less frequently than each business day, as not comparable to Exchange Act daily mark requirements.[58] Accordingly, the proposal would condition substituted compliance for daily mark requirements on the Covered Entity being required to reconcile, and in fact reconciling, the portfolio containing the relevant security-based swap on each business day pursuant to relevant EU requirements.[59]

The proposal would not provide substituted compliance in connection with Exchange Act requirements for SBS Entities to disclose a counterparty's clearing rights under Exchange Act section 3C(g)(5). BaFin's application argued that certain EU provisions related to a counterparty's clearing rights in the European Union are comparable to requirements to disclose the counterparty's Exchange Act-based clearing rights. Because these EU provisions do not require disclosure of these clearing rights, the Commission preliminarily viewed the EU clearing provisions as not comparable to Exchange Act clearing rights disclosure requirements.

B. Commenter Views and Final Provisions

After considering commenter views, the Commission is providing for substituted compliance in connection with fair and balanced communications, disclosure of material risks and characteristics, disclosure of material incentives or conflicts of interest, ''know your counterparty,'' suitability and daily mark disclosure requirements, in each case consistent with the proposal except for one clarifying change regarding substituted compliance for suitability requirements.[60] This action is grounded in the Commission's conclusion that, taken as a whole, applicable requirements under German and EU law subject German Covered Entities to obligations that promote standards of professional conduct, transparency and the fair treatment of parties, and thus produce regulatory outcomes that are comparable to the outcomes associated with the relevant counterparty protection requirements under the Exchange Act.

Consistent with the proposal, substituted compliance is conditioned on certain conditions to help ensure the comparability of outcomes. Substituted compliance for fair and balanced communications,[61] disclosure of material risks and characteristics,[62] disclosure of material incentives or conflicts of interest,[63] ''know your counterparty'' [64] and suitability [65] requirements is conditioned on Covered Entities being subject to, and complying with, relevant German and EU requirements. A commenter requested that the Commission remove from the list of German and EU suitability requirements MiFID article 24(3), WpHG section 63(6) and MiFID Org Reg article 21(1)(b) and (d), stating that these provisions are unrelated to suitability requirements.[66] The Commission notes that a portion of MiFID's suitability requirements directs Member States to require investment firms and credit institutions to ensure that persons giving investment advice or information about financial instruments, investment services or ancillary services to clients on behalf of the firm possess the necessary knowledge and competence to fulfill certain obligations, including the obligation in MiFID article 24(3).[67] In comparing EU and German suitability requirements to Exchange Act suitability requirements, BaFin's application likewise states that firms must ensure persons giving this type of advice ''possess the necessary knowledge and competence to comply with the requirement that all information provided to clients is fair, clear and not misleading [as required by

[53] *See* German Substituted Compliance Notice and Proposed Order, 85 FR at 72735 n.81.

[54] Annex II of MiFID describes which clients are ''professional clients.'' Section I of Annex II describes the types of clients considered to be professional clients unless the client elects non-professional treatment; these clients are per se professional clients. Section II of Annex II describes the types of clients who may be treated as professional clients on request; these clients are elective professional clients. *See* MiFID Annex II. Retail clients are those that are not professional clients. *See* MiFID article 4(1)(11).

[55] *See* German Substituted Compliance Notice and Proposed Order, 85 FR at 72736.

[56] *See* German Substituted Compliance Notice and Proposed Order, 85 FR at 72735.

[57] *See* EMIR RTS article 13(3)(a)(i); EMIR article 10.

[58] *See* German Substituted Compliance Notice and Proposed Order, 85 FR at 72735.

[59] *See* German Substituted Compliance Notice and Proposed Order, 85 FR at 72735.

[60] *See* para. (d) to the Order.

[61] In connection with fair and balanced communications requirements, Covered Entities must be subject to and comply with: (i) Either MiFID art. 24(1), (3) and WpHG sections 63(1), (6) or MiFID art. 30(1) and WpHG section 68(1); and (ii) MiFID art. 24(4)–(5); WpHG sections 63(7) and 64(1); MiFID Org Reg art. 46–48; Market Abuse Regulation art. 12(1)(c) and 15; and MAR Investment Recommendations Regulation art. 5, in each case in relation to the communication for which substituted compliance is applied. *See* para. (d)(5) to the Order.

[62] In connection with requirements related to disclosure of information regarding material risks and characteristics, Covered Entities must be subject to and comply with: MiFID art. 24(4); WpHG sections 63(7) and 64(1); and MiFID Org Reg art. 48–50, in each case in relation to the security-based swap for which substituted compliance is applied. *See* para. (d)(1) to the Order.

[63] In connection with requirements related to disclosure of information regarding material incentives or conflicts of interest, Covered Entities must be subject to and comply with either: (i) MiFID art. 23(2)–(3); WpHG section 63(2); and MiFID Org Reg art. 33–35; (ii) MiFID art. 24(9); WpHG section 70; and MiFID Delegated Directive art. 11(5); or (iii) Market Abuse Regulation art. 20(1), in each case in relation to the security-based swap for which substituted compliance is applied. *See* para. (d)(2) to the Order.

[64] In connection with ''know your counterparty'' requirements, Covered Entities must be subject to and comply with: MiFID art. 16(2); WpHG section 80(1); MiFID Org Reg art. 21–22, 25–26 and applicable parts of Annex I; CRD art. 74(1) and 85(1); KWG section 25a; MLD art. 11 and 13; GwG sections 10–11; MLD art. 8(3) and 8(4)(a) as applied to internal policies, controls and procedures regarding recordkeeping of customer due diligence activities; GwG section 6(1)–(2) as applied to principles, procedures and controls regarding recordkeeping of customer due diligence activities, in each case in relation to the security-based swap for which substituted compliance is applied. *See* para. (d)(3) to the Order.

[65] In connection with suitability requirements, Covered Entities must be subject to and comply with: MiFID art. 24(2)–(3) and 25(1)–(2); WpHG sections 63(5)–(6), 80(9)–(13) and 87(1)–(2); and MiFID Org Reg art. 21(1)(b) and (d), 54 and 55, in each case in relation to the recommendation of a security-based swap or trading strategy involving a security-based swap that is provided by or on behalf of the Covered Entity and for which substituted compliance is applied. *See* para. (d)(4)(i) to the Order.

[66] *See* SIFMA Letter at 14; *see also* Deutsche Bank Letter at 2; EBF Letter at 1.

[67] *See* MiFID art. 24(3) (all information addressed to clients or potential clients must be fair, clear and not misleading); MiFID art. 25(1) (partial suitability requirement applicable to investment firms); MiFID art. 1(3)(b) (when providing one or more investment services and/or performing investment activities, credit institutions are subject to MiFID arts. 24(3) and 25(1)).

MiFID article 24(3)].'' [68] WpHG section 63(6) is the German law transposition of MiFID article 24(3).[69] MiFID Org Reg article 21(1)(b) requires investment firms and credit institutions to ensure that employees are aware of the procedures to be followed for the proper discharge of their responsibilities, which include the knowledge and competence requirements described above.[70] MiFID Org Reg article 21(1)(d) requires investment firms and credit institutions to employ personnel with the skills, knowledge and expertise necessary for the discharge of their responsibilities, which also include the knowledge and competence requirements described above.[71] Because these requirements contribute to the Commission's conclusion that EU and German requirements are comparable to Exchange Act suitability requirements, the Commission is adopting the condition as proposed, and requiring a Covered Entity to be subject to and comply with those EU and German requirements if the Covered Entity wishes to make use of substituted compliance for Exchange Act suitability requirements. The commenter also requested that the Commission clarify Covered Entities relying on substituted compliance must be subject to and comply with these requirements in relation to the recommendation of a security-based swap or trading strategy involving a security-based swap that is provided by or on behalf of the Covered Entity.[72] The Commission agrees that specifying the types of recommendations subject to this condition will provide useful clarity to market participants considering whether to make use of substituted compliance for Exchange Act suitability requirements, and is including this clarification in the Order.[73] Substituted compliance for suitability requirements additionally is conditioned on the counterparty being a per se ''professional client'' as defined in MiFID and not a ''special entity'' as defined in Exchange Act section 15F(h)(2)(C) and Exchange Act rule 15Fh–2(d).[74]

Substituted compliance for daily mark requirements also is conditioned on the Covered Entity being required to reconcile, and in fact reconciling, the portfolio containing the relevant security-based swap on each business day pursuant to relevant EU requirements.[75] A commenter suggested that this condition should apply only to security-based swaps with U.S. counterparties; for all other transactions subject to Exchange Act daily mark requirements, the commenter proposed that the Commission grant substituted compliance if the Covered Entity complies with EU mark-to-market (or mark-to-model) and reporting requirements.[76] The commenter provided three reasons in support of this bifurcated approach and, for the reasons explained below, the Commission declines to adopt it.

First, the commenter stated that non-U.S. security-based swap dealers would face significant challenges and costs to identify which security-based swaps with non-U.S. counterparties were arranged, negotiated or executed by personnel of the security-based swap dealer or its agent located in a U.S. branch or office (''ANE Transactions''), and thus subject to Exchange Act daily mark requirements.[77] According to the commenter, many non-U.S. security-based swap dealers may choose to block U.S. personnel from taking part in security-based swaps with non-U.S. counterparties that are not subject to the EU's daily portfolio reconciliation requirements, thereby avoiding creation of an ANE Transaction that is not eligible for substituted compliance and the attendant challenges and costs of identifying those transactions.[78] The commenter asserted that daily mark requirements should not apply to a non-U.S. security-based swap dealer's ANE Transactions because the Commission did not require compliance with daily mark requirements in connection with the exception provided in Exchange Act rule 3a71–3(d)(1) to counting certain ANE Transactions towards security-based swap dealer registration thresholds.[79] The commenter noted that daily mark requirements do not apply to certain ANE Transactions excepted from those thresholds because there is no ''ongoing relationship between . . . the entity whose personnel interact with the counterparty . . . and the counterparty.'' [80] The commenter stated that a similar rationale applies to the application of daily mark requirements to a non-U.S. security-based swap dealer's ANE Transactions.[81]

The Commission previously has addressed why ANE Transactions are subject to Exchange Act daily mark requirements, as well as the costs and challenges of identifying such transactions.[82] As noted above, substituted compliance does not constitute exemptive relief, but instead provides an alternative method by which non-U.S. SBS Entities may comply with applicable Exchange Act requirements. The Commission is providing for substituted compliance for daily mark requirements based on comparability of outcomes with respect to ANE Transactions to the same extent as it is providing substituted compliance with respect to all other

[68] *See* BaFin Application Annex A category 4 at 75–76.

[69] *See* BaFin Application Annex A category 4 at 75.

[70] *See* MiFID Org Reg art. 21(1)(b) (requirement for investment firm employees to be aware of procedures for the proper discharge of their responsibilities; requirement implements MiFID art. 16(2)–(10)); MiFID Org Reg art. 1(2) (in portions of MiFID Org Reg that implement MiFID requirements to which credit institutions are subject, references to investment firms encompass credit institutions); MiFID art. 1(3)(a) (credit institutions are subject to MiFID art. 16).

[71] *See* MiFID Org Reg art. 21(1)(d) (requirement for investment firms to employ personnel with the knowledge, skills and expertise necessary for the discharge of their responsibilities; requirement implements MiFID art. 16(2)–(10)); MiFID Org Reg art. 1(2) (in portions of MiFID Org Reg that implement MiFID requirements to which credit institutions are subject, references to investment firms encompass credit institutions); MiFID art. 1(3)(a) (credit institutions are subject to MiFID art. 16).

[72] *See* SIFMA Letter at 14; *see also* Deutsche Bank Letter at 2; EBF Letter at 1. The proposed Order would have required a Covered Entity relying on substituted compliance to be subject to and comply with EU and German suitability requirements in relation to a recommendation that is provided by or on behalf of the Covered Entity. *See* German Substituted Compliance Notice and Proposed Order, 85 FR at 72745.

[73] *See* para. (d)(4)(i) to the Order.

[74] *See* para. (d)(4)(ii) to the Order.

[75] Covered Entities must be required to reconcile, and in fact reconcile, the portfolio containing the security-based swap for which substituted compliance is applied, on each business day pursuant to EMIR articles 11(1)(b) and 11(2) and EMIR RTS article 13. *See* para. (d)(6) to the Order.

[76] *See* SIFMA Letter at 6; *see also* Deutsche Bank Letter at 2; EBF Letter at 1.

[77] *See* SIFMA Letter at 3–5.

[78] *See* SIFMA Letter at 4.

[79] *See* SIFMA Letter at 4; *see also* Exchange Act Release No. 87780 (Dec. 18, 2019), 85 FR 6270 (Feb. 4, 2020) (''Cross-Border Adopting Release'').

[80] *See* SIFMA Letter at 4 (citing Cross-Border Adopting Release, 85 FR at 6288).

[81] *See* SIFMA Letter at 4.

[82] *See* Business Conduct Adopting Release, 81 FR at 30065–69 (adoption of cross-border rules governing application of transaction-level requirements such as daily mark requirements to ANE Transactions); Business Conduct Adopting Release, 81 FR at 30065 (applying transaction-level requirements to ANE Transactions will ''help maintain market integrity by subjecting the large number of transactions that involve relevant dealing activity in the United States to these requirements, even if both counterparties are non-U.S. persons''). In response to the commenter's previous statements that business conduct standards such as daily mark requirements should not apply to any transactions between two non-U.S. persons, the Commission concluded, ''given the significant role registered [security-based swap dealers] play in the market, applying the business conduct requirements to their U.S. business should help protect the integrity of the U.S. market.'' *See* Business Conduct Adopting Release, 81 FR at 30066 (considering comment letter from Timothy W. Cameron, Esq., Managing Director, and Laura Martin, Managing Director and Associate General Counsel, Asset Management Group, Securities Industry and Financial Markets Association, dated July 13, 2015, at 2, 5).

transactions. Moreover, the commenters' comparison to the exception from counting certain ANE Transactions towards security-based swap dealer registration thresholds is inapt. As the commenter notes, in connection with that exception, a registered entity whose U.S.-located personnel participates in an ANE Transaction that is eligible for the exception is not a counterparty to the resulting security-based swap.[83] BaFin's application, in contrast, relates to a registered SBS Entity's obligation to provide daily mark disclosure to its counterparty. The security-based swap dealer whose U.S. personnel arranged, negotiated or executed the security-based swap will be a counterparty to the security-based swap and will have an on-going relationship with its counterparty.

Second, the commenter stated that EU mark-to-market (and mark-to-model) requirements are comparable to Exchange Act daily mark requirements.[84] In the proposal, the Commission preliminarily concluded that mark-to-market (and mark-to-model) requirements are not comparable to daily mark requirements because they do not require the Covered Entity to disclose the contract valuation to the counterparty.[85] In reply, the commenter stated that EU variation margin requirements mandate that some counterparties exchange variation margin calculated in accordance with these mark-to-market (or mark-to-model) requirements, with adjustments to these valuations ''generally not permissible.'' [86] However, the variation margin requirements cited by the commenter require only that counterparties determine the amount of variation margin to be collected in respect of the aggregate valuations of all contracts in a netting set; counterparties are not required to disclose the valuations of individual contracts.[87] Moreover, these EU requirements permit the amount of variation margin to be adjusted by the net value of each contract in the netting set at the point of entry into the contract, as well as by values of variation margin previously collected or posted.[88] In determining whether EU variation margin requirements are comparable to Exchange Act daily mark requirements, the Commission is mindful that this comparability is essential to maintaining a level playing field among German SBS Entities, which are potentially eligible to use substituted compliance pursuant to the Order, other SBS Entities that are not U.S. persons, which may apply to use substituted compliance in respect of other applicable foreign requirements, and SBS Entities that are U.S. persons, which are not eligible to use substituted compliance. In the Commission's view, the EU variation margin requirements cited by the commenter, which do not require disclosure of the unadjusted valuation of each contract in the netting set, do not produce outcomes that are comparable to Exchange Act requirements to disclose the individualized daily mark of a security-based swap. Accordingly, the Commission does not view the EU variation margin requirements cited by the commenter as comparable to Exchange Act daily mark requirements.

Third, the commenter stated that the EU reporting requirements cited by BaFin are comparable to Exchange Act daily mark requirements.[89] In the proposal, the Commission preliminarily concluded that in practice U.S. counterparties may encounter challenges when attempting to access daily marks for different security-based swaps reported to multiple EU trade repositories with which they may not otherwise have business relationships.[90] In reply, the commenter stated that these challenges should not be as relevant for EU and other non-U.S. counterparties if they are already subject to EU reporting obligations.[91] The commenter's position, however, highlights that U.S. counterparties, as well as non-U.S. counterparties without existing business relationships with multiple EU trade repositories, still may encounter challenges in receiving daily marks from these daily trade reports. Moreover, the Commission is mindful that allowing Covered Entities to treat U.S. person counterparties differently for purposes of Exchange Act daily mark requirements could lead to disparities in security-based swap market access between U.S. and non-U.S. counterparties. In the proposal, the Commission also expressed concern that daily mark information reported to trade repositories may be less current, given the time necessary for reporting and for the trade repository to make the information available.[92] The commenter reported that in its experience data is available promptly from trade repositories.[93] This report of the commenter's experience lessens the Commission's concern with respect to timing, but does not overcome the Commission's concerns regarding barriers to U.S. counterparties' access to EU trade repository data and the potential for disparities in the availability of substituted compliance for daily mark requirements to reduce U.S. counterparties' access to security-based swap markets. Accordingly, the Commission continues to view the EU trade reporting requirements cited by BaFin as not comparable to Exchange Act daily mark requirements.

The Commission recognizes that there are differences between the approaches taken by fair and balanced communications, disclosure of material risks and characteristics, disclosure of material incentives or conflicts of interest, ''know your counterparty,'' suitability and daily mark disclosure requirements under the Exchange Act, on the one hand, and relevant German and EU requirements, on the other hand. The Commission continues to view those differences, when coupled with the conditions described above, as not so material as to be inconsistent with substituted compliance within the requisite outcomes-oriented context. With respect to clearing rights disclosure requirements, however, consistent with the proposal the Commission is not providing substituted compliance. Because EU clearing provisions do not require disclosure of a counterparty's clearing rights under Exchange Act section 3C(g)(5), the Commission views those provisions as not comparable to Exchange Act clearing rights disclosure requirements.

VII. Substituted Compliance for Recordkeeping, Reporting and Notification Requirements

A. Proposed Approach

BaFin's application in part requests substituted compliance for requirements applicable to SBS Entities under the Exchange Act relating to:

- *Recordmaking*—Requirements that prescribed records be made and kept current.
- *Record Preservation*—Requirements that address preservation of records.
- *Reporting*—Requirements that address certain reports.
- *Notification*—Requirements that address notification of the Commission

[83] *See* Exchange Act rule 3a71–3(d)(1).

[84] *See* SIFMA Letter at 5.

[85] *See* German Substituted Compliance Notice and Proposed Order, 85 FR at 72735.

[86] *See* SIFMA Letter at 5 (citing EMIR Margin RTS art. 10).

[87] *See* EMIR Margin RTS art. 10.

[88] *See* EMIR Margin RTS art. 10.

[89] See SIFMA Letter at 5.

[90] *See* German Substituted Compliance Notice and Proposed Order, 85 FR at 72735; *see also* BaFin Application Annex A category 4 at 54–56.

[91] See SIFMA Letter at 5.

[92] *See* German Substituted Compliance Notice and Proposed Order, 85 FR at 72735.

[93] *See* SIFMA Letter at 5.

when certain financial or operational problems occur.[94]

Taken as a whole, the recordkeeping, reporting, and notification requirements that apply to prudentially regulated SBS Entities are designed to promote the prudent operation of the firm's security-based swap activities, assist the Commission in conducting compliance examinations of those activities, and alert the Commission to potential financial or operational problems that could impact the firm and its customers.

In proposing to provide conditional substituted compliance in connection with this part of BaFin's application, the Commission preliminarily concluded that the relevant German and EU requirements, subject to certain proposed conditions and limitations, would produce regulatory outcomes that are comparable to the outcomes associated with the recordkeeping, reporting, and notification requirements under the Exchange Act applicable to prudentially regulated SBS Entities pursuant to Exchange Act rules 18a–5, 18a–6, 18a–7, and 18a–8.[95]

Substituted compliance under the proposal was to be conditioned in part on SBS Entities being subject to specific conditions necessary to promote consistency in regulatory outcomes, or to reflect the scope of substituted compliance that would be available in connection with associated Exchange Act rules.[96] In addition, substituted compliance in connection with select areas under the proposal would be subject to specific conditions to promote consistency in regulatory outcomes, or to reflect the scope of substituted compliance for associated rules:

- *Recordmaking*—Under the proposal, the SBS Entity would need to: (a) Preserve the data elements to create certain records required by the Commission's rule and furnish the record in the format required by that rule; (b) make certain records related to the SBS Entity segregation rule if the firm is not exempt from that rule; and (c) make certain records related to business conduct requirements for which substituted compliance was proposed to not be available.[97]
- *Record preservation*—Under the proposal, the SBS Entity would need to: (a) Preserve records related to the SBS Entity segregation rule if the firm is not exempt from that rule; and (b) preserve certain records related to Regulation SBSR and business conduct requirements for which substituted compliance was proposed to not be available.[98]
- *Reporting*—Under the proposal, the SBS Entity would need to report financial and operational information in the manner and format specified by Commission order or rule.[99]
- *Notification*—Under the proposal, the SBS Entity would need to: (a) Simultaneously transmit to the Commission a copy of any notice required to be sent by comparable German and EU laws and include contact information of a person who can provide further details about the notice; and (b) comply with the requirement in the Commission's rule to provide notice of failure to make a required deposit into the reserve account required by the SBS Entity segregation rule.[100]

In connection with the proposal, the Commission also addressed the application of inspection and production requirements imposed on SBS Entities under the Exchange Act, and noted that BaFin had provided the Commission with adequate assurances that no law or policy would impede the ability of any entity that is directly supervised by BaFin that may register with the Commission ''to provide prompt access to the Commission to such entity's books and records or to submit to onsite inspection or examination by the Commission.'' [101]

B. Commenter Views and Final Provisions

Commenters supported the Commission's preliminary view that substituted compliance be made available with respect to the recordkeeping, reporting, and notification requirements of Exchange Act rules 18a–5, 18a–6, 18a–7, and 18a–8 applicable to prudentially regulated SBS Entities.[102] Commenters did not address the proposed conditions relating to Exchange rules 18a–5, 18a–6, and 18a–8. After considering commenter views, the Commission is providing for substituted compliance in connection with the recordkeeping, reporting, and notification requirements of Exchange Act rules 18a–5, 18a–6, 18a–7, and 18a–8 applicable to prudentially regulated SBS Entities consistent with the proposal except for two modifications to the condition in paragraph (e)(3)(ii) of the Order relating to rule 18a–7.[103] First, the Commission is modifying the condition to require that the financial information be presented in accordance with generally accepted accounting principles (''GAAP'') that the SBS Entity uses to prepare general purpose publicly available or available to be issued financial statements in Germany.[104] Second, the Order clarifies that the prudentially regulated SBS Entity files ''periodic unaudited'' financial and operational information because Exchange Act rule 18a–7 does not require that the FOCUS Report Part IIC be audited by an independent public accountant.

In response to the Commission's proposal regarding recordkeeping, reporting, and notification requirements, a commenter stated that the Commission should permit substituted compliance for both prudentially regulated and non-prudentially regulated SBS Entities.[105] However, the recordkeeping, reporting, and notification requirements for non-prudentially regulated SBS Entities are broader than the requirements for prudentially regulated SBS Entities. These broader requirements address the fact that the Commission has capital and margin authority and oversight responsibility with respect to non-

[94] *See* German Substituted Compliance Notice and Proposed Order, 85 FR at 72732 (citing Exchange Act rules 18a–5, 18a–6, 18a–7, and 18a–8). The Commission noted that it does not administer or oversee capital and margin requirements for prudentially regulated SBS Entities, and took the preliminary position that it would be appropriate to consider substituted compliance for recordkeeping, reporting and notification requirements applicable to nonbank SBS Entities in connection with a potential substituted compliance request for capital and margin requirements.

[95] The Commission also recognized that the comparability assessment for certain of the recordkeeping and notification requirements also appropriately may consider the extent to which those requirements are linked to separate requirements in the Exchange Act that may be subject to a substituted compliance application. *See id.* at 72736 (noting that a number of recordkeeping requirements serve a primary purpose of promoting and/or documenting SBS Entities' compliance with associated Exchange Act requirements; further stating that when substituted compliance is permitted for the associated Exchange Act requirements, substituted compliance also may be appropriate for the linked recordkeeping and notification requirements).

[96] These included compliance with certain requirements associated with CRD, CRR, EMIR, MiFID, MiFID Org Reg, MiFIR, KWG, WpHG, GwG and certain EU guidelines.

[97] *See id.* at 72737.

[98] *See id.* at 72737–38.

[99] *See id.* at 72738.

[100] *See id.* at 72738–39.

[101] *See id.* at 72739.

[102] *See* SIFMA Letter. *See also* Deutsche Bank Letter; EBF Letter (supporting SIFMA's comments).

[103] *See* paragraph (e)(3)(ii) to the Order.

[104] In the German Substituted Compliance Notice and Proposed Order, the Commission stated that SBS Entities could be permitted to present the information reported in FOCUS Report Part IIC in accordance with GAAP that the SBS Entity uses to prepare publicly available general purpose financial statements in its home jurisdiction instead of U.S. GAAP if other GAAP, such as International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB), is used by the SBS Entity in preparing general purpose financial statements.

[105] *See* SIFMA Letter at 6.

prudentially regulated SBS Entities (but not with respect to prudentially regulated SBS Entities). The Commission continues to believe it is appropriate to defer consideration of requirements that apply to non-prudentially regulated SBS Entities until such time as it receives an application seeking substituted compliance for capital and margin requirements. This will allow the Commission to make a more complete decision that considers the substantive capital and margin requirements that are linked with the recordkeeping, reporting, notification, and securities count rules that apply to non-prudentially regulated SBS Entities.

The Commission received comments regarding the Commission's proposed condition that substituted compliance with respect to Exchange Act rule 18a–7's FOCUS Report Part IIC filing requirement be conditioned on SBS Entities filing unaudited financial and operational information in the manner and format specified by Commission order or rule. The commenters made suggestions about the scope and requirements of such a Commission order or rule. First, commenters requested that SBS Entities be allowed to file other Commission or Federal Reserve Board (''FRB'') filings instead of or in combination with extracts from filings made with home country supervisors.[106] Second, a commenter asked that the financial and operational information in the filings be permitted to be consolidated at the same consolidation level that is used in the relevant Commission, FRB, or home jurisdiction reports.[107] Third, a commenter proposed that the Commission permit an SBS Entity to complete the capital line items in the filings, if the FOCUS Report Part IIC is used as the filing form, in a manner consistent with its home country capital standards and related reporting.[108] Fourth, commenters sought additional time to furnish the filings to the Commission to align with local filing deadlines.[109] Finally, commenters supported a potential approach identified by the Commission under which SBS Entities would be permitted to satisfy their Exchange Act rule 18a–7 obligations for a two-year period by filing the FOCUS Report Part IIC with only a limited number of the required line items completed.[110]

The Commission will consider these comments as it works towards completing a Commission order or rule pursuant to the provision in this Order that substituted compliance with respect to Exchange Act rule 18a–7's FOCUS Report Part IIC filing requirement is conditioned on SBS Entities filing unaudited financial and operational information in the manner and format specified by Commission order or rule.[111] In this regard, the Commission welcomes further comment and engagement from interested parties on: (1) A potential interim two-year order or rule that requires a limited number of the line items on the FOCUS Report Part IIC to be completed; and (2) the nature and scope of a more permanent order or rule for the filing of financial and operational information.

VIII. Supervisory and Enforcement Considerations

A. Preliminary Analysis

Exchange Act rule 3a71–6(a)(2)(i) provides that the Commission's assessments regarding the comparability of foreign requirements in part should take into account ''the effectiveness of the supervisory program administered, and the enforcement authority exercised'' by the foreign financial regulatory authority. This provision is intended to help ensure that substituted compliance is not predicated on rules that appear high-quality on paper if market participants in practice are allowed to fall short of their obligations, while also recognizing that differences among supervisory and enforcement regimes should not be assumed to reflect flaws in one regime or another.[112] BaFin's application accordingly included information regarding the supervisory and enforcement framework applicable to derivatives markets and market participants in Germany.

In proposing to grant substituted compliance in connection with Germany, the Commission preliminarily concluded that the relevant supervisory and enforcement considerations were consistent with substituted compliance. That preliminary conclusion took into account information regarding BaFin's and the ECB's roles and practices in supervising credit institutions located in Germany, as well as their enforcement-related authority and practices.[113]

B. Conclusions

Commenters did not address the Commission's preliminary conclusions regarding supervisory and enforcement considerations, and the Commission continues to conclude that the relevant supervisory and enforcement considerations in Germany are consistent with substituted compliance. In particular, based on the available information regarding BaFin's and the ECB's authority and practices to oversee market participants' compliance with applicable requirements and to take action in the event of violations, the Commission remains of the view that, consistent with rule 3a71–6, comparability determinations reflect German and EU requirements as they apply in practice.

To be clear, the supervisory and enforcement considerations addressed by rule 3a71–6 do not mandate that the Commission make judgments regarding the comparative merits of U.S. and foreign supervisory and enforcement frameworks, or to require specific findings regarding the supervisory and enforcement effectiveness of a foreign regime. The rule 3a71–6 considerations regarding supervisory and enforcement effectiveness instead address whether comparability analyses related to substituted compliance reflect requirements that market participants must follow, and for which market participants are subject to enforcement consequences in the event of violations. Those considerations are satisfied here.

IX. Conclusion

It is hereby determined and ordered, pursuant to rule 3a71–6 under the Exchange Act, that a Covered Entity (as defined in paragraph (f)(1) of this Order) may satisfy the requirements under the Exchange Act that are addressed in paragraphs (b) through (e) of this Order so long as the Covered Entity is subject to and complies with relevant requirements of the Federal Republic of Germany and the European Union and with the conditions to this Order, as may be amended or superseded from time to time.

(a) General Conditions

This Order is subject to the following general conditions, in addition to the

[106] *See* SIFMA Letter at 8; Deutsche Bank Letter at 2.

[107] *See* SIFMA Letter at 8.

[108] *See* SIFMA Letter at 8.

[109] *See* SIFMA Letter at 8; Deutsche Bank Letter at 2.

[110] *See* SIFMA Letter at 8–9; Deutsche Bank Letter at 2.

[111] The Commission intends to issue an order sufficiently in advance of the compliance date for Exchange rule 18a–7 to provide SBS Entities time to configure their systems to comply with the filing requirement. When the order is issued, the Commission will consider whether it would be appropriate to provide additional time before the first filing is required if SBS Entities indicate that they will have trouble configuring their systems to comply with the filing requirement.

[112] *See* German Substituted Compliance Notice and Proposed Order, 85 FR at 72739.

[113] *See id.* at 72739–40.

conditions specified in paragraphs (b) through (e):

(1) *Activities as ''investment services or activities.''* For each condition in paragraphs (b) through (e) of this Order that requires the application of, and the Covered Entity's compliance with, provisions of MiFID, WpHG, and/or other EU and German requirements adopted pursuant to those provisions, the Covered Entity's relevant security-based swap activities constitute ''investment services'' or ''investment activities,'' as defined in MiFID article 4(1)(2) and in WpHG section 2(8), and fall within the scope of the Covered Entity's authorization from BaFin to provide investment services and/or perform investment activities in the Federal Republic of Germany.

(2) *Counterparties as ''clients.''* For each condition in paragraphs (b) through (e) of this Order that requires the application of, and the Covered Entity's compliance with, provisions of MiFID, WpHG and/or other EU and German requirements adopted pursuant to those provisions, the relevant counterparty (or potential counterparty) to the Covered Entity is a ''client'' (or potential ''client''), as defined in MiFID article 4(1)(9) and in WpHG section 67(1).

(3) *Security-based swaps as ''financial instruments.''* For each condition in paragraphs (b) through (e) of this Order that requires the application of, and the Covered Entity's compliance with, provisions of MiFID, WpHG and/or other EU and German requirements adopted pursuant to those provisions, the relevant security-based swap is a ''financial instrument,'' as defined in MiFID article 4(1)(15) and in WpHG section 2(4).

(4) *Covered Entity as ''institution.''* For each condition in paragraph (b) through (e) of this Order that requires the application of, and the Covered Entity's compliance with, the provisions of CRD, KWG, CRR and/or other EU and German requirements adopted pursuant to those provisions, the Covered Entity is an ''institution,'' as defined in CRD article 3(1)(3), in CRR article 4(1)(3) and in KWG section 1(1b).

(5) *Memorandum of Understanding with BaFin.* The Commission and BaFin have a supervisory and enforcement memorandum of understanding and/or other arrangement addressing cooperation with respect to this Order at the time the Covered Entity complies with the relevant requirements under the Exchange Act via compliance with one or more provisions of this Order.

(6) *Notice to Commission.* A Covered Entity relying on this Order must provide notice of its intent to rely on this Order by notifying the Commission in writing. Such notice must be sent to an email address provided on the Commission's website. The notice must include the contact information of an individual who can provide further information about the matter that is the subject of the notice.

(7) *European Union Cross-Border Matters.*

(i) If, in relation to a particular service provided by a Covered Entity, responsibility for ensuring compliance with any provision of MiFID or any other EU or German requirement adopted pursuant to MiFID listed in paragraphs (b) through (e) of this Order is allocated to an authority of the Member State of the European Union in whose territory a Covered Entity provides the service, BaFin must be the authority responsible for supervision and enforcement of that provision or requirement in relation to the particular service.

(ii) If responsibility for ensuring compliance with any provision of MAR or any other EU requirement adopted pursuant to MAR listed in paragraphs (b) through (e) of this Order is allocated to one or more authorities of a Member State of the European Union, one of such authorities must be BaFin.

(b) Substituted Compliance in Connection With Risk Control Requirements

This Order extends to the following provisions related to risk control:

(1) *Internal risk management.* The requirements of Exchange Act section 15F(j)(2) and related aspects of Exchange Act rule 15Fh–3(h)(2)(iii)(I), provided that the Covered Entity is subject to and complies with the requirements of: MiFID articles 16(4) and 16(5); WpHG section 80; MiFID Org Reg articles 21–24; CRD articles 74, 76 and 79–87; KWG sections 25a, 25b, 25c (other than 25c(2)), 25d (other than 25d(3) and 25d(11)), 25(e) and 25(f); CRR articles 286–88 and 293; and EMIR Margin RTS article 2.

(2) *Trade acknowledgement and verification.* The requirements of Exchange Act rule 15Fi–2, provided that the Covered Entity is subject to and complies with the requirements of MiFID article 25(6), WpHG section 63(12), MiFID Org Reg articles 59–61, EMIR article 11(1)(a) and EMIR RTS article 12.

(3) *Portfolio reconciliation and dispute reporting.* The requirements of Exchange Act rule 15Fi–3, provided that:

(i) The Covered Entity is subject to and complies with the requirements of EMIR article 11(1)(b) and EMIR RTS article 13 and 15;

(ii) The Covered Entity provides the Commission with reports regarding disputes between counterparties on the same basis as it provides those reports to competent authorities pursuant to EMIR RTS article 15(2).

(4) *Portfolio compression.* The requirements of Exchange Act rule 15Fi–4, provided that the Covered Entity is subject to and complies with the requirements of EMIR RTS article 14.

(5) *Trading relationship documentation.* The requirements of Exchange Act rule 15Fi–5, other than paragraph (b)(5) to that rule when the counterparty is a U.S. person, provided that:

(i) The Covered Entity is subject to and complies with the requirements of MiFID article 25(5), WpHG section 83(2), MiFID Org Reg articles 24, 58, 73 and applicable parts of Annex I, and EMIR Margin RTS article 2; and

(ii) The Covered Entity does not treat the applicable counterparty as an ''eligible counterparty'' for purposes of MiFID article 30 and WpHG section 68, in relation to the MiFID and WpHG provisions specified in paragraph (b)(5)(i).

(c) Substituted Compliance in Connection With Internal Supervision and Compliance Requirements and Certain Exchange Act Section 15F(J) Requirements

This Order extends to the following provisions related to internal supervision and compliance and Exchange Act section 15F(j) requirements:

(1) *Internal supervision.* The requirements of Exchange Act rule 15Fh–3(h) and Exchange Act sections 15F(j)(4)(A) and (j)(5), provided that:

(i) The Covered Entity is subject to and complies with the requirements identified in paragraph (c)(3);

(ii) The Covered Entity complies with paragraph (c)(4) to this Order; and

(iii) This paragraph (c) does not extend to the requirements of paragraph (h)(2)(iii)(I) to rule 15Fh–3 to the extent those requirements pertain to compliance with Exchange Act sections 15F(j)(2), (j)(3), (j)(4)(B) and (j)(6), or to the general and supporting provisions of paragraph (h) to rule 15Fh–3 in connection with those Exchange Act sections.

(2) *Chief compliance officers.* The requirements of Exchange Act section 15F(k) and Exchange Act rule 15Fk–1, provided that:

(i) The Covered Entity complies with the requirements identified in paragraph (c)(3) to this Order;

(ii) All reports required pursuant to MiFID Org Reg article 22(2)(c) must also:

(A) Be provided to the Commission at least annually, and in the English language;

(B) Include a certification that, under penalty of law, the report is accurate and complete; and

(C) Address the firm's compliance with other applicable conditions to this Order in connection with requirements for which the Covered Entity is relying on this Order.

(3) *Applicable supervisory and compliance requirements.* Paragraphs (c)(1) and (c)(2) are conditioned on the Covered Entity being subject to and complying with the following requirements: MiFID articles 16 and 23; WpHG sections 63, 80, 83 and 84; MiFID Org Reg articles 21–37, 72–76 and Annex IV; CRD articles 74, 76, 79–87, 88(1), 91(1)–(2), 91(7)–(9) and 92–95; and KWG sections 25a, 25b, 25c (other than 25c(2)), 25d (other than 25d(3) and 25d(11)), 25e and 25f.

(4) *Additional condition to paragraph (c)(1).* Paragraph (c)(1) further is conditioned on the requirement that Covered Entities comply with the provisions specified in paragraph (c)(3) as if those provisions also require compliance with:

(i) Applicable requirements under the Exchange Act; and

(ii) The other applicable conditions to this Order in connection with requirements for which the Covered Entity is relying on this Order.

(d) Substituted Compliance in Connection With Counterparty Protection Requirements

This Order extends to the following provisions related to counterparty protection:

(1) *Disclosure of information regarding material risks and characteristics.* The requirements of Exchange Act rule 15Fh–3(b) relating to disclosure of material risks and characteristics of a security-based swap, provided that the Covered Entity is subject to and complies with the requirements of MiFID article 24(4), WpHG sections 63(7) and 64(1) and MiFID Org Reg articles 48–50, in each case in relation to that security-based swap.

(2) *Disclosure of information regarding material incentives or conflicts of interest.* The requirements of Exchange Act rule 15Fh–3(b) relating to disclosure of material incentives or conflicts of interest that a Covered Entity may have in connection with a security-based swap, provided that the Covered Entity, in relation to that security-based swap, is subject to and complies with the requirements of either:

(i) MiFID article 23(2)–(3); WpHG section 63(2); and MiFID Org Reg articles 33–35;

(ii) MiFID article 24(9); WpHG section 70; and MiFID Delegated Directive article 11(5); or

(iii) MAR article 20(1).

(3) ''*Know your counterparty.*'' The requirements of Exchange Act rule 15Fh–3(e), provided that the Covered Entity is subject to and complies with the requirements of MiFID article 16(2); WpHG section 80(1); MiFID Org Reg articles 21–22, 25–26 and applicable parts of Annex I; CRD articles 74(1) and 85(1); KWG section 25a; MLD articles 11 and 13; GwG sections 10–11; MLD articles 8(3) and 8(4)(a) as applied to internal policies, controls and procedures regarding recordkeeping of customer due diligence activities; and GwG section 6(1)–(2) as applied to principles, procedures and controls regarding recordkeeping of customer due diligence activities, in each case in relation to that security-based swap.

(4) *Suitability.* The requirements of Exchange Act rule 15Fh–3(f), provided that:

(i) The Covered Entity is subject to and complies with the requirements of MiFID articles 24(2)–(3) and 25(1)–(2); WpHG sections 63(5)–(6), 80(9)–(13) and 87(1)–(2); and MiFID Org Reg articles 21(1)(b) and (d), 54 and 55, in each case in relation to the recommendation of a security-based swap or trading strategy involving a security-based swap that is provided by or on behalf of the Covered Entity; and

(ii) The counterparty to which the Covered Entity makes the recommendation is a ''professional client'' mentioned in MiFID Annex II section I and WpHG section 67(2) and is not a ''special entity'' as defined in Exchange Act section 15F(h)(2)(C) and Exchange Act rule 15Fh–2(d).

(5) *Fair and balanced communications.* The requirements of Exchange Act rule 15Fh–3(g), provided that the Covered Entity, in relation to the relevant communication, is subject to and complies with the requirements of:

(i) Either MiFID articles 24(1), (3) and WpHG sections 63(1), (6) or MiFID article 30(1) and WpHG section 68(1); and

(ii) MiFID articles 24(4)–(5); WpHG sections 63(7) and 64(1); MiFID Org Reg articles 46–48; MAR articles 12(1)(c) and 15; and MAR Investment Recommendations Regulation article 5.

(6) *Daily mark disclosure.* The requirements of Exchange Act rule 15Fh–3(c), provided that the Covered Entity is required to reconcile, and does reconcile, the portfolio containing the relevant security-based swap on each business day pursuant to EMIR articles 11(1)(b) and 11(2) and EMIR RTS article 13.

(e) Substituted Compliance in Connection With Recordkeeping, Reporting, and Notification Requirements

This Order extends to the following provisions related to Commission requirements to:

(1) *Make and keep current certain records.* The requirements to make and keep current records of Exchange Act rule 18a–5 applicable to prudentially regulated security-based swap dealers and major security-based swap participants; provided that:

(i) The Covered Entity is subject to and complies with the following requirements: CRR articles 103 and 103(b)(ii); EMIR articles 9(2), 11(1)(a), and 39(4); EMIR RTS 148/2013; MiFID articles 9(1), 16(3), 16(6)–16(9), 25(1), 25(5), and 25(6); MiFID Delegated Directive article 2; MiFID Org Reg. articles 16(7), 21(1)(a), 35, 59, 72, 73, 74, 75, 76, and applicable parts of Annex I; MiFID Org Reg. Annex IV; MiFIR article 25; MLD4 articles 11 and 13; EBA/ESMA Guidelines on Management Suitability guidelines 74, 75, and 172, and Annex III; CRD articles 88, 91(1), and 91(8); KWG sections 25c(1) and 25d(1)–(3); WpHG section 63, section 64, section 81 paragraph 1, section 83 paragraphs 1 through 8, and section 84; and GwG section 10, paragraph 1, points 1 through 3;

(ii)(A) The Covered Entity preserves all of the data elements necessary to create the records required by Exchange Act rules 18a–5(b)(1), (2), (3), and (7); and

(B) The Covered Entity upon request furnishes promptly to representatives of the Commission the records required by those rules;

(iii) The Covered Entity makes and keeps current the records required by Exchange Act rules 18a–5(b)(9) and (10) if the Covered Entity is not exempt from the requirements of Exchange Act rule 18a–4;

(iv) The Covered Entity makes and keeps current the records required by Exchange Act rule 18a–5(b)(12); and

(v) Except with respect to requirements of Exchange Act rules 15Fh–3 and 15Fk–1 to which this Order extends pursuant paragraphs (c)(2) and

(d), the Covered Entity makes and keeps current the records required by Exchange Act rule 18a–5(b)(13).

(2) *Preserve records.* The record preservation requirements of Exchange Act rule 18a–6 applicable to prudentially regulated security-based swap dealers and major security-based swap participants; provided that:

(i) The Covered Entity is subject to and complies with the following requirements: CRD articles 88, 91(1), and 91(8); CRR articles 99, 104(1)(j), 294, 394, 415–428, and 430; CRR Reporting ITS Article 14 and Annexes I–V, VIII–XIII; EMIR articles 9(1) and 9(2); MiFID articles 9(1), 16(3), and 69(2); MiFID Org Reg. articles 21(1)(a), 21(2), 35, 58, 72(1), 72(3), 73, and 76; MiFIR articles 16(2), 16(5), 16(6), 16(7), 25(1), 25(5), 31(1) and 72; MLD4 articles 11 and 13; EBA/ESMA Guidelines on Management Suitability guidelines 74, 75, and 172, and Annex III; EBA Guidelines on Outsourcing section 13.3; KWG 25c(1) and 25d(1)–(3); WpHG sections 6, 7, 63, 64, and 80 and section 83 paragraphs 1, 2, 3, and 8; and GwG sections 10 and 11;

(ii) The Covered Entity preserves the records required by Exchange Act rule 18a–6(b)(2)(v) if the Covered Entity is not exempt from the requirements of Exchange Act rule 18a–4;

(iii) Except with respect to requirements of Exchange Act rules 15Fh–3 and 15Fk–1 to which this Order extends pursuant to paragraphs (c)(2) and (d), the Covered Entity preserves the records required by Exchange Act rule 18a–6(b)(2)(vii); and

(iv) The Covered Entity preserves the records required by Exchange Act rule 18a–6(b)(2)(vi) and (b)(2)(viii).

(3) *File Financial and Operational Information.* The reporting requirements of Exchange Act rule 18a–7 applicable to prudentially regulated security-based swap dealers and major security-based swap participants; provided that:

(i) The Covered Entity is subject to and complies with the following requirements: CRR articles 99, 104(1)(j), 394, 415–428, and 430; CRR Reporting ITS chapter 2 and Annexes I–V and VII–XIII; and Commission Delegated Regulation (EU) 2017/1443, as amended or superseded from time to time; and

(ii) The Covered Entity files periodic unaudited financial and operational information with the Commission or its designee in the manner and format required by Commission rule or order and presents the financial information in the filing in accordance with generally accepted accounting principles that the Covered Entity uses to prepare general purpose publicly available or available to be issued financial statements in Germany.

(4) *Provide Notification.* The notification requirements of Exchange Act rule 18a–8 applicable to prudentially regulated security-based swap dealers and major security-based swap participants; provided that:

(i) The Covered Entity is subject to and complies with the following requirements: CRD article 71; MiFID article 73; KWG section 24 paragraph 1; and FinDAG section 4d; and

(ii) The Covered Entity:

(A) Simultaneously transmits to the principal office of the Commission or to an email address provided on the Commission's website a copy of any notice required to be sent by the German and EU laws referenced in paragraph (e)(3)(i) of this order; and

(B) Includes with the transmission the contact information of an individual who can provide further information about the matter that is the subject of the notice;

(iii) The Covered Entity complies with notification requirements of Exchange Act rule 18a–8(g) if the Covered Entity is not exempt from Exchange Act rule 18a–4.

(5) *Examination and Production of Records.* Notwithstanding the forgoing provisions of paragraph (e) of this Order, prudentially regulated security-based swap dealers and major security-based swap participants remains subject to the requirement of Exchange Act section 15F(f) to keep books and records open to inspection by any representative of the Commission and the requirement of Exchange Act rule 18a–6(g) to furnish promptly to a representative of the Commission legible, true, complete, and current copies of those records of the Covered Entity that are required to be preserved under Exchange Act rule 18a–6, or any other records of the Covered Entity that are subject to examination or required to be made or maintained pursuant to Exchange Act section 15F that are requested by a representative of the Commission.

(f) Definitions

(1) ''Covered Entity'' means an entity that:

(i) Is a security-based swap dealer or major security-based swap participant registered with the Commission;

(ii) Is not a ''U.S. person,'' as that term is defined in rule 3a71–3(a)(4) under the Exchange Act; and

(iii) Is an investment firm or credit institution authorized by BaFin to provide investment services or perform investment activities in the Federal Republic of Germany.

(2) ''MiFID'' means the ''Markets in Financial Instruments Directive,'' Directive 2014/65/EU, as amended or superseded from time to time.

(3) ''WpHG'' means Germany's ''Wertpapierhandelsgesetz'', as amended or superseded from time to time.

(4) ''MiFID Org Reg'' means Commission Delegated Regulation (EU) 2017/565, as amended or superseded from time to time.

(5) ''MiFID Delegated Directive'' means Commission Delegated Directive (EU) 2017/593, as amended or superseded from time to time.

(6) ''MLD'' means Directive (EU) 2015/849, as amended or superseded from time to time.

(7) ''GwG'' means Germany's ''Geldwäschegesetz,'' as amended or superseded from time to time.

(8) ''MiFIR'' means Regulation (EU) 600/2014, as amended or superseded from time to time.

(9) ''EMIR'' means the ''European Market Infrastructure Regulation,'' Regulation (EU) 648/2012, as amended or superseded from time to time.

(10) ''EMIR RTS'' means Commission Delegated Regulation (EU) 149/2013, as amended or superseded from time to time.

(11) ''EMIR Margin RTS'' means Commission Delegated Regulation (EU) 2016/2251, as amended or superseded from time to time.

(12) ''CRR Reporting ITS'' means Commission Implementing Regulation (EU) 680/2014, as amended or superseded from time to time.

(13) ''CRD'' means Directive 2013/36/EU, as amended or superseded from time to time.

(14) ''KWG'' means Germany's ''Kreditwesengesetz,'' as amended or superseded from time to time.

(15) ''CRR'' means Regulation (EU) 575/2013, as amended or superseded from time to time.

(16) ''MAR'' means the ''Market Abuse Regulation,'' Regulation (EU) 596/2014, as amended or superseded from time to time.

(17) ''MAR Investment Recommendations Regulation'' means Commission Delegated Regulation (EU) 2016/958, as amended or superseded from time to time.

(18) ''FinDAG'' means Germany's ''Finanzdienstleistungsaufsichtsgesetz,'' as amended or superseded from time to time.

(19) ''BaFin'' means the Bundesanstalt für Finanzdienstleistungsaufsicht.

By the Commission.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2020–28703 Filed 12–28–20; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90743; File No. SR–CboeBZX–2020–089]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Amend Its Fees Schedule

December 21, 2020.

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 December 10, 2020, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II 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

Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to amend its Fee Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary, 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 its fee schedule for its equity options platform (''BZX Options'') by removing certain fee codes related to routed orders and by updating certain fee codes in connection with routing orders in SPY options to Nasdaq PHLX LLC (''PHLX'').[3]

The Exchange first notes that it 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. More specifically, the Exchange is only one of 16 options venues to which market participants may direct their order flow. Based on publicly available information, no single options exchange has more than 16% of the market share and currently the Exchange represents approximately 8% of the market share.[4] Thus, in such a low-concentrated and highly competitive market, no single options exchange, including the Exchange, possesses significant pricing power in the execution of option order flow. The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue to reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain the Exchange's transaction fees, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable.

The Exchange assesses fees in connection with orders routed away to various exchanges. Currently, under the Fee Codes and Associated Fees section of the Fee Schedule, fee codes D1, D2, D3 and D4 are appended to Members' Directed ISOs, a routing option under which an intermarket sweep order (''ISO'') entered by a User bypasses the System and is sent by the System to another options exchange specified by the User.[5] Specifically, these fee codes function as follows:

- Fee code D1 is appended to Directed ISOs to Nasdaq Options Market LLC (''NOM''), NYSE Arca, Inc. (''ARCA'') or ISE Gemini, LLC (''ISE Gemini'') in Non-Penny classes and assesses a charge of $1.25 per contract;
- fee code D2 is appended to Non-Customer Directed ISOs to Nasdaq BX Options (''BX'') in Non-Penny classes and assesses a charge of $0.95 per contract;
- fee code D3 is appended to Non-Customer Directed ISOs to Cboe C2 Exchange, Inc. (''C2'') or PHLX and assesses a charge of $0.95 per contract; and
- fee code D4 is appended to Directed ISOs (unless otherwise specified in the Fee Schedule) and assesses a charge of $0.85 per contract.

The Exchange has observed a minimal amount of volume in recent months in orders yielding fee codes D1, D2, D3 or D4. The Exchange believes that, because so few Users elect to route their orders as Directed ISOs, the current demand does not warrant the infrastructure and ongoing Systems maintenance required to support separate fee codes specifically applicable to Directed ISOs. Therefore, the Exchange now proposes to delete fee codes D1, D2, D3 and D4 in the Fee Schedule. The Exchange notes that Users will continue to be able to choose to route their orders as Directed ISOs and such orders will be assessed the fees currently in place for routed orders generally (*i.e.,* fee codes RN,[6] RO,[7] RP,[8] RQ[9] and RR[10]) as follows:

- A Directed ISO to which fee code D1 would have prior been appended (routed to NOM, ARCA or ISE Gemini in a Non-Penny class) will yield fee code RR, if it is a Customer order, which is appended to Customer orders in Non-Penny classes routed to NOM, ARCA or ISE Gemini (among other exchanges) and assesses a charge of $1.25 per contract, or will yield fee code RO, if it is a Non-Customer order, which is appended to routed Non-Customer

[3] The Exchange initially filed the proposed fee changes on December 1, 2020 (SR–CboeBZX–2020–086). On December 9, 2020, the Exchange withdrew that filing and submitted this proposal.

[4] *See* Cboe Global Markets U.S. Options Market Month-to-Date Volume Summary (November 23, 2020), available at *https://markets.cboe.com/us/options/market_statistics/*.

[5] *See* Rule 21.9(a)(2)(D).

[6] Fee code RN is appended to routed Non-Customer orders in Penny Program classes and assesses a charge of $0.90 per contract.

[7] Fee code RO is appended to all routed Non-Customer orders in Non-Penny classes and assesses a charge of $1.25 per contract.

[8] Fee code RP is appended to routed Customer orders to AMEX, BOX, BX, Cboe, EDGX Options, ISE Mercury, MIAX or PHLX and assesses a charge of $0.25 per contract.

[9] Fee code RQ is appended to routed Customer orders in Penny Program classes to ARCA, C2, ISE, ISE Gemini, MIAX Emerald, MIAX Pearl or NOM and assesses a charge of $0.85 per contract.

[10] Fee code RR is appended to routed Customer orders in Non-Penny classes to ARCA, C2, ISE, ISE Gemini, MIAX Emerald, MIAX Pearl or NOM and assesses a charge of $1.25 per contract.

orders in Non-Penny classes and also assesses a charge of $1.25 per contract;

- a Directed ISO to which fee code D2 would have prior been appended (Non-Customer to BX in a Non-Penny class) will yield fee code RO;
- a Directed ISO to which fee code D3 would have prior been appended (Non-Customer to C2 or PHLX) will yield fee code RN, if in a Penny class, which is appended to Non-Customer orders routed in Penny classes and assesses a charge of $0.90 per contract, or will yield fee code RO, if it is in a Non-Penny class; and
- a Directed ISO to which fee code D4 would have prior been appended (unless otherwise specified) may yield any of fee codes RN, RO, RP, RQ and RR, depending on whether the order is a (1) routed Customer order in a Penny class (to which fee code RP, which assess a charge of $0.25 per contract, or RQ, which assesses a charge of $0.85 per contract, could apply depending on the away exchange), (2) a routed Customer order in a Non-Penny class (to which fee code RP or RR could apply depending on the away exchange), (3) is a routed Non-Customer order in a Penny class (to which fee code RN will apply), or (4) is a routed Non-Customer order in a Non-Penny Class (to which fee code RO will apply).

The Exchange also proposes to update fee codes RP and RQ in connection with routed Customer orders in SPY options to PHLX. Currently, fee code RP is appended to routed Customer orders to NYSE American (''AMEX''), BOX Options Exchange (''BOX''), BX, Cboe Exchange, Inc. (''Cboe''), Cboe EDGX Exchange, Inc. (''EDGX Options''), ISE Mercury, LLC (''ISE Mercury''), MIAX Options Exchange (''MIAX'') or PHLX and assesses a charge of $0.25 per contract. Fee code RQ is appended to routed Customer orders in Penny Program classes to ARCA, C2, ISE, ISE Gemini, MIAX Emerald Exchange (''MIAX Emerald''), MIAX Pearl Exchange (''MIAX Pearl''), or NOM and assesses a charge of $0.85 per contract. The Exchange notes that its current approach to routing fees is to set forth in a simple manner certain sub-categories of fees that approximate the cost of routing to other options exchanges based on the cost of transaction fees assessed by each venue as well as costs to the Exchange for routing (*i.e.,* clearing fees, connectivity and other infrastructure costs, membership fees, etc.) (collectively, ''Routing Costs''). The Exchange then monitors the fees charged as compared to the costs of its routing services and adjusts its routing fees and/or sub-categories to ensure that the Exchange's fees do indeed result in a rough approximation of overall Routing Costs, and are not significantly higher or lower in any area. Currently, PHLX assesses a charge of $0.42 per contract for Customer orders in SPY options that remove liquidity.[11] As described above, the Exchange currently assesses a flat routing fee of $0.25 per contract for Customer orders routed to PHLX which yield fee code RP. This structure does not currently take into account the $0.42 per contract fee assessed by PHLX for Customer orders in SPY options. Therefore, in order to assess fees more in line with the Exchange's current approach to routing fees, that is, in a manner that approximates the cost of routing to Customer orders in SPY options to PHLX, along with other away options exchanges, based on the general cost of transaction fees assessed by the sub-category of away options exchanges for such orders (as well as the Exchange's Routing Costs), the Exchange proposes to exclude Customer orders is SPY options routed to PHLX from orders that yield fee code RP and are assessed a charge of $0.25 per contract and, instead, add Customer orders routed to PHLX in SPY options only to orders that yield fee code RQ[12] and are assessed a charge of $0.85 per contract.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[13] in general, and furthers the objectives of Section 6(b)(4),[14] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and issuers and other persons using its facilities. The Exchange also believes that the proposed rule change is consistent with the objectives of Section 6(b)(5)[15] requirements that the rules of an 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 regulating, clearing, settling, processing information with respect to, and 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, particularly, is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As described 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 rule change reflects a competitive pricing structure designed to incentivize market participants to direct their order flow to the Exchange, which the Exchange believes would enhance market quality to the benefit of all Members. The Exchange notes that other options exchanges currently approximate routing fees in a similar manner as the Exchange's current approach.[16]

In particular, the Exchange believes the proposed rule change to remove fee codes D1, D2, D3 and D4 is reasonable as the Exchange has observed a minimal amount of volume in orders yielding fee codes D1, D2, D3 or D4 and, therefore, the current use of Directed ISO orders does not warrant the infrastructure and ongoing Systems maintenance required to support separate fee codes specifically applicable to Directed ISOs, a type of routing option Users may elect for their orders. As such, the Exchange also believes that is reasonable and equitable to assess Directed ISO orders as it already does for all other routed orders, as applicable (*i.e.,* fee codes RN, RO, RP, RQ and RR).[17] The Exchange notes that the use of Directed ISOs, as well as routing through the Exchange, is optional. The Exchange believes that the proposed rule change is equitable and not unfairly discriminatory because Users will continue to have the option to elect to route their orders as Directed ISOs and such routed orders will be automatically and uniformly assessed the applicable charges already in place for all other routed orders.

The Exchange believes the proposed rule change to amend fee codes RP and RQ to account for PHLX's current assessment of fees for Customer orders in SPY options is reasonable because it

[11] *See* Nasdaq Phlx Options 7 Pricing Schedule, Section 3 ''Rebates and Fees for Adding and Removing Liquidity in SPY'', Part A.

[12] The Exchange notes that SPY options are part of the Penny Program.

[13] 15 U.S.C. 78f.

[14] 15 U.S.C. 78f(b)(4).

[15] 15 U.S.C. 78f.(b)(5).

[16] *See e.g.,* NYSE Arca Options Fees and Charges, ''Routing Fees'', which provides routing fees of ''$0.11 per contract on orders routed and executed on another exchange, plus (i) any transaction fees assessed by the away exchange (calculated on an order-by-order basis since different away exchanges charge different amounts) or (ii) if the actual transaction fees assessed by the away exchange(s) cannot be determined prior to the execution, the highest per contract charge assessed by the away exchange(s) for the relevant option class and type of market participant (*e.g.,* Customer, Firm, Broker/Dealer, Professional Customer or Market Maker).''

[17] *See supra* notes 6–10.

is reasonably designed to assess routing fees in line with the Exchange's current approach to routing fees. That is, the proposed rule change is intended to include Customer orders in SPY options routed to PHLX in the most appropriate sub-category of fees that approximates the cost of routing to a group of away options exchanges (including PHLX) based on the cost of transaction fees assessed by each venue as well as Routing Costs to the Exchange. The Exchange believes that the proposed rule change is equitable and not unfairly discriminatory because all Members' Customer orders in SPY routed to PHLX will automatically yield fee code RQ and uniformly be assessed the corresponding fee.

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 does not believe the proposed rule change will impose any burden on intramarket competition because all Members Directed ISO order will automatically and uniformly be assessed the current fees already in place for routed orders, as applicable (*i.e.,* fee codes RN, RO, RP, RQ and RR).[18] Likewise, all Members' Customer orders in SPY routed to PHLX will automatically yield fee code RQ and uniformly be assessed the corresponding fee.

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that other options exchange approximate routing costs in a similar manner as the Exchange's current approach.[19] Also, as previously discussed, the Exchange operates in a highly competitive market. Members have numerous alternative venues that they may participate on and director their order flow, including 15 other options exchanges and off-exchange venues. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single options exchange has more than 16% of the market share.[20] Therefore, no exchange possesses significant pricing power in the execution of option order flow. Indeed, participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. Moreover, 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.'' [21] The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition* v. *Securities* and *Exchange Commission*, the D.C. Circuit stated as follows: ''[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'. . . .''.[22] Accordingly, the Exchange does not believe its proposed fee change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

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) of the Act [23] and paragraph (f) of Rule 19b–4 [24] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

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 will 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–CboeBZX–2020–089 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–CboeBZX–2020–089. 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make

[18] *See supra* notes 6–10.

[19] *See supra* note 16.

[20] *See supra* note 4.

[21] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[22] *NetCoalition* v. *SEC,* 615 F.3d 525, 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)).

[23] 15 U.S.C. 78s(b)(3)(A).

[24] 17 CFR 240.19b–4(f).

available publicly. All submissions should refer to File Number SR–CboeBZX–2020–089 and should be submitted on or before January 19, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28657 Filed 12–28–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90746; File No. SR–ICEEU–2020–016]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Publication of a Circular Regarding the Interpretation of References to EU Legislation in the Clearing Rules at the End of the Brexit Transition Period

December 21, 2020.

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 December 11, 2020, ICE Clear Europe Limited (''ICE Clear Europe'' or the ''Clearing House'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule changes described in Items I, II and III below, which Items have been prepared primarily by ICE Clear Europe. ICE Clear Europe filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(1) thereunder,[4] such that the proposed rule change was immediately effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

ICE Clear Europe is proposing to publish a Circular, titled ICE Clear Europe: Interpretation of References to EU Legislation in the Clearing Rules Post-Brexit (the ''Circular''), to provide guidance as to the interpretation of references to European Union (''EU'') directives and regulations in the ICE Clear Europe Clearing Rules and Procedures[5] in the event that the United Kingdom (''UK'') ceases to be an EU member state, in circumstances where no withdrawal agreement stipulating that EU laws will continue to apply in the UK has been agreed between the UK and the EU–27. The interpretation contained in the Circular will only apply under such circumstances.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICE Clear Europe 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. ICE Clear Europe has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

The purpose of the proposed Circular is to provide guidance with respect to the interpretation of certain provisions in the Rules and Procedures in the event that the UK exits the Transition Period, in circumstances where no trade agreement has been agreed between the UK and the EU–27 stipulating that EU laws will continue to apply in the UK. In such circumstances, directly applicable EU directives and regulations will be incorporated into UK law with modifications at the end of the Transition Period pursuant to the European Union (Withdrawal) Act 2018 (the ''EUWA''), which would result in there being two versions of a directly applicable EU legislative act which may be applicable to the Rules: (1) The version as enacted in the EU, directly applicable throughout the EU (and, in certain cases, the EEA); and (2) the version incorporated into UK law (referred to as ''on-shored'').

There are various references to EU directives and regulations in the Rules and Procedures; others may arise by implication by virtue of definitions such as that of ''Applicable Laws'' or ''Governmental Authority'' (Rule 101). ICE Clear Europe is proposing to publish the Circular to provide guidance as to the proper interpretation of such references in the event of the end of the Transition Period without a trade agreement in place that provides for continued applicability of EU law in the UK. The guidance is intended to be consistent with the views of legal practitioners in the UK with respect to references to EU directives and regulations in English law contracts generally, but applied to the particular definitions and situations that arise under the Rules and Procedures.

The Circular sets out several principles that will be applied by ICE Clear Europe when interpreting references to an EU regulation or directive in its Rules:

1. Where the reference concerns an obligation on, or otherwise applies to, the Clearing House or a UK Clearing Member:

○ Where the reference is to an EU regulation, it should be interpreted as the regulation as it forms part of UK domestic law through section 3 of the EUWA, and as amended by UK law from time to time; and

○ Where the reference is to an EU directive, it should be interpreted as the UK domestic law corresponding to the directive or provision thereof.

2. Where the reference concerns an obligation on, or otherwise applies to, an EU Clearing Member:

○ Where the reference is to an EU regulation, it should be interpreted as the regulation as it applies in the EU, and as amended by EU law from time to time; and

○ Where the reference is to an EU directive, it should be interpreted as the EU directive, as amended by EU law from time to time and as implemented in the relevant member state of the EU Clearing Member.

The Circular also addresses situations where both sets of laws apply, for example for entities established in the UK with an EU branch (or vice versa) or which continue to be regulated in both systems under cross-border licenses, the UK temporary permissions regime or other grandfathering arrangements (via reverse solicitation or otherwise). By way of example, it explains how Rule requirements that Clearing Members maintain sufficient capital would require UK Clearing Members to comply with the on-shored version of the applicable regulatory requirements as well as applicable EU requirements for any EU branch or to the extent they are subject to EU consolidated supervision. EU Clearing Members with a UK branch or which are subject to UK consolidated supervision would be required to comply with UK capital rules equivalent to the EU rules, to the extent applicable (in addition to their applicable home country requirements). Rule

[25] 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).

[4] 17 CFR 240.19b–4(f)(1).

[5] Capitalized terms used but not defined herein have the meanings specified in the ICE Clear Europe Clearing Rules (the ''Rules'').

requirements that Clearing Members maintain segregated accounts would require UK Clearing Members to comply with the on-shored version of the applicable regulatory requirements, while EU Clearing Members would be required to comply with the existing EU regulations.

The Circular further sets out certain exceptions to these general principles relating to the following:

- A reference to an EU law relating to emission allowance units issued under the EU Emissions Trading Scheme should be interpreted, as regards EU emission allowances, to continue to refer to the EU law;
- References to an EU law, as it relates to UK emission allowances, will refer to the new UK Emissions Trading Scheme (UK ETS). The Circular also notes that UK emissions allowances, unlike the EU emissions allowances, have not been designated as investments under the UK Financial Service and Markets Act and therefore will not be covered as deliveries of financial instruments under the Rules or covered by the Part 12 settlement finality rules in the Rules, unless and until that law is changed;
- References to EU member state laws transposing or implementing an EU directive will be read to include UK laws corresponding to that EU directive;
- Certain references relating to the European Market Infrastructure Regulation (Regulation (EU) No. 648/2012) and related EU authorities will be read to continue to refer to relevant EU law and authorities, for example in the context of ICE Clear Europe's status as a third country central counterparty thereunder;
- As the Clearing House has a designated or deemed national settlement finality directive status in certain EU member states, Part 12 of the Rules will be interpreted as constituting the settlement finality rules applicable to its designated system under the laws of those EU member states; and
- References relating to EU data protection legislation are excluded, since separate amendments will be proposed to the Clearing Rules to address Brexit-related data protection issues.

(b) Statutory Basis

ICE Clear Europe believes that the proposed rule change is consistent with the requirements of Section 17A of the Act[6] and the regulations thereunder applicable to it, including the standards under Rule 17Ad–22.[7] In particular, Section 17A(b)(3)(F) of the Act[8] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, the safeguarding of securities and funds in the custody or control of the clearing agency or for which it is responsible, and the protection of investors and the public interest. The proposed Circular would provide guidance with respect to the interpretation of the Rules that would apply to EU and UK Clearing Members and ICE Clear Europe upon the termination of the Transition Period if there is no trade agreement that provides for EU law to continue to apply in the UK. The interpretation would thus facilitate continued clearing by EU and UK Clearing Members in compliance with applicable law in relevant jurisdictions and promote the prompt and accurate clearance and settlement of transactions by such persons. As such, the interpretation is consistent with the safeguarding of securities and funds in the custody or control of the Clearing House or for which it is responsible, the protection of investors and the public interest.

Moreover, the interpretation is consistent with Rule 17Ad–22(e)(1),[9] which requires that each covered clearing agency establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for a well-founded, clear, transparent, and enforceable legal basis for each aspect of its activities in all relevant jurisdictions. As discussed herein, the interpretation is designed to ensure that references to EU legislation in the Rules and Procedures are properly interpreted should the Transition Period end with no trade agreement stipulating that EU laws will continue to apply in the UK. The guidance set out in the Circular would facilitate continued clearing in light of the requirements of UK and EU law in those circumstances and would minimize the potential for disputes and legal uncertainty. ICE Clear Europe does not expect that the interpretation will adversely impact its ability to comply with the Act or any standards under Rule 17Ad–22.[10]

(B) Clearing Agency's Statement on Burden on Competition

ICE Clear Europe does not believe the proposed guidance in the Circular would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purpose of the Act. The guidance will not change the substantive requirements of any Rules or Procedures but will clarify the proper interpretation of references to EU legislation in order to facilitate that the Clearing House and EU and UK Clearing Members continue to adhere to applicable laws and regulations. ICE Clear Europe does not believe the interpretation will in itself materially affect the cost of, or access to, clearing. As a result, ICE Clear Europe does not believe the proposed rule change imposes any burden on competition that is inappropriate in furtherance of the purposes of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed Circular have not been solicited or received. ICE Clear Europe will notify the Commission of any written comments received by ICE Clear Europe.

III. Date of Effectiveness of the Proposed Rule Change for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and paragraph (f) of Rule 19b–4 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.

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–ICEEU–2020–016 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.

[6] 15 U.S.C. 78q–1.

[7] 17 CFR 240.17Ad–22.

[8] 15 U.S.C. 78q–1(b)(3)(F).

[9] 17 CFR 240.17Ad–22(e)(1).

[10] 17 CFR 240.17Ad–22.

All submissions should refer to File Number SR–ICEEU–2020–016. 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 filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's website at *https://www.theice.com/notices/Notices.shtml?regulatoryFilings.* 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–ICEEU–2020–016 and should be submitted on or before January 19, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28660 Filed 12–28–20; 8:45 am]

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[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90738; File No. SR–EMERALD–2020–20]

Self-Regulatory Organizations; MIAX Emerald, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule To Establish a Fee for Historical Market Data

December 21, 2020.

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 December 10, 2020, MIAX Emerald, LLC (''MIAX Emerald'' or ''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 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 Emerald Fee Schedule (the ''Fee Schedule'').

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/emerald,* at MIAX'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 proposes to amend the Fee Schedule to adopt new section 6(d), Historical Market Data, to describe the production of Exchange historical data and set forth the corresponding fee. The Exchange notes that the description of Historical Market Data and the proposed fee is identical to that currently charged by the Exchange's affiliates, the Miami International Securities Exchange LLC (''MIAX'') and MIAX PEARL, LLC (''MIAX PEARL'').[3]

The Exchange proposes to offer Historical Market Data for MIAX Emerald, which is a data product that offers historical market data for orders entered on MIAX Emerald upon request. The Exchange proposes to charge a modest fee for the Historical Market Data, which will be based on the cost incurred by the Exchange in providing that data. Proposed Section 6(d) of the Fee Schedule describes the fee to be charged market participants that request Historical Market Data from MIAX Emerald. Historical Market Data is intended to aid market participants in analyzing trade and volume data, evaluating historical trends in the trading activity of a particular security, and enabling those market participants to test trading models and analytical strategies. Specifically, Historical Market Data includes all data that is captured and disseminated on the MIAX Emerald Top of Market (''ToM'') data feed, MIAX Emerald Complex Top of Market (''cToM'') data feed, MIAX Emerald Administrative Information Subscriber (''AIS'') data feed, and MIAX Emerald Order feed (''MOR''),[4] and is available on a T + 1 basis.[5]

The Exchange proposes to only assess the fee for Historical Market Data on a user (whether Member or non-Member) that specifically requests such Historical Market Data. Historical Market Data will be uploaded onto an Exchange-provided device, which the Exchange will incur a cost to procure and provide to those that request the data.

The Exchange proposed to charge a flat fee of $500 per device requested. Each device shall have a maximum storage capacity of 8 terabytes. Users may request up to six months of Historical Market Data per device, subject to the device's storage capacity. Historical Data will be made available

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Section 6(d) of the MIAX Fee Schedule, Section 6(c) of the MIAX PEARL Options Fee Schedule, and Section 3(c) of the MIAX PEARL Equities Fee Schedule.

[4] *See* Securities Exchange Act Release No. 85207 (February 27, 2019), 84 FR 7963 (March 5, 2019) (SR–EMERALD–2019–09) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Establish MIAX Emerald Top of Market (''ToM'') Data Feed, MIAX Emerald Complex Top of Market (''cToM'') Data Feed, MIAX Emerald Administrative Information Subscriber (''AIS'') Data Feed, and MIAX Emerald Order Feed (''MOR'')).

[5] *See* Fee Schedule, proposed Section 6(d).

on a T + 1 basis. Only the most recent six months of Historical Market Data shall be available for purchase from the request date.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act [6] in general, and furthers the objectives of Section 6(b)(4) of the Act [7] 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 [8] 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 Exchange believes the proposed fee for Historical Market Data is a reasonable allocation of its costs and expenses among its Members and other persons using its facilities since it is recovering the costs associated with distributing such data should a Member request Historical Market Data. Access to the Exchange is provided on fair and non-discriminatory terms. The Exchange believes the proposed fee for Historical Market Data is equitable and not unfairly discriminatory because the fee level results in a reasonable and equitable allocation of fees amongst users for similar services. Moreover, the decision as to whether or not to purchase Historical Market Data is entirely optional to all users. Potential purchasers are not required to purchase the Historical Market Data, and the Exchange is not required to make the Historical Market Data available. Purchasers may request the data at any time or may decline to purchase such data. The allocation of fees among users is fair and reasonable because, if the market deems the proposed fees to be unfair or inequitable, firms can diminish or discontinue their use of this data.

The Exchange believes that the proposed fee for Historical Market Data is consistent with Section 6(b)(4) of the Act because the proposed fee will permit recovery of the Exchange's costs and will not result in excessive or supra-competitive profit. The proposed fee for Historical Market Data will allow the Exchange to recover a portion (less than all) of the costs incurred by the Exchange associated with providing and maintaining the necessary hardware and other infrastructure as well as network monitoring and support services in order to provide Historical Market Data. The Exchange believes that it is reasonable and appropriate to establish a fee for Historical Market Data at a level that will partially offset the costs to the Exchange associated with maintaining and providing Historical Market Data. For example, Historical Market Data is uploaded onto an Exchange-provided device. Each device shall have a maximum storage capacity of 8 terabytes. The Exchange incurs costs in providing the device, storing the historical data, and utilizing resources to upload the data onto the device. Specifically, the device provided by the Exchange costs approximately $200 to $300. Moreover, the Exchange tracks the number of hours spent by Exchange personnel procuring Historical Data. Based on the Exchange's average cost per full-time employee (''FTE''), the Exchange represents that its cost to provide this service is reasonably related to (and often exceeds) the amount of the Historical Market Data fee the Exchange proposes to charge. Accordingly, the proposed fee would enable the Exchange to recover a material portion of such cost.

The Exchange also notes that the proposed fee is identical to the same fee charged by its affiliate options exchanges, MIAX and MIAX PEARL,[9] for options historical data and less than that charged by other exchanges for their own historical data. For example, all four of the Cboe equity exchanges charge a fee of $500 for one month of historical data and $2,500 for one terabyte drive of data.[10]

Further, in adopting Regulation NMS, the Commission granted self-regulatory organizations and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data:

> ''[E]fficiency is promoted when broker-dealers who do not need the data beyond the prices, sizes, market center identifications of the NBBO and consolidated last sale information are not required to receive (and pay for) such data when broker-dealers may choose to receive (and pay for) additional market data based on their own internal analysis of the need for such data.'' [11]

By removing ''unnecessary regulatory restrictions'' on the ability of exchanges to sell their own data, Regulation NMS advanced the goals of the Act and the principles reflected in its legislative history. If the free market should determine whether proprietary data is sold to broker-dealers at all, it follows that the price at which such data is sold should be set by the market as well.

In July, 2010, Congress adopted H.R. 4173, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (''Dodd-Frank Act''), which amended Section 19 of the Act. Among other things, Section 916 of the Dodd-Frank Act amended paragraph (A) of Section 19(b)(3) of the Act by inserting the phrase ''on any person, whether or not the person is a member of the self-regulatory organization'' after ''due, fee or other charge imposed by the self-regulatory organization.'' As a result, all SRO rule proposals establishing or changing dues, fees or other charges are immediately effective upon filing regardless of whether such dues, fees or other charges are imposed on members of the SRO, non-members, or both. Section 916 further amended paragraph (C) of Section 19(b)(3) of the Act to read, in pertinent part, ''At any time within the 60-day period beginning on the date of filing of such a proposed rule change in accordance with the provisions of paragraph (1) [of Section 19(b)], the Commission summarily may temporarily suspend the change in the rules of the self-regulatory organization made thereby, 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 this title. If the Commission takes such action, the Commission shall institute proceedings under paragraph (2)(B) [of Section 19(b)] to determine whether the proposed rule should be approved or disapproved.''

The Exchange believes that these amendments to Section 19 of the Act reflect Congress's intent to allow the Commission to rely upon the forces of competition to ensure that fees for market data are reasonable and equitably allocated. Although Section 19(b) had formerly authorized immediate effectiveness for a ''due, fee or other charge imposed by the self-regulatory organization,'' the Commission adopted a policy and subsequently a rule stating that fees for

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(4).

[8] 15 U.S.C. 78f(b)(5).

[9] *See supra* note 3.

[10] *See, e.g.,* Cboe BZX Exchange, Inc. fee schedule *available at https://markets.cboe.com/us/equities/membership/fee_schedule/bzx/.*

[11] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

data and other products available to persons that are not members of the self-regulatory organization must be approved by the Commission after first being published for comment. At the time, the Commission supported the adoption of the policy and the rule by pointing out that unlike members, whose representation in self-regulatory organization governance was mandated by the Act, non-members should be given the opportunity to comment on fees before being required to pay them, and that the Commission should specifically approve all such fees. The Exchange believes that the amendment to Section 19 reflects Congress's conclusion that the evolution of self-regulatory organization governance and competitive market structure have rendered the Commission's prior policy on non-member fees obsolete. Specifically, many exchanges have evolved from member-owned, not-for-profit corporations into for-profit, investor-owned corporations (or subsidiaries of investor-owned corporations). Accordingly, exchanges no longer have narrow incentives to manage their affairs for the exclusive benefit of their members, but rather have incentives to maximize the appeal of their products to all customers, whether members or non-members, so as to broaden distribution and grow revenues. Moreover, the Exchange believes that the change also reflects an endorsement of the Commission's determinations that reliance on competitive markets is an appropriate means to ensure equitable and reasonable prices. Simply put, the change reflects a presumption that all fee changes should be permitted to take effect immediately, since the level of all fees are constrained by competitive forces.

Selling proprietary market data, such as Historical Data, is a means by which exchanges compete to attract business. To the extent that exchanges are successful in such competition, they earn trading revenues and also enhance the value of their data products by increasing the amount of data they provide. The need to compete for business places substantial pressure upon exchanges to keep their fees for both executions and data reasonable.[12] The Exchange therefore believes that the fees for Historical Data are properly assessed on Members and Non-Member users.

The decision of the United States Court of Appeals for the District of Columbia Circuit in *NetCoalition* v. *SEC,* No. 09–1042 (D.C. Cir. 2010), although reviewing a Commission decision made prior to the effective date of the Dodd-Frank Act, upheld the Commission's reliance upon competitive markets to set reasonable and equitably allocated fees for 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.' '' [13]

The court's conclusions about Congressional intent are therefore reinforced by the Dodd-Frank Act amendments, which create a presumption that exchange fees, including market data fees, may take effect immediately, without prior Commission approval, and that the Commission should take action to suspend a fee change and institute a proceeding to determine whether the fee change should be approved or disapproved only where the Commission has concerns that the change may not be consistent with the Act.

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 Exchange believes that the proposed Historical Market Data fee does not place certain market participants at a relative disadvantage to other market participants because the pricing of the proposed fee will allow the Exchange to recover a portion (less than all) of the costs incurred by the Exchange associated with providing and maintaining the necessary hardware and other infrastructure as well as network monitoring and support services in order to provide Historical Data, and will not impose a barrier to entry to smaller participants. The Exchange believes the proposed fee does not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the allocation of the proposed fee reflects the Exchange's costs in providing the device, storing the historical data, and utilizing resources to upload the data onto the device. Specifically, the device provided by the Exchange costs approximately $200 to $300 and the proposed fee represents this cost plus the Exchange's average cost per FTE to procure the Historical Data and send it to the recipient, regardless of the category of market participant.

The Exchange believes the proposed fee does not place an undue burden on competition on other SROs that is not necessary or appropriate. MIAX Emerald launched trading operations on March 1, 2019 and has a market share of approximately 3–4%, with significantly less members than other SROs. The Exchange's affiliate options exchanges, MIAX and MIAX PEARL, charge the same price that the Exchange proposes to charge for their historical data.[14] Additionally, other exchanges have similar historical data products, but with much higher rates.[15] The Exchange is also unaware of any assertion that the proposed fee would somehow unduly impair its competition with other exchanges. To the contrary, if the fees charged are deemed too high by market participants, they can simply not request historical data from the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor 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 Act,[16] and Rule 19b–4(f)(2) [17] 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.

[12] *See* Sec. Indus. Fin. Mkts. Ass'n (SIFMA), Initial Decision Release No. 1015, 2016 SEC LEXIS 2278 (ALJ June 1, 2016) (finding the existence of vigorous competition with respect to non-core market data).

[13] *NetCoalition,* at 15 (quoting H.R. Rep. No. 94–229, at 92 (1975), as reprinted in 1975 U.S.C.C.A.N. 321, 323).

[14] *See supra* note 3.

[15] *See supra* note 10.

[16] 15 U.S.C. 78s(b)(3)(A)(ii).

[17] 17 CFR 240.19b–4(f)(2).

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–EMERALD–2020–20 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–EMERALD–2020–20. 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 to make available publicly. All submissions should refer to File Number SR–EMERALD–2020–20, and should be submitted on or before January 19, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28680 Filed 12–28–20; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90742; File No. SR–CboeEDGX–2020–062]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating To Amend Its Fees Schedule

December 21, 2020.

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 December 10, 2020, Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (the ''Commission'') the 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

Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to amend its Fee Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), at the Exchange's Office of the Secretary, 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 proposes to amend its fee schedule for its equity options platform (''EDGX Options'') by removing certain fee codes related to routed orders, by updating certain fee codes in connection with routing orders in SPY options to Nasdaq PHLX LLC (''PHLX''), and removing certain fee codes in light of the recent delisting of XSP options on the Exchange.[3]

The Exchange first notes that it 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. More specifically, the Exchange is only one of 16 options venues to which market participants may direct their order flow. Based on publicly available information, no single options exchange has more than 16% of the market share and currently the Exchange represents approximately 4% of the market share.[4] Thus, in such a low-concentrated and highly competitive market, no single options exchange, including the Exchange, possesses significant pricing power in the execution of option order flow. The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow or discontinue to reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain the Exchange's transaction fees, and market participants can readily trade on competing venues if they deem pricing levels at those other venues to be more favorable.

The Exchange assesses fees in connection with orders routed away to various exchanges. Currently, under the Fee Codes and Associated Fees section of the Fee Schedule, fee codes D1, D2, D3 and D4 are appended to Members'

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[18] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange initially filed the proposed fee changes on December 1, 2020 (SR–CboeEDGX–2020–057). On December 9, 2020, the Exchange withdrew that filing and submitted this proposal.

[4] *See* Cboe Global Markets U.S. Options Market Month-to-Date Volume Summary (November 23, 2020), available at *https://markets.cboe.com/us/options/market_statistics/.*

Directed ISOs, a routing option under which an intermarket sweep order (''ISO'') entered by a User bypasses the System and is sent by the System to another options exchange specified by the User.[5] Specifically, these fee codes function as follows:

- Fee code D1 is appended to Directed ISOs to Nasdaq Options Market LLC (''NOM''), NYSE Arca, Inc. (''ARCA'') or ISE Gemini, LLC (''ISE Gemini'') in Non-Penny classes and assesses a charge of $1.25 per contract;
- fee code D2 is appended to Non-Customer Directed ISOs to Nasdaq BX Options (''BX'') in Non-Penny classes and assesses a charge of $0.95 per contract;
- fee code D3 is appended to Non-Customer Directed ISOs to Cboe C2 Exchange, Inc. (''C2'') or PHLX and assesses a charge of $0.95 per contract; and
- fee code D4 is appended to Directed ISOs (unless otherwise specified in the Fee Schedule) and assesses a charge of $0.85 per contract.

The Exchange has observed a minimal amount of volume in recent months in orders yielding fee codes D1, D2, D3 or D4. The Exchange believes that, because so few Users elect to route their orders as Directed ISOs, the current demand does not warrant the infrastructure and ongoing Systems maintenance required to support separate fee codes specifically applicable to Directed ISOs. Therefore, the Exchange now proposes to delete fee codes D1, D2, D3 and D4 in the Fee Schedule. The Exchange notes that Users will continue to be able to choose to route their orders as Directed ISOs and such orders will be assessed the fees currently in place for routed orders generally (*i.e.,* fee codes RN,[6] RO,[7] RP,[8] RQ[9] and RR[10]) as follows:

- A Directed ISO to which fee code D1 would have prior been appended (routed to NOM, ARCA or ISE Gemini in a Non-Penny class) will yield fee code RR, if it is a Customer order, which is appended to Customer orders in Non-Penny classes routed to NOM, ARCA or ISE Gemini (among other exchanges) and assesses a charge of $1.25 per contract, or will yield fee code RO, if it is a Non-Customer order, which is appended to routed Non-Customer orders in Non-Penny classes and also assesses a charge of $1.25 per contract;
- a Directed ISO to which fee code D2 would have prior been appended (Non-Customer to BX in a Non-Penny class) will yield fee code RO;
- a Directed ISO to which fee code D3 would have prior been appended (Non-Customer to C2 or PHLX) will yield fee code RN, if in a Penny Pilot class, which is appended to Non-Customer orders routed in Penny Pilot classes and assesses a charge of $0.90 per contract, or will yield fee code RO, if in a Non-Penny class; and
- a Directed ISO to which fee code D4 would have prior been appended (unless otherwise specified) may yield any of fee codes RN, RO, RP, RQ and RR, depending on whether the order is a (1) routed Customer order in a Penny Pilot class (to which fee code RP, which assess a charge of $0.25 per contract, or RQ, which assesses a charge of $0.85 per contract, could apply depending on the away exchange), (2) a routed Customer order in a Non-Penny class (to which fee code RP or RR could apply depending on the away exchange), (3) is a routed Non-Customer order in a Penny Pilot class (to which fee code RN will apply), or (4) is a routed Non-Customer order in a Non-Penny Class (to which fee code RO will apply).

The Exchange also proposes to update fee codes RP and RQ in connection with routed Customer orders in SPY options to PHLX. Currently, fee code RP is appended to routed Customer orders to NYSE American (''AMEX''), BOX Options Exchange (''BOX''), BX, Cboe Exchange, Inc. (''Cboe''), ISE Mercury, LLC (''ISE Mercury''), MIAX Options Exchange (''MIAX'') or PHLX and assesses a charge of $0.25 per contract. Fee code RQ is appended to routed Customer orders in Penny Pilot classes to ARCA, Cboe BZX Exchange, Inc. (''BZX Options''), C2, Nasdaq ISE (''ISE''), ISE Gemini, MIAX Emerald Exchange (''MIAX Emerald''), MIAX Pearl Exchange (''MIAX Pearl''), or NOM and assesses a charge of $0.85 per contract. The Exchange notes that its current approach to routing fees is to set forth in a simple manner certain sub-categories of fees that approximate the cost of routing to other options exchanges based on the cost of transaction fees assessed by each venue as well as costs to the Exchange for routing (*i.e.,* clearing fees, connectivity and other infrastructure costs, membership fees, etc.) (collectively, ''Routing Costs''). The Exchange then monitors the fees charged as compared to the costs of its routing services and adjusts its routing fees and/or sub-categories to ensure that the Exchange's fees do indeed result in a rough approximation of overall Routing Costs, and are not significantly higher or lower in any area. Currently, PHLX assesses a charge of $0.42 per contract for Customer orders in SPY options that remove liquidity.[11] As described above, the Exchange currently assesses a flat routing fee of $0.25 for Customer orders routed to PHLX which yield fee code RP. This structure does not currently take into account the $0.42 per contract fee assessed by PHLX for Customer orders in SPY options. Therefore, in order to assess fees more in line with the Exchange's current approach to routing fees, that is, in a manner that approximates the cost of routing to Customer orders in SPY options to PHLX, along with other away options exchanges, based on the general cost of transaction fees assessed by the sub-category of away options exchanges for such orders (as well as the Exchange's Routing Costs), the Exchange proposes to exclude Customer orders in SPY options routed to PHLX from orders that yield fee code RP and are assessed a charge of $0.25 per contract and, instead, add Customer orders routed to PHLX in SPY options only to orders that yield fee code RQ[12] and are assessed a charge of $0.85 per contract.

The Exchange also proposes to eliminate fee codes associated with orders in XSP options as the Exchange recently delisted XSP options for trading on the Exchange. Specifically, under the Fees and Associated Fee Codes section of the Fee Schedule, the proposed rule change removes fees codes XB, XC, XD, XF, XL, XM, XN, XO, XP, XR, XS, XT and XV, all of which were appended to various orders in XSP options. The proposed rule change also removes references to fee codes associated with orders in XSP options from the Step Up Mechanism (''SUM'') Auction Pricing Tier in footnote 3 and AIM and SAM Pricing in footnote 6.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with

[5] *See* Rule 21.9(a)(2)(D).

[6] Fee code RN is appended to routed Non-Customer orders in Penny Pilot classes and assesses a charge of $0.90 per contract.

[7] Fee code RO is appended to all routed Non-Customer orders in Non-Penny classes and assesses a charge of $1.25 per contract.

[8] Fee code RP is appended to routed Customer orders to AMEX, BOX, BX, Cboe, ISE Mercury, MIAX or PHLX and assesses a charge of $0.25 per contract.

[9] Fee code RQ is appended to routed Customer orders in Penny Pilot classes to ARCA, BZX Options, C2, ISE, ISE Gemini, MIAX Emerald, MIAX Pearl or NOM and assesses a charge of $0.85 per contract.

[10] Fee code RR is appended to routed Customer orders in Non-Penny classes to ARCA, BZX Options, C2, ISE, ISE Gemini, MIAX Emerald, MIAX Pearl or NOM and assesses a charge of $1.25 per contract.

[11] *See* Nasdaq Phlx Options 7 Pricing Schedule, Section 3 ''Rebates and Fees for Adding and Removing Liquidity in SPY'', Part A.

[12] The Exchange notes that SPY options are part of the Penny Pilot Program.

the objectives of Section 6 of the Act,[13] in general, and furthers the objectives of Section 6(b)(4),[14] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and issuers and other persons using its facilities. The Exchange also believes that the proposed rule change is consistent with the objectives of Section 6(b)(5) [15] requirements that the rules of an 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 regulating, clearing, settling, processing information with respect to, and 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, particularly, is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

As described 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 rule change reflects a competitive pricing structure designed to incentivize market participants to direct their order flow to the Exchange, which the Exchange believes would enhance market quality to the benefit of all Members. The Exchange notes that other options exchanges currently approximate routing fees in a similar manner as the Exchange's current approach.[16]

In particular, the Exchange believes the proposed rule change to remove fee codes D1, D2, D3 and D4 is reasonable as the Exchange has observed a minimal amount of volume in orders yielding fee codes D1, D2, D3 or D4 and, therefore, the current use of Directed ISO orders does not warrant the infrastructure and ongoing Systems maintenance required to support separate fee codes specifically applicable to Directed ISOs, a type of routing option Users may elect for their orders. As such, the Exchange also believes that is reasonable and equitable to assess Directed ISO orders as it already does for all other routed orders, as applicable (*i.e.,* fee codes RN, RO, RP, RQ and RR).[17] The Exchange notes that the use of Directed ISOs, as well as routing through the Exchange, is optional. The Exchange believes that the proposed rule change is equitable and not unfairly discriminatory because Users will continue to have the option to elect to route their orders as Directed ISOs and such routed orders will be automatically and uniformly assessed the applicable charges already in place for all other routed orders.

The Exchange believes the proposed rule change to amend fee codes RP and RQ to account for PHLX's current assessment of fees for Customer orders in SPY options is reasonable because it is reasonably designed to assess routing fees in line with the Exchange's current approach to routing fees. That is, the proposed rule change is intended to include Customer orders in SPY options routed to PHLX in the most appropriate sub-category of fees that approximates the cost of routing to a group of away options exchanges (including PHLX) based on the cost of transaction fees assessed by each venue as well as Routing Costs to the Exchange. The Exchange believes that the proposed rule change is equitable and not unfairly discriminatory because all Members' Customer orders in SPY routed to PHLX will automatically yield fee code RQ and uniformly be assessed the corresponding fee.

The Exchange believes that it is reasonable and equitable to remove fee codes associated with orders in XSP options, as well as references in the Fee Schedule to such orders, because the Exchange no longer lists XSP options for trading. Therefore, the proposed rule change is reasonably designed to update the Fee Schedule to accurately reflect the Exchange's current product offerings. The Exchange believes that the proposed rule change is equitable and not unfairly discriminatory because all Members are equally unable to submit orders in the delisted product, and the removal of references to orders in XSP options merely updates the Fee Schedule to reflect this.

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 does not believe the proposed rule change will impose any burden on intramarket competition because all Members Directed ISO order will automatically and uniformly be assessed the current fees already in place for routed orders, as applicable (*i.e.,* fee codes RN, RO, RP, RQ and RR).[18] Likewise, all Members' Customer orders in SPY routed to PHLX will automatically yield fee code RQ and uniformly be assessed the corresponding fee. The Exchange believes that the proposed rule change to remove fee codes associated with and references to orders in XSP options merely updates the Fee Schedule to reflect that the product have been delisted.

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that other options exchange approximate routing costs in a similar manner as the Exchange's current approach.[19] Also, as previously discussed, the Exchange operates in a highly competitive market. Members have numerous alternative venues that they may participate on and director their order flow, including 15 other options exchanges and off-exchange venues. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single options exchange has more than 16% of the market share.[20] Therefore, no exchange possesses significant pricing power in the execution of option order flow. Indeed, participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. Moreover, 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

[13] 15 U.S.C. 78f.

[14] 15 U.S.C. 78f(b)(4).

[15] 15 U.S.C. 78f(b)(5).

[16] *See e.g.,* NYSE Arca Options Fees and Charges, ''Routing Fees'', which provides routing fees of ''$0.11 per contract on orders routed and executed on another exchange, plus (i) any transaction fees assessed by the away exchange (calculated on an order-by-order basis since different away exchanges charge different amounts) or (ii) if the actual transaction fees assessed by the away exchange(s) cannot be determined prior to the execution, the highest per contract charge assessed by the away exchange(s) for the relevant option class and type of market participant (*e.g.,* Customer, Firm, Broker/Dealer, Professional Customer or Market Maker).''

[17] *See supra* notes 6–10.

[18] *See supra* notes 6–10.

[19] *See supra* note 16.

[20] *See supra* note 4.

investors and listed companies.'' [21] The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated as follows: ''[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.'. . .''[22] Accordingly, the Exchange does not believe its proposed fee change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

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) of the Act [23] and paragraph (f) of Rule 19b–4 [24] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

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 will 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–CboeEDGX–2020–062 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–CboeEDGX–2020–062. 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; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeEDGX–2020–062 and should be submitted on or before January 19, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28670 Filed 12–28–20; 8:45 am]

BILLING CODE 8011–01–P

[21] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[22] *NetCoalition* v. *SEC,* 615 F.3d 525, 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)).

[23] 15 U.S.C. 78s(b)(3)(A).

[24] 17 CFR 240.19b–4(f).

[25] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90744; File No. SR–NYSE–2020–102]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Price List

December 21, 2020.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on December 15, 2020, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. 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 proposes to amend its Price List to extend the waiver of equipment and related service charges and trading license fees for NYSE Trading Floor-based member organizations. The Exchange proposes to implement the fee changes effective January 1, 2021. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, 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 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

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 amend its Price List to extend the waiver of equipment and related service charges and trading license fees for NYSE Trading Floor-based member organizations that have been unable to resume their Floor operations to a certain capacity level, as discussed below. The Exchange proposes to implement the fee change effective January 1, 2021.

As proposed, the Exchange would waive 50% of the Telephone System charges and Service Charges (except for the internet Equipment Monthly Hosting Fee) and trading license fees for the billing month of January 2021 only for member organizations that (1) meet the current requirements for these waivers, and (2) are unable to operate at more than 50% of their March 2020 on-Floor staffing levels or, for member organizations that began Floor operations after March 2020, are unable to operate at more than 50% of their Exchange-approved on-Floor staffing levels, both excluding part-time Floor brokers.

Background

Beginning on March 16, 2020, in order to slow the spread of the novel coronavirus (''COVID–19'') through social distancing measures, significant limitations were placed on large gatherings throughout the country. As a result, on March 18, 2020, the Exchange determined that beginning March 23, 2020, the physical Trading Floor facilities located at 11 Wall Street in New York City would close and that the Exchange would move, on a temporary basis, to fully electronic trading.[4] Following the temporary closure of the Trading Floor, the Exchange waived certain equipment fees for the booth telephone system on the Trading Floor and associated service charges for the months of April and May.[5]

On May 14, 2020, the Exchange announced that on May 26, 2020 trading operations on the Trading Floor would resume on a limited basis to a subset of Floor brokers, subject to health and safety measures designed to prevent the spread of COVID–19.[6] On June 15, 2020, the Exchange announced that on June 17, 2020, the Trading Floor would reintroduce a subset of DMMs, also subject to health and safety measures designed to prevent the spread of COVID–19.[7] Following this partial reopening of the Trading Floor, the Exchange extended the equipment fee waiver for the months of June through December 2020.[8] The Trading Floor continues to operate with reduced headcount and additional health and safety precautions.[9]

Proposed Rule Change

In response to the unprecedented events surrounding the spread of COVID–19 in 2020, the Exchange waived certain equipment and related service charges and trading license fees for NYSE Trading Floor-based member organizations for the months of April through December 2020.

Specifically, during that period the Exchange waived the Annual Telephone Line Charge of $400 per phone number and the $129 fee for a single line phone, jack, and data jack. The Exchange also waived related service charges, as follows: $161.25 to install single jack (voice or data); $107.50 to relocate a jack; $53.75 to remove a jack; $107.50 to install voice or data line; $53.75 to disconnect data line; $53.75 to change a phone line subscriber; and miscellaneous telephone charges billed at $106 per hour in 15 minute increments.[10] These fees were waived for (1) member organizations with at least one trading license, a physical Trading Floor presence, and Floor broker executions accounting for 40% or more of the member organization's combined adding, taking, and auction volumes during March 1 to March 20, 2020, or, beginning in August 2020, if not a member organization during March 1 to March 20, 2020, based on the member organization's combined adding, taking, and auction volumes during its first month as a member organization on or after May 26, 2020, *i.e.,* the date the Trading Floor re-opened on a limited basis, and (2) member organizations with at least one trading license that are Designated Market Makers with 30 or fewer assigned securities for the billing month of March 2020.

In addition, to further reduce costs for member organizations with a Trading Floor presence, the Exchange waived the monthly portion of all applicable annual fees between April and December 2020, for (1) member organizations with at least one trading license, a physical Trading Floor presence and Floor broker executions accounting for 40% or more of the member organization's combined adding, taking, and auction volumes during March 1 to March 20, 2020, or, beginning in August 2020, if not a member organization during March 1 to March 20, 2020, based on the member organization's combined adding, taking, and auction volumes during its first month as a member organization on or after May 26, 2020, and (2) member organizations with at least one trading license that are DMMs with 30 or fewer assigned securities for the billing month of March 2020.[11]

Because the Trading Floor continues to operate with reduced capacity, the Exchange proposes to extend the waiver of these Trading Floor-based fees for the billing month of January 2021. As proposed, the Exchange would waive 50% of the Annual Telephone Line Charge of $400 per phone number; the $129 fee for a single line phone, jack, and data jack; the related service charges ($161.25 to install single jack (voice or data); $107.50 to relocate a jack; $53.75 to remove a jack; $107.50 to install voice or data line; $53.75 to disconnect data line; $53.75 to change a phone line subscriber; and miscellaneous telephone charges billed

[4] *See* Press Release, dated March 18, 2020, available here: *https://ir.theice.com/press/press-releases/allcategories/2020/03-18-2020-204202110.*

[5] *See* Securities Exchange Act Release No. 88602 (April 8, 2020), 85 FR 20730 (April 14, 2020) (SR–NYSE–2020–27); Securities Exchange Act Release No. 88874 (May 14, 2020), 85 FR 30743 (May 20, 2020) (SR–NYSE–2020–29). *See* footnote 11 of the Price List.

[6] *See* Trader Update, dated May 14, 2020, available here: *https://www.nyse.com/traderupdate/history#110000251588.*

[7] *See* Trader Update, dated June 15, 2020, available here: *https://www.nyse.com/trader-update/history#110000272018.*

[8] *See* Securities Exchange Act Release No. 89050 (June 11, 2020), 85 FR 36637 (June 17, 2020) (SR–NYSE–2020–49); Securities Exchange Act Release No. 89324 (July 15, 2020), 85 FR 44129 (July 21, 2020) (SR–NYSE–2020–59); Securities Exchange Act Release No. 89754 (September 2, 2020), 85 FR 55550 (September 8, 2020) (SR–NYSE–2020–71); Securities Exchange Act Release No. 89798 (September 9, 2020), 85 FR 57263 (September 15, 2020) (SR–NYSE–2020–72); Securities Exchange Act Release No. 90161 (October 13, 2020), 85 FR 66370 (October 19, 2020) (SR–NYSE–2020–81); and Securities Exchange Act Release No. 90391 (November 10, 2020), 85 FR 73326 (November 17, 2020) (SR–NYSE–2020–92).

[9] *See* Trader Update, dated June 15, 2020, available here: *https://www.nyse.com/trader-update/history#110000272018.* DMMs continue to support a subset of NYSE-listed securities remotely.

[10] The Service Charges also include an internet Equipment Monthly Hosting Fee that the Exchange did not previously waive and that the Exchange does not propose to waive for January 2021.

[11] *See* notes 5–8, *supra. See* footnote 15 of the Price List. Beginning in August 2020, member organizations with a physical trading Floor presence that became member organizations on or after April 1, 2020 became eligible for a one-time credit for the member organization's indicated annual trading license fee for the months of April through July 2020 if the member organization meets the other requirements for the waiver described in footnote 15 of the Price List. The Exchange proposes to delete this language from the Price List as moot.

at $106 per hour in 15 minute increments); and the monthly portion of all applicable annual fees only for member organizations that

• meet the current requirements of having at least one trading license, a physical trading Floor presence and Floor broker executions accounting for 40% or more of the member organization's combined adding, taking, and auction volumes during March 1 to March 20, 2020 or, if not a member organization during March 1 to March 20, 2020, based on the member organization's combined adding, taking, and auction volumes during its first month as a member organization on or after May 26, 2020, and

• are unable to operate at more than 50% of their March 2020 on-Floor staffing levels or, for member organizations that began Floor operations after March 2020, are unable to operate at more than 50% of their Exchange-approved on-Floor staffing levels, both excluding part-time Floor brokers known as ''flex brokers'' (hereinafter, ''Qualifying Firms'').

Because the Trading Floor will continue to operate with reduced capacity, the Exchange proposes to extend the fee waiver for Qualifying Firms for the billing month of January 2021. The Exchange proposes to cap the waiver at 50%. The Exchange also proposes to clarify that Qualifying Firms would include firms that began Floor operations after March 2020 that are unable to operate at more than 50% of their Exchange-approved on-Floor staffing levels, both excluding part-time Floor brokers. The Exchange does not propose to extend the waiver of equipment and related service charges and trading license fees for DMMs with at least one trading license and 30 or fewer assigned securities for the billing month of March 2020, which expire at the end of December 2020.

The proposed fee change is designed to reduce monthly costs for all Qualifying Firms whose operations continue to be disrupted even though the Trading Floor has partially reopened. In reducing this monthly financial burden, the proposed change would allow Qualifying Firms that that are unable to operate at more than 50% of their March 2020 or Exchange-approved on-Floor staffing levels to reallocate funds to assist with the cost of shifting and maintaining their prior fully-staffed on-Floor operations to off-Floor and recoup losses resulting from the partial reopening. The Exchange believes that all Qualifying Firms would benefit from the proposed fee change.

The proposed changes are not otherwise intended to address other issues, and the Exchange is not aware of any significant problems that market participants would have in complying with the proposed changes.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[13] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange operates in a highly competitive market. 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.'' [14]

While Regulation NMS has enhanced competition, it has also fostered a ''fragmented'' market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that ''such competition can lead to the fragmentation of order flow in that stock.'' [15] Indeed, equity trading is currently dispersed across 16 exchanges,[16] 31 alternative trading systems,[17] and numerous broker-dealer internalizers and wholesalers, all competing for order flow. Based on publicly-available information, no single exchange has more than 16% market share.[18] Therefore, no exchange possesses significant pricing power in the execution of equity order flow. More specifically, the Exchange's market share of trading in Tape A, B and C securities combined is less than 12%.

The Proposed Change Is Reasonable

The proposed extension of the waiver of equipment and related service fees and the applicable monthly trading license fee for Qualified Firms is reasonable in light of the continued partial closure of the NYSE Trading Floor as a result of spread of COVID–19. The proposed change is reasonable because it would reduce monthly costs for all Qualifying Firms whose operations have been disrupted despite the fact that the Trading Floor has partially reopened because of the social distancing requirements and/or other health concerns related to resuming operation on the Trading Floor. In reducing this monthly financial burden, the proposed change would allow Qualifying Firms that that are unable to operate at more than 50% of their March 2020 or Exchange-approved on-Floor staffing levels to reallocate funds to assist with the cost of shifting and maintaining their prior fully-staffed on-Floor operations to off-Floor and recoup losses resulting from the partial reopening of the Trading Floor.

The Proposal Is an Equitable Allocation of Fees

The Exchange believes the proposed extension of the waiver of equipment and related service fees and the applicable monthly trading license fee for Qualified Members is an equitable allocation of fees. The proposed waivers apply to all Trading Floor-based firms meeting specific requirements during the specified period that the Trading Floor remains partially open. The Exchange believes the proposed rule change is an equitable allocation of its fees and credits as it continues the previous fee waiver for Qualifying Firms, which affects fees charged only to Floor participants and does not apply to participants that conduct business off-Floor. The Exchange believes it is an equitable allocation of fees and credits to extend the fee waiver for Qualifying Firms because such firms have either no more than half of their Floor staff (as measured by either the March 2020 or Exchange-approved) levels, and this reduction in staffing levels on the Trading Floor impacts the speed, volume and efficiency with which these

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(4) & (5).

[14] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37495, 37499 (June 29, 2005) (S7–10–04) (Final Rule) (''Regulation NMS'').

[15] *See* Securities Exchange Act Release No. 61358, 75 FR 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

[16] *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.*

[17] *See* FINRA ATS Transparency Data, available at *https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is *available at https://www.sec.gov/foia/docs/atslist.htm.*

[18] *See* Cboe Global Markets U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

firms can operate, to their financial detriment.

The Proposal Is Not Unfairly Discriminatory

The Exchange believes that the proposal is not unfairly discriminatory because the proposed continuation of the fee waiver would affect all similarly-situated market participants on an equal and non-discriminatory basis. The Exchange is not proposing to waive the Trading Floor-related fees indefinitely, but rather during the specified period during which the Trading Floor is not fully open. The Exchange believes that it is reasonable to clarify that firms that began Floor operations on the Exchange after March 2020 would be included as ''Qualifying Firms'' if such firms are unable to operate at more than 50% of their Exchange-approved on-Floor staffing levels insofar as such treatment places all firms on a level playing field, meet the current requirements for the waiver, and avoids placing ''newer'' Qualifying Firms at a financial disadvantage. The Exchange also believes that the proposed change would add clarity and transparency and reduce the potential for confusion in the Fee Schedule as relates to the treatment new Floor participants. Moreover, as noted, the proposed fee change is designed to ease the financial burden on Trading Floor-based member organizations that cannot fully conduct Floor operations.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[19] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed changes would encourage the continued participation of member organizations on the Exchange by providing certainty and fee relief during the ongoing pandemic. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [20]

Intramarket Competition. The proposed continued waiver of equipment and related service fees and the applicable monthly trading license fee for Qualified Firms is designed to reduce monthly costs for those Floor participants whose operations continue to be impacted by the COVID–19 pandemic despite the fact that the Trading Floor has partially reopened. In reducing this monthly financial burden, the proposed change would allow Qualifying Firms that had Floor operations in March 2020 to reallocate funds to assist with the cost of shifting and maintaining their previously on-Floor operations to off-Floor. Absent this change, all Qualifying Firms may experience an unintended increase in the cost of doing business on the Exchange, given that the Trading Floor has only reopened in a limited capacity. The Exchange believes that the proposed waiver of fees for Qualifying Firms would not impose a disparate burden on competition among market participants on the Exchange because off-Floor market participants are not subject to these Floor-based fixed fees. In addition, Floor-based firms that are not subject to the extent of staffing shortfalls as are Qualifying Firms, *i.e.,* firms that have more than 50% of their March 2020, or Exchange-approved staffing levels on the Trading Floor, do not face the same operational level of disruption and potential financial impact during the partial reopening of the Trading Floor. As noted, the proposal would apply to all similarly situated member organizations on the same and equal terms, who would benefit from the changes on the same basis. Accordingly, the proposed change would not impose a disparate burden on competition among market participants on the Exchange.

Intermarket Competition. As described above, the Exchange operates in a highly competitive market in which market participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. The Exchange believes that the proposed rule change reflects this competitive environment because it permits impacted member organizations to continue to conduct market-making operations on the Exchange and avoid unintended costs of doing business on the Exchange while the Trading Floor is not fully open, which could make the Exchange a less competitive venue on which to trade as compared to other equities markets. In reducing this monthly financial burden, the proposed change would allow affected participants to reallocate funds to assist with the cost of shifting and maintaining their prior fully-staffed on-Floor operations to off-Floor. Absent this change, Qualifying Firms may experience an unintended increase in the cost of doing business on the Exchange, which would make the Exchange a less competitive venue on which to trade as compared to other options exchanges.

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. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [21] of the Act and subparagraph (f)(2) of Rule 19b–4 [22] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such 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 under Section 19(b)(2)(B) [23] of the Act 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–NYSE–2020–102 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.

[19] 15 U.S.C. 78f(b)(8).

[20] Regulation NMS, 70 FR at 37498–99.

[21] 15 U.S.C. 78s(b)(3)(A).

[22] 17 CFR 240.19b–4(f)(2).

[23] 15 U.S.C. 78s(b)(2)(B).

All submissions should refer to File Number SR–NYSE–2020–102. 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–NYSE–2020–102 and should be submitted on or before January 19, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28664 Filed 12–28–20; 8:45 am]

BILLING CODE 8011–01–P

[24] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34144; 812–15167]

ETF Series Solutions and ClearShares, LLC

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

SUMMARY: ETF Series Solutions (''Trust''), a Delaware statutory trust registered under the Act as an open-end management investment company with multiple series (each a ''Fund'') and ClearShares LLC (''Initial Adviser''), a Delaware limited liability company registered as an investment adviser under the Investment Advisers Act of 1940 (''Advisers Act'') that serves an investment adviser to the Funds (collectively with the Trust, the ''Applicants'') have applied for an exemption from the Investment Company Act of 1940. The requested exemption would permit Applicants to enter into and materially amend sub-advisory agreements with sub-advisers without shareholder approval and would grant relief from the Disclosure Requirements as they relate to fees paid to the sub-advisers.

DATES: The application was filed on September 29, 2020.

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: *michael.barolsky@usbank.com.*

FOR FURTHER INFORMATION CONTACT: Nina Kostyukovsky, Senior Counsel, at (202) 551–8833, or Parisa Haghshenas, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: Notice of an application under Section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from Section 15(a) of the Act, as well as from certain disclosure requirements in Rule 20a–1 under the Act, Item 19(a)(3) of Form N–1A, Items 22(c)(1)(ii), 22(c)(1)(iii), 22(c)(8) and 22(c)(9) of Schedule 14A under the Securities Exchange Act of 1934 (''1934 Act''), and Sections 6–07(2)(a), (b), and (c) of Regulation S–X (''Disclosure Requirements'').

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 by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving Applicants with a copy of the request by email. Hearing requests should be received by the Commission by 5:30 p.m. on January 15, 2021, and should be accompanied by proof of service on the 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.

The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number or an Applicant using the ''Company'' name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

I. Requested Exemptive Relief

1. Applicants request an order to permit the Adviser,[1] subject to the approval of the board of trustees of the Trust (collectively, the ''Board''),[2] including a majority of the trustees who are not ''interested persons'' of the Trust or the Adviser, as defined in Section 2(a)(19) of the Act (the ''Independent Trustees''), without obtaining shareholder approval, to: (i) Select investment sub-advisers (''Sub-Advisers'') for all or a portion of the assets of one or more of the Funds pursuant to an investment sub-advisory agreement with each Sub-Adviser (each a ''Sub-Advisory Agreement''); and (ii) materially amend Sub-Advisory Agreements with the Sub-Advisers.

2. Applicants also request an order exempting the Sub-Advised Funds (as defined below) from the Disclosure Requirements, which require each Fund to disclose fees paid to a Sub-Adviser. Applicants seek relief to permit each Sub-Advised Fund to disclose (as a dollar amount and a percentage of the Fund's net assets): (i) The aggregate fees paid to the Adviser and any Wholly-Owned Sub-Advisers; and (ii) the aggregate fees paid to Affiliated and Non-Affiliated Sub-Advisers (''Aggregate Fee Disclosure'').[3]

[1] The term ''Adviser'' means (i) the Initial Adviser, (ii) its successors, and (iii) any entity controlling, controlled by or under common control with, the Initial Adviser or its successors that serves as the primary adviser to a Sub-Advised Fund. For the purposes of the requested order, ''successor'' is limited to an entity or entities that result from a reorganization into another jurisdiction or a change in the type of business organization. Any other Adviser also will be registered with the Commission as an investment adviser under the Advisers Act.

[2] The term ''Board'' also includes the board of trustees or directors of a future Sub-Advised Fund (as defined below), if different from the board of trustees (''Trustees'') of the Trust.

[3] A ''Wholly-Owned Sub-Adviser'' is any investment adviser that is (1) an indirect or direct ''wholly-owned subsidiary'' (as such term is defined in Section 2(a)(43) of the Act) of the Adviser, (2) a ''sister company'' of the Adviser that is an indirect or direct ''wholly-owned subsidiary'' of the same company that indirectly or directly wholly owns the Adviser (the Adviser's ''parent company''), or (3) a parent company of the Adviser. An ''Affiliated Sub-Adviser'' is any investment sub-adviser that is not a Wholly-Owned Sub-Adviser, but is an ''affiliated person'' (as defined in Section 2(a)(3) of the Act) of a Sub-Advised Fund or the Adviser for reasons other than serving as investment sub-adviser to one or more Funds. A ''Non-Affiliated Sub-Adviser'' is any investment adviser that is not an ''affiliated person'' (as defined in the Act) of a Fund or the Adviser, except to the extent that an affiliation arises solely because the Sub-Adviser serves as a sub-adviser to one or more Funds.

Applicants seek an exemption to permit a Sub-Advised Fund to include only the Aggregate Fee Disclosure.[4]

3. Applicants request that the relief apply to Applicants, as well as to any future Fund and any other existing or future registered open-end management investment company or series thereof that intends to rely on the requested order in the future and that: (i) Is advised by the Adviser; (ii) uses the multi-manager structure described in the application; and (iii) complies with the terms and conditions of the application (each, a ''Sub-Advised Fund'').[5]

II. Management of the Sub-Advised Funds

4. The Adviser serves or will serve as the investment adviser to each Sub-Advised Fund pursuant to an investment advisory agreement with the Fund (each an ''Investment Advisory Agreement''). Each Investment Advisory Agreement has been or will be approved by the Board, including a majority of the Independent Trustees, and by the shareholders of the relevant Sub-Advised Fund in the manner required by Sections 15(a) and 15(c) of the Act. The terms of these Investment Advisory Agreements comply or will comply with Section 15(a) of the Act. Applicants are not seeking an exemption from the Act with respect to the Investment Advisory Agreements. Pursuant to the terms of each Investment Advisory Agreement, the Adviser, subject to the oversight of the Board, will provide continuous investment management for each Sub-Advised Fund. For its services to each Sub-Advised Fund, the Adviser receives or will receive an investment advisory fee from that Fund as specified in the applicable Investment Advisory Agreement.

5. Consistent with the terms of each Investment Advisory Agreement, the Adviser may, subject to the approval of the Board, including a majority of the Independent Trustees, and the shareholders of the applicable Sub-Advised Fund (if required by applicable law), delegate portfolio management responsibilities of all or a portion of the assets of a Sub-Advised Fund to a Sub-Adviser. The Adviser will retain overall responsibility for the management and investment of the assets of each Sub-Advised Fund. This responsibility includes recommending the removal or replacement of Sub-Advisers, allocating the portion of that Sub-Advised Fund's assets to any given Sub-Adviser and reallocating those assets as necessary from time to time.[6] The Sub-Advisers will be ''investment advisers'' to the Sub-Advised Funds within the meaning of Section 2(a)(20) of the Act and will provide investment management services to the Funds subject to, without limitation, the requirements of Sections 15(c) and 36(b) of the Act.[7] The Sub-Advisers, subject to the oversight of the Adviser and the Board, will determine the securities and other investments to be purchased, sold or entered into by a Sub-Advised Fund's portfolio or a portion thereof, and will place orders with brokers or dealers that they select.[8]

6. The Sub-Advisory Agreements will be approved by the Board, including a majority of the Independent Trustees, in accordance with Sections 15(a) and 15(c) of the Act. In addition, the terms of each Sub-Advisory Agreement will comply fully with the requirements of Section 15(a) of the Act. The Adviser may compensate the Sub-Advisers or the Sub-Advised Funds may pay advisory fees to the Sub-Advisers directly.

7. Sub-Advised Funds will inform shareholders of the hiring of a new Sub-Adviser pursuant to the following procedures (''Modified Notice and Access Procedures''): (a) Within 90 days after a new Sub-Adviser is hired for any Sub-Advised Fund, that Fund will send its shareholders either a Multi-Manager Notice or a Multi-Manager Notice and Multi-Manager Information Statement;[9] and (b) the Sub-Advised Fund will make the Multi-Manager Information Statement available on the website identified in the Multi-Manager Notice no later than when the Multi-Manager Notice (or Multi-Manager Notice and Multi-Manager Information Statement) is first sent to shareholders, and will maintain it on that website for at least 90 days.[10]

III. Applicable Law

8. Section 15(a) of the Act states, in part, that it is unlawful for any person to act as an investment adviser to a registered investment company ''except pursuant to a written contract, which contract, whether with such registered company or with an investment adviser of such registered company, has been approved by the vote of a majority of the outstanding voting securities of such registered company.''

9. Form N–1A is the registration statement used by open-end investment companies. Item 19(a)(3) of Form N–1A requires a registered investment company to disclose in its statement of additional information the method of computing the ''advisory fee payable'' by the investment company with respect to each investment adviser, including the total dollar amounts that the investment company ''paid to the adviser (aggregated with amounts paid to affiliated advisers, if any), and any advisers who are not affiliated persons of the adviser, under the investment advisory contract for the last three fiscal years.''

10. Rule 20a–1 under the Act requires proxies solicited with respect to a registered investment company to comply with Schedule 14A under the 1934 Act. Items 22(c)(1)(ii), 22(c)(1)(iii), 22(c)(8) and 22(c)(9) of Schedule 14A, taken together, require a proxy statement for a shareholder meeting at which the advisory contract will be

[4] Applicants note that all other items required by Sections 6–07(2)(a), (b) and (c) of Regulation S–X will be disclosed.

[5] All registered open-end investment companies that currently intend to rely on the requested order are named as Applicants. All Funds that currently are, or that currently intend to be, Sub-Advised Funds are identified in this application. Any entity that relies on the requested order will do so only in accordance with the terms and conditions contained in the application.

[6] Applicants represent that if the name of any Sub-Advised Fund contains the name of a sub-adviser, the name of the Adviser that serves as the primary adviser to the Fund, or a trademark or trade name that is owned by or publicly used to identify the Adviser, will precede the name of the sub-adviser.

[7] The Sub-Advisers will be registered with the Commission as an investment adviser under the Advisers Act or not subject to such registration.

[8] A ''Sub-Adviser'' also includes an investment sub-adviser that will provide the Adviser with a model portfolio reflecting a specific strategy, style or focus with respect to the investment of all or a portion of a Sub-Advised Fund's assets. The Adviser may use the model portfolio to determine the securities and other instruments to be purchased, sold or entered into by a Sub-Advised Fund's portfolio or a portion thereof, and place orders with brokers or dealers that it selects.

[9] A ''Multi-Manager Notice'' will be modeled on a Notice of internet Availability as defined in Rule 14a–16 under the 1934 Act, and specifically will, among other things: (a) Summarize the relevant information regarding the new Sub-Adviser (except as modified to permit Aggregate Fee Disclosure); (b) inform shareholders that the Multi-Manager Information Statement is available on a website; (c) provide the website address; (d) state the time period during which the Multi-Manager Information Statement will remain available on that website; (e) provide instructions for accessing and printing the Multi-Manager Information Statement; and (f) instruct the shareholder that a paper or email copy of the Multi-Manager Information Statement may be obtained, without charge, by contacting the Sub-Advised Fund. A ''Multi-Manager Information Statement'' will meet the requirements of Regulation 14C, Schedule 14C and Item 22 of Schedule 14A under the 1934 Act for an information statement, except as modified by the requested order to permit Aggregate Fee Disclosure. Multi-Manager Information Statements will be filed with the Commission via the EDGAR system.

[10] In addition, Applicants represent that whenever a new Sub-Adviser is retained, an existing Sub-Adviser is terminated, or a Sub-Advisory Agreement is materially amended, the Sub-Advised Fund's prospectus and statement of additional information will be supplemented promptly pursuant to Rule 497(e) under the Securities Act of 1933.

voted upon to include the ''rate of compensation of the investment adviser,'' the ''aggregate amount of the investment adviser's fee,'' a description of the ''terms of the contract to be acted upon,'' and, if a change in the advisory fee is proposed, the existing and proposed fees and the difference between the two fees.

11. Regulation S–X sets forth the requirements for financial statements required to be included as part of a registered investment company's registration statement and shareholder reports filed with the Commission. Sections 6–07(2)(a), (b), and (c) of Regulation S–X require a registered investment company to include in its financial statements information about investment advisory fees.

12. Section 6(c) of the Act provides that the Commission may exempt any person, security, or transaction or any class or classes of persons, securities, or transactions from any provisions of the Act, or any rule thereunder, if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants state that the requested relief meets this standard for the reasons discussed below.

IV. Arguments in Support of the Requested Relief

13. Applicants assert that, from the perspective of the shareholder, the role of the Sub-Advisers is substantially equivalent to the limited role of the individual portfolio managers employed by an investment adviser to a traditional investment company. Applicants also assert that the shareholders expect the Adviser, subject to review and approval of the Board, to select a Sub-Adviser who is in the best position to achieve the Sub-Advised Fund's investment objective. Applicants believe that permitting the Adviser to perform the duties for which the shareholders of the Sub-Advised Fund are paying the Adviser—the selection, oversight and evaluation of the Sub-Adviser—without incurring unnecessary delays or expenses of convening special meetings of shareholders is appropriate and in the interest of the Fund's shareholders, and will allow such Fund to operate more efficiently. Applicants state that each Investment Advisory Agreement will continue to be fully subject to Section 15(a) of the Act and approved by the relevant Board, including a majority of the Independent Trustees, in the manner required by Section 15(a) and 15(c) of the Act.

14. Applicants submit that the requested relief meets the standards for relief under Section 6(c) of the Act. Applicants state that the operation of the Sub-Advised Fund in the manner described in the application must be approved by shareholders of that Fund before it may rely on the requested relief. Applicants also state that the proposed conditions to the requested relief are designed to address any potential conflicts of interest or economic incentives, and provide that shareholders are informed when new Sub-Advisers are hired.

15. Applicants contend that, in the circumstances described in the application, a proxy solicitation to approve the appointment of new Sub-Advisers provides no more meaningful information to shareholders than the proposed Multi-Manager Information Statement. Applicants state that, accordingly, they believe the requested relief is necessary or appropriate in the public interest, and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

16. With respect to the relief permitting Aggregate Fee Disclosure, Applicants assert that disclosure of the individual fees paid to the Sub-Advisers does not serve any meaningful purpose. Applicants contend that the primary reasons for requiring disclosure of individual fees paid to Sub-Advisers are to inform shareholders of expenses to be charged by a particular Sub-Advised Fund and to enable shareholders to compare the fees to those of other comparable investment companies. Applicants believe that the requested relief satisfies these objectives because the Sub-Advised Fund's overall advisory fee will be fully disclosed and, therefore, shareholders will know what the Sub-Advised Fund's fees and expenses are and will be able to compare the advisory fees a Sub-Advised Fund is charged to those of other investment companies. In addition, Applicants assert that the requested relief would benefit shareholders of the Sub-Advised Fund because it would improve the Adviser's ability to negotiate the fees paid to Sub-Advisers. In particular, Applicants state that if the Adviser is not required to disclose the Sub-Advisers' fees to the public, the Adviser may be able to negotiate rates that are below a Sub-Adviser's ''posted'' amounts as the rate would not be disclosed to the Sub-Adviser's other clients. Applicants assert that the relief will also encourage Sub-Advisers to negotiate lower sub-advisory fees with the Adviser if the lower fees are not required to be made public.

V. Relief for Affiliated Sub-Advisers

17. The Commission has granted the requested relief with respect to Wholly-Owned and Non-Affiliated Sub-Advisers through numerous exemptive orders. The Commission also has extended the requested relief to Affiliated Sub-Advisers.[11] Applicants state that although the Adviser's judgment in recommending a Sub-Adviser can be affected by certain conflicts, they do not warrant denying the extension of the requested relief to Affiliated Sub-Advisers. Specifically, the Adviser faces those conflicts in allocating fund assets between itself and a Sub-Adviser, and across Sub-Advisers, as it has an interest in considering the benefit it will receive, directly or indirectly, from the fee the Sub-Advised Fund pays for the management of those assets. Applicants also state that to the extent the Adviser has a conflict of interest with respect to the selection of an Affiliated Sub-Adviser, the proposed conditions are protective of shareholder interests by ensuring the Board's independence and providing the Board with the appropriate resources and information to monitor and address conflicts.

18. With respect to the relief permitting Aggregate Fee Disclosure, Applicants assert that it is appropriate to disclose only aggregate fees paid to Affiliated Sub-Advisers for the same reasons that similar relief has been granted previously with respect to Wholly-Owned and Non-Affiliated Sub-Advisers.

VI. Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. Before a Sub-Advised Fund may rely on the order requested in the application, the operation of the Sub-Advised Fund in the manner described in the application will be, or has been, approved by a majority of the Sub-Advised Fund's outstanding voting securities as defined in the Act, or, in the case of a Sub-Advised Fund whose public shareholders purchase shares on the basis of a prospectus containing the disclosure contemplated by condition 2 below, by the initial shareholder before such Sub-Advised Fund's shares are offered to the public.

2. The prospectus for each Sub-Advised Fund will disclose the

[11] *Carillon Series Trust, et al.,* Investment Co. Act Rel. Nos. 33464 (May 2, 2019) (notice) and 33494 (May 29, 2019) (order).

existence, substance and effect of any order granted pursuant to the application. In addition, each Sub-Advised Fund will hold itself out to the public as employing the multi-manager structure described in the application. The prospectus will prominently disclose that the Adviser has the ultimate responsibility, subject to oversight by the Board, to oversee the Sub-Advisers and recommend their hiring, termination, and replacement.

3. The Adviser will provide general management services to each Sub-Advised Fund, including overall supervisory responsibility for the general management and investment of the Sub-Advised Fund's assets, and subject to review and oversight of the Board, will (i) set the Sub-Advised Fund's overall investment strategies, (ii) evaluate, select, and recommend Sub-Advisers for all or a portion of the Sub-Advised Fund's assets, (iii) allocate and, when appropriate, reallocate the Sub-Advised Fund's assets among Sub-Advisers, (iv) monitor and evaluate the Sub-Advisers' performance, and (v) implement procedures reasonably designed to ensure that Sub-Advisers comply with the Sub-Advised Fund's investment objective, policies and restrictions.

4. Sub-Advised Funds will inform shareholders of the hiring of a new Sub-Adviser within 90 days after the hiring of the new Sub-Adviser pursuant to the Modified Notice and Access Procedures.

5. At all times, at least a majority of the Board will be Independent Trustees, and the selection and nomination of new or additional Independent Trustees will be placed within the discretion of the then-existing Independent Trustees.

6. Independent Legal Counsel, as defined in Rule 0–1(a)(6) under the Act, will be engaged to represent the Independent Trustees. The selection of such counsel will be within the discretion of the then-existing Independent Trustees.

7. Whenever a Sub-Adviser is hired or terminated, the Adviser will provide the Board with information showing the expected impact on the profitability of the Adviser.

8. The Board must evaluate any material conflicts that may be present in a sub-advisory arrangement. Specifically, whenever a sub-adviser change is proposed for a Sub-Advised Fund (''Sub-Adviser Change'') or the Board considers an existing Sub-Advisory Agreement as part of its annual review process (''Sub-Adviser Review''):

(a) The Adviser will provide the Board, to the extent not already being provided pursuant to Section 15(c) of the Act, with all relevant information concerning:

(i) Any material interest in the proposed new Sub-Adviser, in the case of a Sub-Adviser Change, or the Sub-Adviser in the case of a Sub-Adviser Review, held directly or indirectly by the Adviser or a parent or sister company of the Adviser, and any material impact the proposed Sub-Advisory Agreement may have on that interest;

(ii) any arrangement or understanding in which the Adviser or any parent or sister company of the Adviser is a participant that (A) may have had a material effect on the proposed Sub-Adviser Change or Sub-Adviser Review, or (B) may be materially affected by the proposed Sub-Adviser Change or Sub-Adviser Review;

(iii) any material interest in a Sub-Adviser held directly or indirectly by an officer or Trustee of the Sub-Advised Fund, or an officer or board member of the Adviser (other than through a pooled investment vehicle not controlled by such person); and

(iv) any other information that may be relevant to the Board in evaluating any potential material conflicts of interest in the proposed Sub-Adviser Change or Sub-Adviser Review.

(b) the Board, including a majority of the Independent Trustees, will make a separate finding, reflected in the Board minutes, that the Sub-Adviser Change or continuation after Sub-Adviser Review is in the best interests of the Sub-Advised Fund and its shareholders and, based on the information provided to the Board, does not involve a conflict of interest from which the Adviser, a Sub-Adviser, any officer or Trustee of the Sub-Advised Fund, or any officer or board member of the Adviser derives an inappropriate advantage.

9. Each Sub-Advised Fund will disclose in its registration statement the Aggregate Fee Disclosure.

10. In the event that the Commission adopts a rule under the Act providing substantially similar relief to that in the order requested in the application, the requested order will expire on the effective date of that rule.

11. Any new Sub-Advisory Agreement or any amendment to an existing Investment Advisory Agreement or Sub-Advisory Agreement that directly or indirectly results in an increase in the aggregate advisory fee rate payable by the Sub-Advised Fund will be submitted to the Sub-Advised Fund's shareholders for approval.

For the Commission, by the Division of Investment Management, under delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28688 Filed 12–28–20; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Rule 17f–1; SEC File No. 270–236, OMB Control No. 3235–0222

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collections of information summarized below. The Commission plans to submit these existing collections of information to the Office of Management and Budget for extension and approval.

Rule 17f–1 (17 CFR 270.17f–1) under the Investment Company Act of 1940 (the ''Act'') (15 U.S.C. 80a) is entitled: ''Custody of Securities with Members of National Securities Exchanges.'' Rule 17f–1 provides that any registered management investment company (''fund'') that wishes to place its assets in the custody of a national securities exchange member may do so only under a written contract that must be ratified initially and approved annually by a majority of the fund's board of directors. The written contract also must contain certain specified provisions. In addition, the rule requires an independent public accountant to examine the fund's assets in the custody of the exchange member at least three times during the fund's fiscal year. The rule requires the written contract and the certificate of each examination to be transmitted to the Commission. The purpose of the rule is to ensure the safekeeping of fund assets.

Commission staff estimates that each fund makes 1 response and spends an average of 3.5 hours annually in complying with the rule's requirements. Commission staff estimates that on an annual basis it takes: (i) 0.5 Hours for the board of directors [1] to review and

[1] Estimates of the number of hours are based on conversations with representatives of mutual funds

Continued

ratify the custodial contracts; and (ii) 3 hours for the fund's controller to assist the fund's independent public auditors in verifying the fund's assets. Approximately 6 funds rely on the rule annually, with a total of 6 responses.[2] Thus, the total annual hour burden for rule 17f–1 is approximately 21 hours.[3]

Funds that rely on rule 17f–1 generally use outside counsel to prepare the custodial contract for the board's review and to transmit the contract to the Commission. Commission staff estimates the cost of outside counsel to perform these tasks for a fund each year is $978.[4] Funds also must have an independent public accountant verify the fund's assets three times each year and prepare the certificate of examination. Commission staff estimates the annual cost for an independent public accountant to perform this service is $9,050.[5] Therefore, the total annual cost burden for a fund that relies on rule 17f–1 would be approximately $10,028.[6] As noted above, the staff estimates that 6 funds rely on rule 17f–1 each year, for an estimated total annualized cost burden of $60,168.[7]

The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act, and is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules. Compliance with the collections of information required by rule 17f–1 is mandatory for funds that place their assets in the custody of a national securities exchange member. Responses will not be kept confidential. 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 control number.

The Commission requests written comments on: (a) Whether the collections of information are necessary for the proper performance of the functions of the Commission, including whether the information has practical utility; (b) the accuracy of the Commission's estimate of the burdens of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, C/O Cynthia Roscoe, 100 F Street NE, Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: December 22, 2020.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2020–28768 Filed 12–28–20; 8:45 am]

BILLING CODE 8011–01–P

that comply with the rule. The actual number of hours may vary significantly depending on individual fund assets. The hour burden for rule 17f–1 does not include preparing the custody contract because that would be part of customary and usual business practice.

[2] Based on a review of Form N–17f–1 filings over the last three years the Commission staff estimates that an average of 6 funds rely on rule 17f–1 each year.

[3] This estimate is based on the following calculation: (6 Respondents × 3.5 hours = 21 hours). The annual burden for rule 17f–1 does not include time spent preparing Form N–17f–1. The burden for Form N–17f–1 is included in a separate collection of information.

[4] This estimate is based on the following calculation: (2 hours of outside counsel time × $489 = $978). The staff has estimated the average cost of outside counsel at $489 per hour, based on information received from funds and their counsel.

[5] This estimate is based on information received from fund representatives estimating the aggregate annual cost of an independent public accountant's periodic verification of assets and preparation of the certificate of examination.

[6] This estimate is based on the following calculation: ($978 + $9,050 = $10,028).

[7] This estimate is based on the following calculation: (6 funds × $10,028 = $60,168).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90766; File No. S7–22–20]

Notice of Substituted Compliance Application Submitted by the French Autorité des Marchés Financiers and the Autorité de Contrôle Prudential et de Résolution in Connection With Certain Requirements Applicable to Non-U.S. Security-Based Swap Dealers and Major Security-Based Swap Participants Subject to Regulation in the French Republic; Proposed Order

AGENCY: Securities and Exchange Commission.

ACTION: Notice of application for substituted compliance determination; proposed order.

SUMMARY: The Securities and Exchange Commission (''Commission'' or ''SEC'') is soliciting public comment on an application by the French Autorité des Marchés Financiers (''AMF'') and the Autorité de Contrôle Prudential et de Résolution (''ACPR'') requesting that, pursuant to rule 3a71–6 under the Securities Exchange Act of 1934 (''Exchange Act''), the Commission determine that registered security-based swap dealers and registered major security-based swap participants (''SBS Entities'') that are not U.S. persons and that are subject to certain regulation in the French Republic (''France'') may comply with certain requirements under the Exchange Act via compliance with corresponding requirements of France and the European Union. The Commission also is soliciting comment on a proposed Order providing for conditional substituted compliance in connection with the application.

DATES: Submit comments on or before January 25, 2021.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/proposed.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number S7–22–20 on the subject line.

Paper Comments

- Send paper comments to Vanessa A. Countryman, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number S7–22–20. 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/proposed.shtml*). Comments are also 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. All comments received will be posted without change. Persons submitting comments are cautioned that the Commission does not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Carol M. McGee, Assistant Director or Laura Compton, Senior Special Counsel at 202–551–5870, Office of Derivatives Policy, Division of Trading and Markets, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–7010.

SUPPLEMENTARY INFORMATION:

The Commission is soliciting public comment on an application by the AMF

and the ACPR (''French Authorities'') requesting that the Commission determine that SBS Entities that are not U.S. persons and that are subject to certain regulation in France may satisfy certain requirements under the Exchange Act by complying with comparable requirements in France including relevant European Union (''EU'') requirements. The Commission also is soliciting comment on a proposed Order, set forth in Attachment A, providing for conditional substituted compliance in connection with that application.

I. Background

Exchange Act rule 3a71–6 conditionally provides that non-U.S. SBS Entities may satisfy certain requirements under Exchange Act section 15F by complying with comparable regulatory requirements of a foreign jurisdiction.[1] Substituted compliance potentially is available in connection with requirements regarding business conduct and supervision, chief compliance officers, trade acknowledgment and verification, non-prudentially regulated capital and margin, recordkeeping and reporting, and portfolio reconciliation, portfolio compression and trading relationship documentation.[2]

Substituted compliance in part is predicated on the Commission determining the analogous foreign requirements are ''comparable'' to the applicable requirements under the Exchange Act, after accounting for factors such as the ''scope and objectives'' of the relevant foreign regulatory requirements, and the effectiveness of the foreign authority's supervisory and enforcement frameworks.[3] Substituted compliance further requires that the Commission and foreign financial regulatory authorities have entered into an effective supervisory and enforcement memorandum of understanding and/or other arrangement addressing cooperation and other matters related to substituted compliance.[4] Also, foreign regulatory authorities may submit a substituted compliance application only if the authorities provide ''adequate assurances'' that no law or policy would impede the ability of any entity that is directly supervised by the authorities and that may register with the Commission ''to provide prompt access to the Commission to such entity's books and records or to submit to onsite inspection or examination by the Commission.'' [5]

Commission rule 0–13 addresses procedures for filing substituted compliance applications, and provides that the Commission will publish notice when a completed application has been submitted, and that any person may submit to the Commission ''any information that relates to the Commission action requested in the application.'' [6]

II. French Authorities' Substituted Compliance Request

The French Authorities have submitted a complete substituted compliance application to the Commission.[7] Pursuant to rule 0–13, the Commission is publishing notice of the application together with a proposed Order to conditionally grant substituted compliance to certain French SBS Entities in connection with certain requirements under the Exchange Act. The Commission will consider public comments on the French Authorities' Application and the proposed Order.

The French Authorities seek substituted compliance for French market participants in connection with a number of requirements under Exchange Act section 15F:

A. Relevant Market Participants

The Commission will consider whether to make substituted compliance available to any entity that: (i) Is registered with the Commission as a security-based swap dealer or major security-based swap participant; (ii) is not a U.S. person; (iii) has been authorized by the AMF as an investment firm or by the ACPR as a credit institution after approval by the AMF of the credit institution's program of operations; and (iv) is subject to relevant French and EU financial regulatory requirements and to supervision and enforcement by the French Authorities' in connection with its security-based swap activity.

B. Relevant Section 15F Requirements

The French Authorities request that the Commission issue an order determining that—for substituted compliance purposes—applicable requirements in France are comparable with the following requirements under Exchange Act section 15F:

Risk control requirements—Requirements related to internal risk management systems, trade acknowledgment and verification, portfolio reconciliation and dispute resolution, portfolio compression and trading relationship documentation.[8]

Capital and margin requirements—Requirements related to capital and margin applicable to non-prudentially regulated security-based swap dealer and major security-based swap participants.[9]

[1] The Commission has also discussed the parameters of substituted compliance in connection with a substituted compliance request and accompanying Order regarding the Federal Republic of Germany. *See* Exchange Act Release No. 34–90378 (Nov. 9, 2020), 85 FR 72726 (Nov.13, 2020) (''German Notice and Proposed Order''); Exchange Act Release No. 34–90765 (Dec. 22, 2020), (''German Substituted Compliance Order'').

[2] *See* Exchange Act rule 3a71–6(d). Substituted compliance under rule 3a71–6 is not available in connection with certain antifraud prohibitions (Exchange Act sections 10(b) and 15F(h)(4)(A), Exchange Act rules 10b–5 and 15Fh–4(a), and Securities Act of 1933 section 17(a)), information-related provisions (15F(j)(2) and 15F(j)(4)(B)), requirements related to transactions with counterparties that are not eligible contract participants (''ECPs'') (Exchange Act section 6(l) and Securities Act section 5(e)), provisions related to segregation of customer assets (Exchange Act section 3E and Exchange Act rule 18a–4), required clearing upon counterparty election (Exchange Act section 3C(g)(5)), regulatory reporting and public dissemination (Regulation SBSR, 17 CFR 242.900 et seq.) and registration of offerings (Securities Act section 5).

[3] *See* Exchange Act rule 3a71–6(a)(2)(i).

[4] *See* Exchange Act rule 3a71–6(a)(2)(ii). The Commission and the French Authorities are in the process of negotiating a memorandum of understanding to address cooperation matters related to substituted compliance. In light of the ECB's authority with respect to certain requirements, including margin and capital, for which the French Authorities seek substituted compliance, the Commission and the ECB are also in the process of developing a memorandum of understanding or other arrangement to address cooperation matters related to substituted compliance. These MOUs or other arrangements will need to be in place before the Commission may allow Covered Entities to use substituted compliance to satisfy obligations under the Exchange Act. The Commission expects to publish any such memorandum of understanding or arrangement on its website at *www.sec.gov* under the ''Substituted Compliance'' tab, which is located on the ''Security-Based Swap Markets'' page in the Division of Trading and Markets section of the site.

[5] *See* Exchange Act rule 3a71–6(a)(3). The French Authorities have satisfied this prerequisite in the Commission's preliminary view, taking into account information and representations that French Authorities provided regarding certain French and EU requirements that are relevant to the Commission's ability to inspect, and access the books and records of, security-based swap dealers in France.

[6] *See* Commission rule 0–13(h). The Commission may take final action on a substituted compliance application no earlier than 25 days following publication of the notice in the **Federal Register**.

[7] *See* Letter from Robert Ophèle, Chairman, AMF and Denis Beau, Chairmen, ACPR to Vanessa A. Countryman, Secretary, Commission, dated December 10, 2020 (''French Authorities' Application''). The application is available on the Commission's website at *https://www.sec.gov/files/full-french-application.pdf.*

[8] *See* part IV, *infra.*

[9] *See* part V, *infra.* The French Authorities request substituted compliance in connection with capital and margin requirements that are applicable to non-prudentially regulated SBS Entities pursuant to Exchange Act section 15F(e) and Exchange Act

Continued

Internal supervision, chief compliance officer and additional section 15F(j) requirements—Requirements related to diligent supervision and chief compliance officers, as well as requirements related to conflicts of interest and information gathering under Exchange Act section 15F(j).[10]

Counterparty protection requirements—Requirements related to disclosure of material risks and characteristics and material incentives or conflicts of interest, disclosure of daily marks, fair and balanced communications, disclosure of clearing rights, ''know your counterparty'' and suitability of recommendations.[11]

Recordkeeping, reporting, notification, and securities count requirements—Requirements related to making and keeping current certain prescribed records, the preservation of records, reporting, notification, and securities counts.[12]

C. Comparability Considerations and Proposed Order

Because France is a member of the European Union, market participants in France are subject to French regulations implemented pursuant to EU directives, and to applicable EU regulations. Those include requirements related to: Organization, compliance and conduct[13]; risk-mitigation;[14] prudential matters;[15] and certain other matters relevant to the application.[16] In the view of the French Authorities, French and EU requirements taken as a whole produce regulatory outcomes that are comparable to those of the relevant requirements under the Exchange Act.[17]

In the Commission's preliminary view, requirements under the Exchange Act and French/EU requirements maintain similar approaches with respect to achieving regulatory goals in several respects, but follow differing approaches or incorporate disparate elements in certain other respects. The Commission has considered those similarities and differences when analyzing comparability and developing preliminary views, while recognizing that differences in approach do not necessarily preclude substituted compliance in light of the Commission's holistic, outcomes-oriented framework for assessing comparability.[18]

Based on the Commission's analysis of the application and review of relevant French and EU requirements, the Commission is proposing an Order, located at Attachment A, granting substituted compliance subject to specific conditions and limitations. When SBS Entities seek to rely on substituted compliance to satisfy particular requirements under the Exchange Act, non-compliance with the applicable French and EU requirements would lead to a violation of those requirements under the Exchange Act and potential enforcement action by the Commission (as opposed to automatic revocation of the substituted compliance order).

rules 18a–1 through 18a–1d, and 18a–3. The proposed Order defines the term ''prudentially regulated'' to mean an SBS Entity that has a ''prudential regulator'' as that term is defined in Exchange Act section 3(a)(74). *See* para. (g)(24) to the proposed Order.

[10] *See* part VI, *infra.*

[11] *See* part VII, *infra.* The French Authorities are not requesting substituted compliance in connection with: Eligible contract participant (''ECP'') verification requirements (Exchange Act section 15F(h)(3)(A) and Exchange Act rule 15Fh–3(a)(1)); ''special entity'' provisions (Exchange Act sections 15F(h)(4) and (5) and Exchange Act rules 15Fh–3(a)(2) and (3), 15Fh–4(b) and 15Fh–5); and political contribution provisions (Exchange Act rule 15Fh–6).

[12] *See* part VIII, *infra.*

[13] *See* EU's Markets in Financial Instruments Directive (''MiFID''), Directive 2014/65/EU, which has been implemented in France as part of article L. 511 to the French Monetary and Financial Code—Code monétaire et financier (''MFC''). These address, *inter alia,* organizational, compliance and conduct requirements applicable to nonbank ''investment firms.'' In relevant part, those requirements also apply to credit institutions that provide investment services or perform investment activities. Additional relevant requirements are: (i) Commission Delegated Regulation (EU) 2017/565 (''MiFID Org Reg''), which in part supplements MiFID with respect to organizational requirements for firms; (ii) Markets in Financial Instruments Regulation (''MiFIR''), Regulation (EU) 648/2012, which generally addressing trading venues and transparency; (iii) Commission Delegated Directive (EU) 2017/593 (''MiFID Delegated Directive''), which in part supplements MiFID with regard to safeguarding client property, and in France is implemented in relevant part by the Règlement Général de L'Autorité des Marchés Financiers (''AMF General Regulation''); and (iv) Directive (EU) 2015/849 (''MLD'') addresses requirements on the prevention of the use of the financial system for the purposes of money laundering or terrorist financing, and in France has been implemented by article L.561 to the MFC.

[14] Relevant requirements are: (i) European Market Infrastructure Regulation (''EMIR''), Regulation (EU) 648/2012, which in part imposes certain risk-mitigation requirements on counterparties in connection with uncleared OTC transactions; (ii) Delegated Regulation (EU) 149/2013 (''EMIR RTS''), which supplements EMIR with various regulatory technical standards, including standards addressing confirmations, portfolio reconciliation, portfolio compression and dispute resolution; and (iii) Delegated Regulation (EU) 2016/2251 (''EMIR Margin RTS''), which further supplements EMIR with regulatory technical standards related to risk mitigation techniques.

[15] The EU's Capital Requirements Directive IV (''CRD''), Directive 2013/36/EU has been adopted in France as part of article L.533 to the MFC, and set forth prudential requirements and certain related requirements applicable to credit institutions and certain nonbank investment firms. Certain CRD requirements regarding reporting obligations have been incorporated into French law as part of articles L. 511 and L.634 to the MFC. The Capital Requirements Regulation (''CRR''), Regulation (EU) 575/2013, further addresses prudential requirements and related recordkeeping requirements for credit institutions and certain investment firms. Commission Implementing Regulation (EU) 680/2014 (''CRR Reporting ITS'') sets forth implementing technical standard regarding supervisory reporting. Pursuant to amendments that will become effective in June 2021, the requirements of CRD and the CRR will apply to credit institutions and to certain nonbank undertakings (that carry on activities involving dealing, portfolio management, investment advice and underwriting/placing) that meet specified thresholds (*e.g.,* consolidated assets of €30 billion or more). *See generally* Investment Firms Regulation (''IFR''), Regulation (EU) 2019/2033, art. 62 (amending certain definitions in the CRR).

[16] The Market Abuse Regulation (''MAR''), Regulation (EU) 596/2014, sets forth requirements to enhance market integrity and investor protection. The Investment Recommendations Regulation adopted pursuant to MAR (''MAR Investment Recommendations Regulation''), Commission Delegated Regulation (EU) 2016/958, supplements MAR with respect to regulatory technical standards regarding investment recommendations.

[17] In support, the application incorporates and relies on a series of European Commission analyses that compare EU requirements with applicable requirements under the Exchange Act, in addition to analyses specific to French law and practices. The application particularly incorporates and builds upon European Commission analyses related to: Risk control (*see* French Authorities' Application Annex 1 category 1), books and records (*see* the French Authorities' Application Annex 1 category 2), internal supervision and compliance (*see* the French Authorities' Application Annex 1 category 3), and counterparty protection (*see* the French Authorities' Application Annex 1 category 4).

[18] In this context, the Commission recognizes that other regulatory regimes will have exclusions, exceptions and exemptions that may not align perfectly with the corresponding requirements under the Exchange Act. Where the Commission preliminarily has found that the French regime produces comparable outcomes notwithstanding those particular differences, the Commission proposes to make a positive determination on substituted compliance. Where the Commission preliminarily has found that those exclusions, exemptions and exceptions lead to outcomes that are not comparable, however, the proposal would not provide for substituted compliance.

III. Applicable Entities and General Conditions

A. Covered Entities for Which the Commission Is Proposing a Positive Conditional Substituted Compliance Determination

Under the proposed Order, substituted compliance would be available to ''Covered Entities''—a term that would limit the scope of the substituted compliance determination to SBS Entities that are subject to applicable French and EU requirements and oversight. Consistent with the parameters of substituted compliance under Exchange Act rule 3a71–6, the proposed ''Covered Entity'' definition would provide that the relevant entities must be security-based swap dealers or major security-based swap participants registered with the Commission, and that those entities cannot be U.S. persons.[19]

The proposed ''Covered Entity'' definition further would provide that the entities must be investment firms that the AMF authorize to provide investment services or perform investment activities in France or credit institutions that the ACPR authorize after approval by the AMF of the credit institution's program of operations to provide investment services or perform investment activities in France.[20] This is intended to help ensure that those entities are subject to relevant French and EU requirements and oversight.

B. General Conditions and Prerequisites

Substituted compliance under the proposed Order would be subject to a number of conditions and other prerequisites, to help ensure that the relevant French and EU requirements that form the basis for substituted compliance in practice will apply to the SBS Entity's security-based swap business and activities, and to promote the Commission's oversight over entities that avail themselves of substituted compliance.

1. ''Subject to and Complies With'' Applicability Provisions

Each relevant section of the proposed Order would be subject to the condition that the Covered Entity ''is subject to and complies with'' the applicable French and EU requirements that are needed to establish comparability. Accordingly, the proposed Order would not provide substituted compliance when an SBS Entity is excused from compliance with relevant foreign provisions, such as, for example, if relevant member French or EU requirements do not apply to the security-based swap activities of a third-country branch of a French SBS Entity.

2. Additional General Conditions

Substituted compliance under the proposed Order further would be subject to general conditions intended to help ensure the applicability of relevant French and EU requirements, and to facilitate the Commission's oversight of firms that avail themselves of substituted compliance. In particular:

- *MiFID ''investment services or activities''*—The Covered Entity's security-based swap activities must constitute ''investment services or activities'' for purposes of applicable provisions under MiFID, provisions under MFC that implement MiFID and/or other EU and French requirements adopted pursuant to those provisions, and must fall within the scope of the firm's authorization from the AMF or from the ACPR after approval by the AMF of the firm's program of operations.[21]
- *MiFID ''clients''*—The Covered Entity's counterparties (or potential counterparties) must be ''clients'' (or potential ''clients'') for purposes of applicable provisions under MiFID, provisions under MFC that implement MiFID and/or other EU and French requirements adopted pursuant to those provisions.[22]
- *MiFID ''financial instruments''*—The relevant security-based swaps must be ''financial instruments'' for purposes of applicable provisions under MiFID, provisions of MFC that implement MiFID and/or other EU and French requirements adopted pursuant to those provisions.[23]
- *CRD ''institutions''*—The Covered Entity must be an ''institution'' for purposes of applicable provisions under CRD, provisions of MFC that implement CRD, CRR and/or other EU and French requirements adopted pursuant to those provisions.[24]
- *Memoranda of Understanding*—The Commission and the AMF and ACPR must have an applicable memorandum of understanding or other arrangement addressing cooperation with respect to the Order at the time the Covered Entity makes use of substituted compliance.[25] For Covered Entities that are credit institutions, the AMF, ACPR and ECB share responsibility for supervising compliance with some of the provisions of EU and French law addressed by the proposed Order.[26] To ensure the Commission's ability to receive information about these Covered Entities that may belong to the ECB, the proposed Order would require that, at the time such a Covered Entity makes use of substituted compliance with respect to those requirements, the Commission and the ECB, and/or AMF and/or the ACPR also must have a memorandum of understanding and/or other arrangement addressing cooperation with respect to the Order as it pertains to this ECB-owned information.[27]
- *Notice of reliance on substituted compliance*—An SBS Entity relying on the substituted compliance order must provide notice of its intent to rely on the order by notifying the Commission in writing.[28]

3. European Union Cross-Border Matters

The cross-border application of MiFID, MAR and EU and Member State

[19] *See* para. (g)(1)(i) and (ii) to the proposed Order.

[20] *See* para. (g)(1)(iii) to the proposed Order.

[21] *See* para. (a)(1) to the proposed Order (relevant activities must constitute ''investment services'' or ''investment activities'' as defined in MiFID art. 4(1)(2) and MFC L. 321–1 in connection with applicable provisions). Under this condition, an SBS Entity's security-based swap activities must constitute ''investment services or activities'' only to the extent that the relevant part of the Order requires the entity to be subject to and comply with provisions of MiFID, MFC or related EU and French requirements. The security-based swap activities need not be ''investment services or activities'' when the relevant part of the Order does not require compliance with one of those provisions (*e.g.,* paragraph (e)(6) addressing substituted compliance for daily mark disclosure requirements).

[22] *See* para. (a)(2) to the proposed Order (relevant counterparties or potential counterparties must be ''clients'' or potential ''clients'' as defined in MiFID art. 4(1)(9) and as used in the relevant provision of MFC, in connection with applicable provisions).

[23] *See* para. (a)(3) to the proposed Order (relevant security-based swaps must be ''financial instruments'' as defined in MiFID art. 4(1)(15) and MFC L. 211–1 and D. 211–1A in connection with applicable provisions).

[24] *See* para. (a)(4) to the proposed Order (relevant Covered Entities must be ''institutions,'' as defined in CRD art. 3(1)(3) and CRR art. 4(1)(3), and either a credit institution or finance company, each as defined in MFC L. 511–1).

[25] *See* para. (a)(5) to the proposed Order.

[26] *See, e.g.,* para. (c)(1) to the proposed Order (substituted compliance for Exchange Act capital requirements available to Covered Entities that are subject to and comply with certain provisions of CRR, BRRD, CRD and provisions of French law that implement BRRD and/or CRD and/or other EU and French requirements adopted pursuant to those provisions); para. (c)(2) of the proposed Order (substituted compliance for Exchange Act margin requirements available to Covered Entities that are subject to and comply with certain provisions of CRR, CRD and provisions of French law that implement CRD and/or other EU and French requirements adopted pursuant to those provisions).

[27] *See* para. (a)(6) to the proposed Order. In accordance with the terms of the proposed Order, this arrangement will need to be in place at the time a Covered Entity makes use of substituted compliance by complying with any EU or French requirements for which the ECB, AMF and ACPR share supervisory responsibility.

[28] See para. (a)(7) to the proposed Order.

requirements adopted pursuant to MiFID or MAR raises special issues. For some EU requirements under MiFID (and other EU and French requirements adopted pursuant to MiFID), EU law allocates the responsibility for supervising and enforcing those requirements to authorities of the Member State in whose territory a Covered Entity provides certain services.[29] To help ensure that the prerequisites to substituted compliance with respect to supervision and enforcement are satisfied in fact, when the proposed Order requires a Covered Entity to be subject to or comply with one of those MiFID requirements (or other EU or French requirements adopted pursuant to MiFID), the AMF or the ACPR must be the authority responsible for supervision and enforcement of those requirements in relation to the particular service for which substituted compliance is used.[30] Similarly, for some of the EU requirements under MAR (and other EU requirements adopted pursuant to MAR), EU law allocates the responsibility for supervising and enforcing those requirements to authorities of potentially multiple Member States. To help ensure that the prerequisites to substituted compliance with respect to supervision and enforcement are satisfied in fact, when the proposed Order requires a Covered Entity to be subject to or comply with one of those MAR requirements (or other EU requirements adopted pursuant to MAR), the Covered Entity may use substituted compliance only if one of the authorities responsible for supervision and enforcement of those requirements is the AMF or the ACPR.[31]

IV. Substituted Compliance for Risk Control Requirements

A. The French Authorities' Request and Associated Analytic Considerations

The French Authorities' Application in part requests substituted compliance in connection with risk control requirements under the Exchange Act relating to:

- *Risk management systems*—Internal risk management system requirements pursuant to Exchange Act section 15F(j)(2) and relevant aspects of Exchange Act rule 15Fh–3(h)(2)(iii)(I). Those provisions address the obligation of registered entities to follow policies and procedures reasonably designed to help manage the risks associated with their business activities.[32]
- *Trade acknowledgment and verification*—Trade acknowledgment and verification requirements pursuant to Exchange Act section 15F(i) and Exchange Act rule 15Fi–2. Those provisions help avoid legal and operational risks by requiring definitive written records of transactions and for procedures to avoid disagreements regarding the meaning of transaction terms.[33]
- *Portfolio reconciliation and dispute reporting*—Portfolio reconciliation and dispute reporting requirements pursuant to Exchange Act section 15F(i) and Exchange Act rule 15Fi–3. Those provisions require that counterparties engage in portfolio reconciliation and resolve discrepancies in connection with uncleared security-based swaps, and promptly notify the Commission and applicable prudential regulators regarding certain valuation disputes.[34]
- *Portfolio compression*—Portfolio compression requirements pursuant to Exchange Act section 15F(i) and Exchange Act rule 15Fi–4. Those provisions require that SBS Entities have procedures addressing bilateral offset, bilateral compression and multilateral compression in connection with uncleared security-based swaps.[35]
- *Trading relationship documentation*—Trading relationship documentation requirements pursuant to Exchange Act section 15F(i) and Exchange Act rule 15Fi–5. Those provisions require that SBS Entities have procedures to execute written security-based swap trading relationship documentation with their counterparties prior to, or contemporaneously with, executing certain security-based swaps.[36]

Taken as a whole, these risk control requirements help to promote market stability by mandating that registered entities follow practices that are appropriate to manage the market, credit, counterparty, operational and legal risks associated with their security-based swap businesses. The Commission's comparability assessment accordingly focuses on whether the analogous foreign requirements—taken as a whole—produce comparable outcomes with regard to providing that registered entities follow risk mitigation and documentation practices that are appropriate to the risks associated with their security-based swap businesses.

B. Preliminary Views and Proposed Order

1. General Considerations

In the Commission's preliminary view based on the French Authorities' Application and the Commission's review of applicable provisions, relevant French and EU requirements would produce regulatory outcomes that are comparable to those associated with these risk control requirements, by subjecting French SBS Entities to risk mitigation and documentation practices that are appropriate to the risks associated with their security-based swap businesses. Substituted compliance accordingly would be conditioned on Covered Entities being subject to the French and EU provisions that in the aggregate establish a framework that produces outcomes comparable to those associated with these risk control requirements under the Exchange Act.[37]

[29] *See* MiFID art. 35(8).

[30] *See* para. (a)(8) to the proposed Order.

[31] *See* para. (a)(8) to the proposed Order.

[32] *See* Exchange Act Release No. 68071 (Oct. 18, 2012), 77 FR 70214, 70250 (Nov. 23, 2012) (proposing capital and margin requirements for security-based swap dealers and major security-based swap participants). The French Authorities' application discusses French and EU requirements that address SBS Entities' obligations related to risk management. *See* French Authorities' Application Annex 1 category 1 at 66–79.

[33] *See* Exchange Act Release No. 78011 (Jun. 8, 2016), 81 FR 39808, 39809 & 39820 (Jun. 17, 2019) (''Trade Acknowledgment and Verification Adopting Release''). The French Authorities' Application discusses French and EU requirements that address SBS Entities' obligations related to confirmations and to information to be provided to clients regarding executed orders. *See* French Authorities' Application Annex 1 category 1 at 80–102.

[34] *See* Exchange Act Release No. 87782 (Dec. 18, 2019), 85 FR 6359, 6360–61 (Feb. 4, 2020) (''Risk Mitigation Adopting Release''). The French Authorities' Application discusses French and EU requirements that address portfolio reconciliation and dispute resolution and reporting. *See* French Authorities' Application Annex 1 category 1 at 104–12.

[35] *See* Risk Mitigation Adopting Release, 85 FR at 6361. The French Authorities' Application discusses EU portfolio compression requirements. *See* French Authorities' Application Annex 1 category 1 at 113–16.

[36] *See* Risk Mitigation Adopting Release, 85 FR at 6361. The French Authorities' Application discusses French and EU requirements regarding records of rights, obligations and terms of investment firm services. *See* French Authorities' Application Annex 1 category 1 at 116–32.

[37] In connection with risk management system requirements, Covered Entities particularly must comply with: MiFID art. 16(4)–(5) and MFC L. 533–10.II (4) and (5) (addressing administrative and accounting procedures, internal control mechanisms, risk assessment procedures and information processing system safeguards); MiFID Org Reg art. 21–24 (addressing risk management and internal audit); CRD art. 74, 76 and 79–87 and MFC L. 511–41–1–B and L. 511–41–1–C, L. 511–55 through L. 511–57, L. 511–60 through L. 511–66, L. 511–89 through L. 511–97; Internal Control Order articles 106, 111, 114–15, 121–22, 130–34, 146–86, 211–12, 214–15; Prudential Supervision and Risk Assessment Order article 7 (addressing internal governance and the treatment of various categories of risk); EMIR Margin RTS art. 2 (addressing required risk management procedures for the exchange of collateral for non-centrally cleared over-the-counter derivatives contracts); CRR art.

While the Commission recognizes that there are certain differences between those French and EU requirements and the applicable risk control requirements under the Exchange Act, in the Commission's preliminary view those differences on balance would not preclude substituted compliance for these requirements, particularly as requirement-by-requirement similarity is not needed for substituted compliance.

2. Additional Conditions and Scope Issues

Substituted compliance in connection with these requirements would be subject to certain additional conditions to help ensure the comparability of outcomes:

a. Trading Relationship Documentation—MiFID ''Eligible Counterparty'' Exception Not Applicable

Under the proposed Order, substituted compliance in connection with the trading relationship documentation provisions of Exchange Act rule 15Fi–5 would be conditioned on the requirement that the non-U.S. firm not treat its counterparties as ''eligible counterparties'' for purposes of the relevant MiFID provisions needed to establish comparability.[38]

Certain of the relevant French and EU requirements that provide for this type of documentation [39] do not apply to investment firms' transactions with ''eligible counterparties.'' [40] Frameworks that completely exclude compliance in connection with a particular category of security-based swap counterparty would not promote the associated risk control purposes sufficiently to produce a comparable regulatory outcome.

The Commission is mindful that compliance with this condition may require French SBS Entities that wish to rely on substituted compliance to supplement their existing practices and incur additional time and cost burdens to follow relevant French and EU documentation requirements in connection with their security-based swap business involving ''eligible counterparties.'' On balance, however, this prerequisite to substituted compliance is necessary to promote comparability in light of the risk control purposes of the trading relationship documentation requirement, and that requirement's lack of a comparable carveout based on counterparty categories.

b. Trading Relationship Documentation—Disclosure Regarding Legal and Bankruptcy Status

Under the proposed Order, substituted compliance in connection with trading relationship documentation would not extend to disclosures regarding legal and bankruptcy status that are required by paragraph (b)(5) to rule 15Fi–5 when the counterparty is a U.S. person.[41] Documentation requirements under applicable French and EU law do not address the disclosure of information related to insolvency procedures under U.S. law.

c. Dispute Reporting—Provision of Dispute Reports Consistent With EU Law

Under the proposed Order, substituted compliance further would be conditioned on Covered Entities having to provide the Commission with reports regarding disputes between counterparties, on the same basis as the Covered Entities provide those reports to competent authorities pursuant to EU law.[42] This condition promotes comparability with the Exchange Act rule requiring reporting to the Commission regarding significant valuation disputes,[43] while leveraging EU reporting provisions to avoid the need for Covered Entities to create additional *de novo* reporting frameworks.[44]

286–88 and 293 (addressing counterparty credit risk management and risk management systems); and EMIR Margin RTS art. 2 (addressing general provisions for risk management procedures). *See* para. (b)(1) to the proposed Order. In connection with trade acknowledgement and verification requirements, firms must comply with MiFID art. 25(6) and MFC L. 533–15 (addressing reports on services), MiFID Org Reg art. 59–61 (addressing essential information regarding executed orders and portfolio management), EMIR art. 11(1)(a) (addressing required bilateral confirmations for uncleared over-the-counter derivatives) and EMIR RTS art. 12 (addressing timeliness of confirmations). *See* para. (b)(2) to the proposed Order. In connection with portfolio reconciliation and dispute reporting requirements, firms must comply with EMIR art. 11(1)(b) (addressing required portfolio reconciliation and dispute resolution for uncleared over-the-counter derivatives) and EMIR RTS art. 13 and 15 (addressing further requirements related to portfolio reconciliation and dispute resolution). *See* para. (b)(3) to the proposed Order. In connection with portfolio compression requirements, firms must comply with EMIR RTS art. 14 (also addressing portfolio protection). *See* para. (b)(4) to the proposed Order. In connection with trading relationship documentation requirements, firms must comply with: MiFID art. 25(5) and MFC L. 533–14 (addressing required records of documents regarding parties' rights and obligations and other terms on which the investment firm will provide services); MiFID Org Reg art. 24, 58, 73 and applicable parts of Annex I (addressing audit requirements, records related to appropriateness assessments, client agreements and parties' rights and obligations); and EMIR Margin RTS art. 2 (addressing general provisions for risk management procedures, including procedures providing for or specifying the terms of agreements). *See* para. (b)(5) to the proposed Order. The above EMIR requirements apply only to ''OTC derivatives contracts,'' which are defined as derivatives contracts not executed on certain ''regulated markets'' or equivalent ''third-country markets.'' *See* EMIR art. 2(7). The EMIR-related conditions accordingly will not impede substituted compliance in connection with exchange-traded or market-traded security-based swaps that do not constitute ''OTC derivatives contracts.''

[38] *See* para. (b)(5)(ii) to the proposed Order (incorporating condition that the Covered Entity cannot treat applicable counterparties as ''eligible counterparties'' for purposes of MiFID art. 30 or MFC article L. 533–14 in relation to the relevant MiFID and MFC provisions). Because trading relationship documentation is an entity-level requirement, this condition generally would disapply the ''eligible counterparty'' exception in connection with the relevant MiFID and MFC provisions for all of the entity's applicable counterparties, including non-U.S. counterparties. Rule 15Fi–5 does not apply to existing security-based swaps, or to cleared and certain security-based swaps executed anonymously on a national security exchange or a security-based swap execution facility. *See* rule 15Fi–5(a)(1).

[39] E.g., MiFID art. 25(5) (requiring that investment firms establish a record that includes documents ''that set out the rights and obligations of the parties, and the other terms on which the investment firm will provide services to the client''); MFC L.533–14; MiFID Org Reg art. 58.

[40] See MiFID art. 30(1); MFC L.533–20.

[41] Those disclosures address information regarding the status of the SBS Entity or its counterparty as an insured depository institution or financial counterparty, and regarding the possibility that in certain circumstances the SBS Entity or its counterparty may be subject to the insolvency regime set forth under Title II of the Dodd-Frank Act or the Federal Deposit Insurance Act, which may affect rights to terminate, liquidate or net security-based swaps. *See* Risk Mitigation Adopting Release, 85 FR at 6374 (discussing potential application of alternatives to the liquidation schemes established under the Securities Investor Protection Act of 1970 or the U.S. Bankruptcy Code). The absence of such disclosure would not appear to preclude a comparable regulatory outcome when the counterparty is not a U.S. person, as the insolvency-related consequences that are the subject of the disclosure would not be applicable to non-U.S. counterparties in most cases. *See* also EMIR Margin RTS (in part addressing procedures providing for or specifying the terms of agreements entered into by counterparties, including applicable governing law for non-cleared derivatives, and further providing that counterparties which enter into a netting or collateral exchange agreement must perform an independent legal review regarding enforceability).

[42] *See* para. (b)(3)(ii) to the proposed Order (requiring that the Covered Entity provide the Commission with reports regarding counterparty disputes on the same basis that it provides those reports to competent authorities pursuant to EMIR RTS art. 15(2)).

[43] In proposing the notice provision, the Commission recognized that valuation inaccuracies may lead to uncollaterialized credit exposure and the potential for loss in the event of default. *See* Exchange Act Release No. 84861 (Dec. 19, 2018), 84 FR 4614, 4621 (Feb. 15, 2019). It thus is important that the Commission be informed regarding valuation disputes affecting registered entities.

[44] The principal difference between the two sets of requirements concerns the timing of notices. Under Exchange Act rule 15Fi–3, SBS Entities must promptly report, to the Commission, valuation disputes in excess of $20 million that have been outstanding for three or five business days (depending on counterparty types). Under EMIR

Continued

V. Substituted Compliance for Capital and Margin Requirements

A. The French Authorities' Request and Associated Analytic Considerations

The French Authorities' Application in part requests substituted compliance in connection with requirements under the Exchange Act relating to:

• *Capital*—Capital requirements pursuant to Exchange Act section 15F(e) and Exchange Act rule 18a–1 *et seq.* (for non-prudentially regulated security-based swap dealers). The capital provisions for non-prudentially regulated security-based swap dealers help to ensure the registered entity maintains at all times sufficient liquid assets to promptly satisfy its liabilities, and to provide a cushion of liquid assets in excess of liabilities to covered potential market, credit, and other risks.[45] This net liquid assets test standard protects customers and counterparties and mitigates the consequences of a firm's failure by promoting the ability of the firm to absorb financial shocks and, if necessary, to self-liquidate in an orderly manner.[46] As part of the capital requirements, non-prudentially regulated security-based swap dealers also must comply with the internal risk management control requirements of Exchange Act Rule 15c3–4 with respect to certain activities.[47]

• *Margin*—Margin requirements pursuant to Exchange Act section 15F(e) and Exchange Act rule 18a–3 for non-prudentially regulated security-based swap dealers and major security-based swap participants. The margin provisions are designed to protect the registered entity from the consequences of a counterparty's default.[48]

Taken as a whole, these capital and margin requirements help to promote market stability by mandating that registered entities follow practices that are appropriate to manage the market, credit, liquidity, solvency, counterparty, and operational risks associated with their security-based swap businesses. The Commission's comparability assessment accordingly focuses on whether the analogous foreign requirements—taken as a whole—produce comparable outcomes with regard to providing that registered entities follow capital and margin requirements that are appropriate to the risks associated with their security-based swap businesses.

B. Preliminary Views and Proposed Order

In the Commission's preliminary view, based on the French Authorities' Application and the Commission's review of applicable provisions, relevant French and EU requirements would produce regulatory outcomes that are comparable to those associated with the above capital and margin requirements, by subjecting French SBS Entities to financial responsibility practices that are appropriate to the risks associated with their security-based swap businesses. Substituted compliance accordingly would be conditioned on SBS Entities being subject to the French and EU provisions that, in the aggregate, establish a framework that produces outcomes comparable to those associated with the capital and margin requirements under the Exchange Act.[49] For example, in adopting its final margin requirements for non-cleared security-based swaps, the Commission stated that it modified the proposal to more closely align the final rule with the margin rules of the Commodity Futures Trading Commission and the U.S. prudential regulators and, in doing so, with the recommendations made by the Basel Committee on Banking Supervision (''BCBS'') and the Board of the International Organizations of Securities Commissions (''IOSCO'') with respect to margin requirements for non-centrally cleared derivatives.[50]

While the Commission recognizes that there are certain differences between those French and EU requirements and the applicable risk control requirements under the Exchange Act, in the Commission's preliminary view, those differences on balance would not preclude substituted compliance for these requirements, particularly as requirement-by-requirement similarity is not needed for substituted compliance.

VI. Substituted Compliance for Internal Supervision, Chief Compliance Officers and Additional Exchange Act Section 15F(j) Requirements

A. The French Authorities' Request and Associated Analytic Considerations

The French Authorities also request substituted compliance in connection with requirements under the Exchange Act relating to:

RTS art. 15(2), firms must report at least monthly, to competent authorities, disputes between counterparties in excess of £15 million and outstanding for at least 15 business days. The Commission is mindful that the EU provision does not provide for notice as quickly as rule 15Fi–3(c), but in the Commission's preliminary view, on balance this difference would not be inconsistent with the conclusion that the two sets of risk control requirements—taken as a whole—produce comparable regulatory outcomes.

[45] *See* Exchange Act Release No. 86175 (June 21, 2019), 84 FR 42872, 43947 (August 22, 2019) (''Capital and Margin Adopting Release''). The French Authorities' Application discusses French and EU requirements that address firms' capital requirements. *See* the French Authorities' Application Annex 1 category 1 capital portion at 1–24. *See also* French Authorities' Application Annex 1 category 1 at 75–79 (generally discussing internal risk management requirements).

[46] *See* Capital and Margin Adopting Release, 84 FR at 43881. The Exchange Act rule 18a–1 capital requirement (applicable to non-prudentially regulated security-based swap dealers that are not also registered broker-dealers, other than OTC derivatives dealers) is grounded in the net liquid asset test applicable to registered-broker dealers. The net liquid asset test seeks to promote liquidity by requiring that a firm maintain sufficient liquid assets to meet all liabilities, including obligations to customers, counterparties, and other creditors, and, in the event a firm fails financially, to have adequate additional resources to wind-down its business in an orderly manner without the need for a formal proceeding. *See* Capital and Margin Adopting Release, 84 FR at 43879.

[47] *See* Exchange Act rule 18a–1(f).

[48] See Capital and Margin Adopting Release, 84 FR at 43947; *see also* id. at 43949 (''Obtaining collateral is one of the ways OTC derivatives dealers manage their credit risk exposure to OTC derivatives counterparties. Prior to the financial crisis, in certain circumstances, counterparties were able to enter into OTC derivatives transactions without having to deliver collateral. When ''trigger events'' occurred during the financial crisis, those counterparties faced significant liquidity strains when they were required to deliver collateral''). The French Authorities' Application discusses French and EU requirements that address firms' margin requirements. *See* the French Authorities' Application Annex 1 category 1 at 7–74.

[49] In connection with capital requirements, Covered Entities must comply with: The capital requirements of the CRR, including recitals 40, 43 and 87, and articles 26, 28, 50–52, 61–63, 92, 111, 113(1), 114–122, 143, 153(8), 177(2), 283, 290, 300–311, 312(2), 362–377, 382–383, 412(1), 413(1), 416(1), 427(1), 413, 429, 430, and 499; MiFid Org. Reg., article 23(1); BRRD, articles 27(1), 31(2), 31(1)(a) and (5), 32(5), 45(6) and 81(1); CRD, articles 73, 79, 86, 97, 98(1)(e), 98(6), 99, 100(1), 102(1), 104, 104(1), 105, 129, 129(1), 130, 130(1), 130(5), 131, 133, 133(1), 133(4), 141, 142, 142(2), and 142(4); MFC articles L. 511–13, L. 511–15, 511–41–1 A, 511–41–1 A(XIV), L. 511–41–1 B, L. 511–41–1 C, L. 511–41–3, L. 511–41–3.II, L. 511–41–3.III, L. 511–41–3.IV, L. 511–41–4, L. 511–41–5, L. 511–42, L. 532–6, L. 533–2–1, L. 533–2–2, L. 533–2–3, L. 612–24, R. 612–30, L. 612–32, R. 612–32, L. 612–33.I, L. 612–33.II, L. 612–40, L. 613–44, L. 613–49. L. 613–49.II, L. 613–50.I, L. 631–2–1; Decree of 3 November 2014 on internal control, articles 10, 94–197, and 211–230; Ministerial Order on the Supervisory Review and Evaluation Process, articles 6–10; Decree of 3 November 2014 relating to capital buffers, articles 2, 16, 23, 37, 38, 56–64; and EMIR Margin RTS, recital 31, articles 2, 3(b), 7, and 19(1)(d)–(e), (3) and (8). In connection with margin requirements, Covered Entities must comply with: EMIR article 11; EMIR Margin RTS; CRR articles 103, 105(3); 105(10); 111(2), 224, 285, 286, 286(7), 290, 295, 296(2)(b), 297(1), 297(3), and 298(1); MiFID Org Reg. article 23(1); CRD articles 74 and 79(b); MFC articles L. 511–41–1–B, L. 533–2–2, L. 533–29, I al. 1, and L. 511–55 al. 1; and Decree *of* 3 November 2014 on internal control, article 114.

[50] *See* Capital and Margin Adopting Release, 84 FR at 43908–43909. *See also* BCBS/IOSCO, Margin Requirements for Non-centrally Cleared Derivatives (April 2020), available at *https://www.bis.org/bcbs/publ/d499.pdf* (''BCBS/IOSCO Paper''). The EU and French margin requirements also are based on the recommendation in the BCBS/IOSCO Paper.

• *Internal supervision*—Diligent supervision is required pursuant to Exchange Act section 15F(h)(1)(B) and Exchange Act rule 15Fh–3(h), and additional conflict of interest provisions under Exchange Act section 15F(j)(5). These provisions generally require that SBS Entities establish, maintain and enforce supervisory policies and procedures that reasonably are designed to prevent violations of applicable law, and implement certain systems and procedures related to conflicts of interest.[51]

• *Chief compliance officers*—Chief compliance officer requirements are set out in Exchange Act section 15F(k) and Exchange Act rule 15Fk–1. These provisions in general require that SBS Entities designate individuals with the responsibility and authority to establish, administer and review compliance policies and procedures, to resolve conflicts of interest, and to prepare and certify an annual compliance report to the Commission.[52]

• *Additional Exchange Act section 15F(j) requirements*—Additional requirements related to information-gathering pursuant to Exchange Act section 15F(j)(4)(A), and certain antitrust prohibitions specified by Exchange Act section 15F(j)(6).[53]

Taken as a whole, these internal supervision, chief compliance officer and additional Exchange Act section 15F(j) requirements help to promote SBS Entities' use of structures, processes and responsible personnel reasonably designed to promote compliance with applicable law, to identify and cure instances of non-compliance, and to manage conflicts of interest. The comparability assessment accordingly may focus on whether the analogous foreign requirements—taken as a whole—produce comparable outcomes with regard to providing that registered entities have structures and processes reasonably designed to promote compliance with applicable law, identify and cure instances of non-compliance, and to manage conflicts of interest, in part through the designation of an individual with responsibility and authority over compliance matters.

B. Preliminary Views and Proposed Order

1. General Considerations

Based on the French Authorities' Application and the Commission's review of applicable provisions, in the Commission's preliminary view the relevant French and EU requirements would produce regulatory outcomes that are comparable to those associated with the above-described internal supervision, chief compliance officer, conflict of interest and information-related requirements by providing that French SBS Entities have structures and processes that reasonably are designed to promote compliance with applicable law and to identify and cure instances of non-compliance and manage conflicts of interest.[54] As elsewhere, this part of the proposed Order conditions substituted compliance on SBS Entities being subject to and complying with specified French and EU requirements that are necessary to establish comparability.[55]

In taking this proposed approach, the Commission recognizes that certain differences are present between those French and EU requirements and the applicable requirements under the Exchange Act. In the Commission's preliminary view, on balance, however, those differences would not preclude substituted compliance within the relevant outcomes-oriented context.

2. Additional Conditions and Scope Issues

Substituted compliance in connection with these requirements would be subject to certain additional conditions to help ensure the comparability of outcomes.

a. Application of French and EU Supervisory and Compliance Requirements to Residual U.S. Requirements and Order Conditions

Under the proposed Order, substituted compliance for the relevant internal supervision requirements would be conditioned on relevant French SBS Entities complying with applicable French and EU supervisory and compliance provisions *as if* those provisions also require SBS Entities to comply with applicable requirements under the Exchange Act and the other applicable conditions to the Order.[56]

This condition addresses the fact that, even with substituted compliance, SBS Entities still would be subject directly to a number of requirements under the Exchange Act and to the conditions to the final Order.[57] In some cases,

[51] The French Authorities' Application addresses French and EU provisions that address firms' supervisory frameworks, persons with supervisory authority, supervisory policies and procedures, general compliance and internal recordkeeping, investigation of personnel, conflicts of interest, personal trading and remuneration. *See* French Authorities' Application Annex 1 category 3 at 3–27, 29–74.

[52] The French Authorities' Application discusses French and EU requirements that address compliance officers and their responsibilities, compliance officer appointment, removal and compensation, related conflict of interest provisions, and compliance-related reports. *See* French Authorities' Application Annex 1 category 3 at 75–108.

[53] Section 15F(j)(4)(A) particularly requires firms to have systems and procedures to obtain necessary information to perform functions required under section 15F. The French Authorities' application in turn discusses French and EU provisions generally addressing information gathering and disclosure. *See* French Authorities' Application Annex 1 category 3 at 27–28. Section 15F(j)(6) prohibits firms from adopting any process or taking any action that results in any unreasonable restraint of trade, or to impose any material anticompetitive burden on trading or clearing. The French Authorities' application addresses EU antitrust requirements. *See* French Authorities' Application Annex 1 category 3 at 32.

[54] This portion of the proposed Order accordingly would extend generally to the internal supervision provisions of Exchange Act rule 15Fh–3(h), the information gathering provisions of Exchange Act section 15F(j)(4)(A), and the conflict of interest provisions of Exchange Act section 15F(j)(5). *See* para. (d)(1) to the proposed Order. This portion of the proposed Order does not extend to applicable portions of rule 15Fh–3(h) as that rule mandates supervisory policies and procedures in connection with: The risk management system provisions of Exchange Act section 15F(j)(2) (which are addressed by proposed paragraph (b)(1) to the Order in connection with internal risk management); the information-related provisions of Exchange Act sections 15F(j)(3) and (j)(4)(B) (for which substituted compliance is not available); and the antitrust provisions of Exchange Act section 15F(j)(6) (for which the Commission is not proposing to provide substituted compliance). *See* para. (d)(1)(iii) to the proposed Order.

[55] In connection with these internal supervision, chief compliance officer and conflict of interest and information gathering provisions, SBS Entities particularly must comply with: MiFID art. 16 and 23 and MFC articles L. 533–2, L. 533–10.II and III, L. 533–24 and L. 533–24–1 (addressing organizational requirements and conflicts of interest); MiFID Org Reg art. 21–37 (addressing organizational requirements, compliance, risk management, internal audit, senior management responsibility, complaints handling, remuneration policies and practices, personal transaction restrictions, outsourcing, conflicts of interest and investment research and marketing); MiFID Org Reg 72–76 and Annex IV (addressing recordkeeping, including records of orders, transactions and communications); and CRD articles 74, 76, 79–87, 88(1) and 91(1)–(2), 91(7)–(9), 92–95 and MFC articles L. 511–41–1–B and L. 511–41–1–C, L. 511–51, L. 511–52 I, L. 511.53, L. 511–55 through L. 511–69, L. 511–71 through 86, L. 511–89 through L. 511–97, L. 511–102, R. 511–16–2 and R. 511–16–3; Internal Control Order articles 106, 111, 114, 115, 121–22, 130–34, 146–86, 211–12, 214–15; and Prudential Supervision and Risk Assessment Order article 7 (addressing internal governance, recovery and resolution plans, risk management policies, and management body and remuneration policies). *See* para. (d)(3) to the proposed Order.

[56] *See* para. (d)(4) to the proposed Order.

[57] As noted, substituted compliance does not extend to antifraud prohibitions or to certain other requirements under the Exchange Act (*e.g.,* requirements related to transactions with counterparties that are not eligible contract participants (''ECP''), segregation requirements). *See* note 2, *supra.* Also, substituted compliance also does not extend to requirements under the Exchange Act that are outside of the scope of the French Authorities' request (*e.g.,* ECP verification and special entity requirements), *see* note 11, *supra,* or to requirements under the Exchange Act for which the Commission has not found comparability.

particular requirements under the Exchange Act are outside the ambit of substituted compliance.[58] In other cases, certain requirements under the Exchange Act may not have comparable French or EU requirements, or may be outside the scope of the French Authorities' request.[59] While the French and EU regulatory frameworks in general reasonably appear to promote SBS Entities' compliance with applicable French and EU laws, those requirements do not appear to promote SBS Entities' compliance with requirements under the Exchange Act that are not subject to substituted compliance, or promote SBS Entities' compliance with the applicable conditions to substituted compliance. This condition would allow SBS Entities to use their existing internal supervision and compliance frameworks to comply with the relevant Exchange Act requirements and order conditions, rather than having to establish separate special-purpose supervision and compliance frameworks.

b. Compliance Reports

Under the proposed Order, substituted compliance in connection with the compliance report requirements under Exchange Act section 15F(k)(3) and Exchange Act rule 15Fk–1(c) also would be subject to the condition that the compliance reports required pursuant to MiFID Org Reg article 22(2)(c) must: (a) Be provided to the Commission annually and in the English language, (b) include a certification under penalty of law that the report is accurate and complete, and (c) address the SBS Entity's compliance with other applicable conditions to this Order.[60]

Although certain French and EU requirements address firms' use of internal compliance reports, those provisions do not require those entities to submit compliance reports to the Commission. Under this condition, SBS Entities could leverage the compliance reports that they otherwise are required to produce, by extending those reports to address compliance with the conditions to the Order.[61]

c. Antitrust Considerations

Under the proposed Order, substituted compliance would not extend to Exchange Act section 15F(j)(6) (and related internal supervision requirements of Exchange Act rule 15Fh–3(h)(2)(iii)(I)). Allowing an alternative means of compliance would not appear to lead to outcomes comparable to that statutory prohibition.[62]

VII. Substituted Compliance for Counterparty Protection Requirements

A. The French Authorities' Request and Associated Analytic Considerations

The French Authorities further request substituted compliance in connection with provisions under the Exchange Act relating to:

• *Disclosure of material risks and characteristics and material incentives or conflicts of interest*—Exchange Act rule 15Fh–3(b) requires that SBS Entities disclose to certain counterparties to a security-based swap certain information about the material risks and characteristics of the security-based swap, as well as material incentives or conflicts of interest that the SBS Entity may have in connection with the security-based swap. These provisions address the need for security-based swap market participants to have information that is sufficient to make informed decisions regarding potential transactions involving particular counterparties and particular financial instruments.[63]

• *Daily mark disclosure*—Exchange Act rule 15Fh–3(c) requires that SBS Entities provide daily mark information to certain counterparties. These provisions address the need for market participants to have effective access to daily mark information necessary to manage their security-based swap positions.[64]

• *Fair and balanced communications*—Exchange Act rule 15Fh–3(g) requires that SBS Entities communicate with counterparties in a fair and balanced manner based on principles of fair dealing and good faith. These provisions promote complete and honest communications as part of SBS Entities' security-based swap businesses.[65]

• *Clearing rights disclosure*—Exchange Act rule 15Fh–3(d) requires that SBS Entities provide certain counterparties with information regarding clearing rights under the Exchange Act.[66]

• *''Know your counterparty''*—Exchange Act rule 15Fh–3(e) requires that SBS Entities establish, maintain and enforce written policies and procedures to obtain and retain certain information regarding a counterparty that is necessary for conducting business with that counterparty. This provision accounts for the need that SBS Entities obtain essential counterparty information necessary to promote effective compliance and risk management.[67]

[58] Substituted compliance does not extend to certain Exchange Act antifraud prohibitions and other requirements under the Exchange Act (*e.g.,* requirements related to transactions with non-ECPs, and segregation requirements). Substituted compliance also does not extend to requirements under the Exchange Act that are outside of the scope of the French Authorities' request (*e.g.,* ECP verification and special entity requirements), or to requirements under the Exchange Act for which the Commission has not found comparability.

[59] For example, the French Authorities are not requesting substituted compliance in connection with ECP verification requirements, ''special entity'' provisions and political contribution provisions. *See* note 11, *supra.*

[60] *See* para. (d)(2)(ii) to the proposed Order. MiFID Org Reg art. 22(2)(c) particularly requires that a firm's compliance function ''report to the management body, on at least an annual basis, on the implementation and effectiveness of the overall control environment for investment services and activities, on the risks that have been identified and on the complaints-handling reporting as well as remedies undertaken or to be undertaken[.]'' Under the proposed condition, those reports, as submitted to the Commission and the firm's management body, also would address SBS Entities' compliance with the other conditions to the Order (in addition to addressing those firms' compliance with applicable French and EU provisions).

[61] In practice, SBS Entities may satisfy this condition by identifying relevant Order conditions, and reporting on the implementation and effectiveness of their controls with regard to compliance with those Order conditions.

[62] *See also* German Substituted Compliance Order part IV.B, 85 FR at ____. The Commission is not taking any position regarding the applicability of the section 15F(j)(6) antitrust prohibitions in the cross-border context. Non-U.S. SBS Entities should assess the applicability of those prohibitions to their security-based swap businesses.

[63] *See* Release No. 77617 (Apr. 14, 2016), 81 FR 29960, 29983–86 (May 13, 2016) (''Business Conduct Adopting Release''). The French Authorities' Application discusses French and EU requirements that address disclosure of product information and firm information. *See* French Authorities' Application Annex 1 category 4 at 24–41.

[64] *See* Business Conduct Adopting Release, 81 FR at 29986–91. The French Authorities' Application discusses French and EU requirements that address valuation, portfolio reconciliation and trade reporting. *See* French Authorities' Application Annex 1 category 4 at 42–53.

[65] *See* Business Conduct Adopting Release, 81 FR at 30000–02. The French Authorities' Application discusses French and EU requirements that address communications standards. *See* French Authorities' Application Annex 1 category 4 at 2–24.

[66] Exchange Act section 3C(g)(5) [15 U.S.C. 78c–3(g)(5)] provides certain rights for counterparties to select the clearing agency at which a security-based swap is cleared. For all security-based swaps that an SBS Entity enters into with certain counterparties, the counterparty has the sole right to select the clearing agency at which the security-based swap is cleared. For security-based swaps that are not subject to mandatory clearing (pursuant to Exchange Act sections 3C(a) and (b)) and that an SBS Entity enters into with certain counterparties, the counterparty also may elect to require clearing of the security-based swap. Substituted compliance is not available in connection with this provision. The French Authorities' Application discusses French and EU provisions that address clearing rights. *See* French Authorities' Application Annex 1 category 4 at 76–83.

[67] *See* Business Conduct Adopting Release, 81 FR at 29993–94. The French Authorities' Application discusses French and EU suitability requirements regarding information that firms must obtain

• *Suitability*—Exchange Act rule 15Fh–3(f) requires a security-based swap dealer that recommends to certain counterparties a security-based swap or trading strategy involving a security-based swap, to undertake reasonable diligence to understand the potential risks and rewards associated with the recommendation and to have a reasonable basis to believe that the recommendation is suitable for the counterparty.[68] This provision accounts for the need to guard against security-based swap dealers making unsuitable recommendations.[69]

Taken as a whole, the counterparty protection requirements under section 15F of the Exchange Act help to ''bring professional standards of conduct to, and increase transparency in, the security-based swap market and to require registered [entities] to treat parties to these transactions fairly.'' [70] The comparability assessment accordingly may focus on whether the analogous foreign requirements—taken as a whole—produce similar outcomes with regard to promoting professional standards of conduct, increasing transparency and requiring SBS Entities to treat parties fairly.

B. Preliminary Views and Proposed Order

1. General Considerations

Based on the French Authorities' Application and the Commission's review of applicable provisions, in the Commission's preliminary view, the relevant French and EU requirements produce regulatory outcomes that are comparable to counterparty protection requirements under Exchange Act section 15F(h) related to fair and balanced communications; disclosure of material risks and characteristics; disclosure of material incentives or conflicts of interest; ''know your counterparty''; suitability; and daily mark disclosure, by subjecting French SBS Entities to obligations that promote standards of professional conduct, transparency and the fair treatment of parties.

The proposed Order accordingly would provide conditional substituted compliance in connection with those requirements.[71] The proposed Order preliminarily does not provide substituted compliance in connection with requirements related to clearing rights disclosure, however, for reasons addressed below.

In taking this proposed approach, the Commission recognizes that there are certain differences between relevant French and EU requirements, on the one hand, and the relevant communications, disclosure, ''know your counterparty'' and suitability requirements under the Exchange Act, on the other hand. On balance, however, in the Commission's preliminary view, those differences, when coupled with the conditions in the proposed Order, are not so material as to be inconsistent with substituted compliance within the requisite outcomes-oriented context. As elsewhere, the counterparty protection provisions of the proposed Order in part condition substituted compliance on SBS Entities being subject to, and complying with, specified French and EU requirements that are necessary to establish comparability.[72] Substituted compliance in connection with these counterparty protection requirements also would be subject to specific conditions and limitations necessary to promote consistency in regulatory outcomes.

2. Additional Conditions and Scope Issues

a. Daily Mark Disclosure

The proposed Order would provide substituted compliance in connection with daily mark disclosure requirements pursuant to Exchange Act rule 15Fh–3(c) to the extent that the Covered Entity participates in daily portfolio reconciliation exercises that include the relevant security-based swap pursuant to French and EU requirements.[73] The

regarding counterparties. *See* French Authorities' Application Annex 1 category 4 at 54–62.

[68] *See* Business Conduct Adopting Release, 81 FR at 29994–30000. A security-based swap dealer may satisfy its counterparty-specific suitability obligation with respect to an ''institutional counterparty,'' as defined in Exchange Act rule 15Fh–3(f)(4), if the security-based swap dealer reasonably determines that the counterparty or its agent is capable of independently evaluating relevant investment risks, the counterparty or its agent represents in writing that it is exercising independent judgment in evaluating the recommendation, and the security-based swap dealer discloses that it is acting as counterparty and is not undertaking to assess the suitability of the recommendation for the counterparty. *See* Exchange Act rules 15Fh–3(f)(2) and (3).

[69] *See* Business Conduct Adopting Release, 81 FR at 29997. The French Authorities' Application discusses French and EU suitability requirements that are more targeted for transactions with ''professional clients.'' *See* French Authorities' Application Annex 1 category 4 at 63–75.

[70] *See* Business Conduct Adopting Release, 81 FR at 30065. These transaction-level requirements generally apply only to a non-U.S. SBS Entity's activities involving U.S. counterparties (unless the transaction is arranged, negotiated or executed in the United States). In particular, for non-U.S. SBS Entities, the counterparty protection requirements under Exchange Act section 15F(h) apply only to the SBS Entity's transactions with U.S. counterparties (apart from certain transactions conducted through a foreign branch of the U.S. counterparty), or to transactions arranged, negotiated or executed in the United States. *See* Exchange Act rule 3a71–3(c) [17 CFR 240.3a71–3(c)] (exception from business conduct requirements for a security-based swap dealer's ''foreign business''); see also Exchange Act rules 3a71–3(a)(3), (8) and (9) [17 CFR 240.3a71–3(a)(3), (8) and (9)] (definitions of ''transaction conducted through a foreign branch,'' ''U.S. business'' and ''foreign business'').

[71] *See generally* para. (e) to the proposed Order.

[72] In connection with requirements related to disclosure of information regarding material risks and characteristics, Covered Entities must be subject to and comply with: MiFID art. 24(4); MFC L. 533–12.II and D. 533–15; and MiFID Org Reg art. 48–50, in each case in relation to the security-based swap for which substituted compliance is applied. *See* para. (e)(1) to the proposed Order. In connection with requirements related to disclosure of information regarding material incentives or conflicts of interest, Covered Entities must be subject to and comply with either: (i) MiFID art. 23(2)–(3); MFC L .533–10.II(3); and MiFID Org Reg art. 33–35; (ii) MiFID art. 24(9); MFC L. 533–12–4; MiFID Delegated Directive art. 11(5); and AMF General Regulation art. 314–17; or (iii) MAR art. 20(1), in each case in relation to the security-based swap for which substituted compliance is applied. *See* para. (e)(2) to the proposed Order. In connection with ''know your counterparty'' requirements, Covered Entities must be subject to and comply with: MiFID art. 16(2); MFC L. 533–10.II(2); MiFID Org Reg art. 21–22, 25–26 and applicable parts of Annex I; CRD art. 74(1) and 85(1); MFC L. 511–55 and L. 511–41–1–B; MLD art. 11 and 13; MFC L. 561–5, L. 561–5–1, L. 561–6, L. 561–10, L. 561–4–1, R. 561–5, R. 561–5–1, R. 561–5–2, R. 561–5–4, R. 561–7, R. 561–10–3, R. 561–11–1 and R. 561–12; MLD art. 8(3) and 8(4)(a) as applied to internal policies, controls and procedures regarding recordkeeping of customer due diligence activities; and MFC L. 561–4–1 as applied to vigilance measures regarding recordkeeping of customer due diligence activities, in each case in relation to the security-based swap for which substituted compliance is applied. *See* para. (e)(3) to the proposed Order. In connection with suitability requirements, Covered Entities must be subject to and comply with: MiFID art. 24(2)–(3) and 25(1)–(2); MFC L. 533–24, L. 533–24–1, L. 533–12.I, L. 533–12–6 and L. 533–13.I; and MiFID Org Reg art. 21(1)(b) and (d), 54 and 55, in each case in relation to the recommendation of a security-based swap or trading strategy involving a security-based swap for which substituted compliance is applied. *See* para. (e)(4)(i) to the proposed Order. In connection with fair and balanced communications requirements, Covered Entities must be subject to and comply with: (i) either MiFID art. 24(1), (3) and MFC L. 533–11 and L. 533–12.I or MiFID art. 30(1) and MFC L. 533–20; and (ii) MiFID art. 24(4)–(5); MFC L. 533–12.II–III and D. 533–15; MiFID Org Reg art. 46–48; MAR art. 12(1)(c) and 15; and MAR Investment Recommendations Regulation art. 5, in each case in relation to the communication for which substituted compliance is applied. *See* para. (e)(5) to the Proposed Order. In connection with daily mark disclosure requirements, Covered Entities must be required to reconcile, and in fact reconcile, the portfolio containing the security-based swap for which substituted compliance is applied, on each business day pursuant to EMIR articles 11(1)(b) and 11(2) and EMIR RTS article 13. *See* para. (e)(6) to the Proposed Order.

[73] The Commission received a comment on the German Notice and Proposed Order suggesting that a similar condition should apply only to security-based swaps with U.S. counterparties; for all other transactions subject to Exchange Act daily mark requirements, the commenter proposed that the Commission grant substituted compliance if the

Continued

French Authorities' Application takes the view that EU requirements directing certain types of derivatives counterparties to mark-to-market (or mark-to-model) uncleared transactions each day are comparable to Exchange Act requirements. In the Commission's preliminary view, however, these EU mark-to-market (or mark-to-model) requirements are not comparable to Exchange Act requirements because the EU requirements do not require disclosure to counterparties. In the alternative, the French Authorities' Application notes that certain derivatives counterparties must report to an EU trade repository updated daily valuations for each OTC derivative contract and that all counterparties have the right to access these valuations at the relevant EU trade repository. In the Commission's preliminary view, in practice, U.S. counterparties may encounter challenges when attempting to access daily marks for different security-based swaps reported to multiple EU trade repositories with which they may not otherwise have business relationships. In addition, the information may be less current, given the time necessary for reporting and for the trade repository to make the information available.[74] For these reasons, in the Commission's preliminary view, these EU reporting requirements also are not comparable to Exchange Act requirements. Finally, the French Authorities' Application describes the EU's portfolio reconciliation requirements for uncleared OTC derivative contracts, which include a requirement to exchange valuations of those contracts directly between counterparties. The required frequency of portfolio reconciliations varies depending on the types of counterparties and the size of the portfolio of OTC derivatives between them, with daily reconciliation required only for the largest portfolios. For security-based swaps to which the EU's daily portfolio reconciliation requirements apply (*i.e.,* security-based swaps of a financial counterparty or non-financial counterparty subject to the clearing obligation in EMIR, if the counterparties have 500 or more OTC derivatives contracts outstanding with each other[75]), the Commission preliminarily views these requirements as comparable to Exchange Act requirements. For all other security-based swaps in portfolios that are not required to be reconciled on each business day, the Commission preliminarily views the EU's portfolio reconciliation requirements as not comparable to Exchange Act requirements.

b. No Substituted Compliance in Connection With Clearing Rights Disclosure

The proposed Order would not provide substituted compliance in connection with clearing rights disclosure requirements pursuant to Exchange Act rule 15Fh–3(d). For those requirements, the French Authorities' Application cites certain provisions related to clearing rights in the EU that are unrelated to the clearing rights provided by Exchange Act section 3C(g)(5).[76] The section 3C(g)(5) clearing rights are not eligible for substituted compliance, and the EU provisions do not require disclosure of these section 3C(g)(5) clearing rights. In the Commission's preliminary view, substituted compliance based on EU clearing provisions would not lead to comparable disclosure of a counterparty's clearing rights under the Exchange Act.

c. Suitability

Under the proposed Order, substituted compliance in connection with the suitability provisions of Exchange Act rule 15Fh–3(f) in part would be conditioned on the requirement that the counterparty be a per se ''professional client'' as defined in MiFID and not be a ''special entity'' as defined in Exchange Act section 15F(h)(2)(C) and Exchange Act rule 15Fh–2(d).[77] Accordingly, the proposed Order would not provide substituted compliance for Exchange Act suitability requirements for a recommendation made to a counterparty that is a ''retail client'' or an elective ''professional client,'' as such terms are defined in MiFID,[78] or for a ''special entity'' as defined in the Exchange Act. In the Commission's preliminary view, absent such a condition the MiFID suitability requirement would not be expected to produce a counterparty protection outcome that is comparable with the outcome produced by the suitability requirements under the Exchange Act.[79]

VIII. Substituted Compliance for Recordkeeping, Reporting, Notification, and Securities Count Requirements

A. French Authorities' Request and Associated Analytic Considerations

The French Authorities' Application in part requests substituted compliance for requirements applicable to SBS Entities under the Exchange Act relating to:

- *Recordmaking*—Exchange Act rule 18a–5 requires prescribed records to be made and kept current.[80]

Covered Entity complies with EU mark-to-market (or mark-to-model) and reporting requirements. *See* Letter from Kyle Brandon, Managing Director, Head of Derivative Policy, SIFMA (Dec. 8, 2020) (''SIFMA Letter'') at 6. The Commission did not adopt that bifurcated approach in response to BaFin's application. See German Substituted Compliance Order. Similarly, the Commission is proposing one approach to substituted compliance for daily mark requirements in response to the French Authorities' Application. This approach would provide substituted compliance for daily mark requirements based on comparability of outcomes with respect to transactions with U.S. counterparties to the same extent as it would provide substituted compliance with respect to all other transactions.

[74] The Commission received a comment on the German Notice and Proposed Order that the same EU reporting requirements cited by the French Authorities are comparable to Exchange Act daily mark requirements. *See* SIFMA Letter at 5. The commenter stated that these access and timing challenges should not be as relevant for EU and other non-U.S. counterparties if they are already subject to EU reporting obligations and that in its experience data is available promptly from trade repositories. *See id.* The commenter's position, however, highlights that U.S. counterparties, as well as non-U.S. counterparties without existing business relationships with multiple EU trade repositories, still may encounter challenges in receiving timely marks from these trade reports. *See also* German Substituted Compliance Order.

[75] *See* EMIR RTS article 13(3)(a)(i); EMIR article 10.

[76] *See* note 66, *supra.*

[77] *See* para. (e)(4)(ii) to the proposed Order.

[78] Annex II of MiFID describes which clients are ''professional clients.'' Section I of Annex II describes the types of clients considered to be professional clients unless the client elects non-professional treatment; these clients are per se professional clients. Section II of Annex II describes the types of clients who may be treated as professional clients on request; these clients are elective professional clients. *See* MiFID Annex II.

[79] The Commission recognizes that Exchange Act rules permit security-based swap dealers, when making a recommendation to an ''institutional counterparty,'' to satisfy some elements of the suitability requirement if the security-based swap dealer reasonably determines that the counterparty or its agent is capable of independently evaluating relevant investment risks, the counterparty or its agent represents in writing that it is exercising independent judgment in evaluating recommendations, and the security-based swap dealer discloses to the counterparty that it is acting as counterparty and is not undertaking to assess the suitability of the recommendation for the counterparty. *See* Exchange Act rule 15Fh–3(f)(2). However, the institutional counterparties to whom this alternative applies are only a subset of the ''professional clients'' to whom more narrowly tailored suitability requirements apply under MiFID. The Commission notes that the institutional counterparty alternative under the Exchange Act would remain available, in accordance with its terms, for recommendations that are not eligible for, or for which a Covered Entity does not rely on, substituted compliance.

[80] The French Authorities' Application discusses French and EU requirements that address firms' record creation obligations related to matters such as transactions, counterparties and their property, personnel and business conduct. *See* the French Authorities' Application Annex 1 category 2 at 2–42.

• *Record Preservation*—Exchange Act rule 18a–6 requires preservation of records.[81]

• *Reporting*—Exchange Act rule 18a–7 requires certain reports.[82]

• *Notification*—Exchange Act rule 18a–8 requires notification of the Commission when certain financial or operational problems occur.[83]

• *Securities Count*—Exchange Act rule 18a–9 requires non-prudentially regulated SBS Entities to perform a quarterly securities count.[84]

Taken as a whole, the recordkeeping, reporting, notification, and securities count requirements that apply to SBS Entities are designed to promote the prudent operation of the firm's security-based swap activities, assist the Commission in conducting compliance examinations of those activities, and alert the Commission to potential financial or operational problems that could impact the firm and its customers. The comparability assessment accordingly may focus on whether the analogous foreign requirements—taken as a whole—produce comparable outcomes with regard to recordkeeping, reporting, notification, securities counts, and related practices that support the Commission's oversight of these registrants. A foreign jurisdiction need not have analogues to every requirement under Commission rules.[85]

For certain of the recordkeeping, reporting, and notification requirements, the comparability assessment also appropriately may consider the extent to which those requirements are linked to separate requirements in the Exchange Act that may be subject to a substituted compliance application. In particular, a number of recordkeeping requirements serve a primary purpose of promoting and/or documenting SBS Entities' compliance with associated Exchange Act requirements.[86] When substituted compliance is permitted for the associated Exchange Act requirements, substituted compliance also may be appropriate for the linked recordkeeping, reporting, and notification requirements. Conversely, when substituted compliance is not available or requested for Exchange Act requirements, substituted compliance may not be appropriate for linked recordkeeping, reporting, or notification requirements.

B. Preliminary Views and Proposed Order

1. General Considerations

Based on the French Authorities' Application and the Commission's review of applicable provisions, in the Commission's preliminary view, the relevant French and EU requirements, subject to the conditions and limitations of the proposed Order, would produce regulatory outcomes that are comparable to the outcomes associated with the recordkeeping, reporting, notification, and securities count requirements under the Exchange Act applicable to SBS Entities pursuant to Exchange Act rules 18a–5, 18a–6, 18a–7, 18a–8, and 18a–9.

In reaching this preliminary conclusion, the Commission recognizes that there are certain differences between those French and EU requirements and the applicable recordkeeping, reporting, notification, and securities count requirements under the Exchange Act. In the Commission's preliminary view, on balance, those differences generally would not be inconsistent with substituted compliance for these requirements. As noted, ''requirement-by-requirement similarity'' is not needed for substituted compliance.

As discussed below, in select areas, substituted compliance in connection with these requirements is subject to specific conditions necessary to promote consistency in regulatory outcomes, or to reflect the scope of substituted compliance that would be available in connection with associated Exchange Act rules.

2. Additional Conditions

i. Additional Conditions Applicable to Exchange Act Rule 18a–5

Under the proposed Order, substituted compliance in connection with the recordmaking requirements of Exchange Act rule 18a–5 is subject to the condition that the SBS Entity: (1) Preserves all of the data elements necessary to create the records required by Exchange Act rules 18a–5(a)(1), (2), (3), (4), and (7) (if not prudentially regulated) or Exchange Act rules 18a–5(b)(1), (2), (3), and (7) (if prudentially regulated); and (2) upon request furnishes promptly to representatives of the Commission the records required by those rules.[87] This condition is modeled on the alternative compliance mechanism in paragraph (c) of Exchange Act rule 18a–5. In effect, a firm will not be required to create a record formatted pursuant to the Commission's rules each day, but instead only when requested to do so by Commission staff. The objective is to require—on a very limited basis—the production of a record that consolidates the information required by Exchange Act rules 18a–5(a)(1), (2), (3), (4), and (7) (if not prudentially regulated) or Exchange Act rules 18a–5(b)(1), (2), (3), and (7) (if prudentially regulated) in a single record and, as applicable, in a blotter or ledger format. This will assist the Commission staff in reviewing the information on the record.

Under the proposed Order, substituted compliance in connection with the recordmaking requirements of Exchange Act rule 18a–5 is subject to the condition that the SBS Entity make and keep current the records required by Exchange Act rules 18a–5(a)(13) and (14) (if not prudentially regulated) or Exchange Act rules 18a–5(b)(9) and (10) (if prudentially regulated) if the firm is not exempt from the requirements of Exchange Act rule 18a–4.[88] These recordmaking rules require the SBS Entity to make a record of compliance with the possession or control

[81] The French Authorities' Application discusses French and EU requirements that address firms' record preservation obligations related to records that firms are required to create, as well as additional records such as records of communications. *See* the French Authorities' Application Annex 1 category 2 at 43–81.

[82] The French Authorities' Application discusses French and EU requirements that address firms' obligations to make certain reports. *See* the French Authorities' Application Annex 1 category 2 at 82–95, 98–104.

[83] The French Authorities' Application discusses French and EU requirements that address firms' obligations to make certain notifications. *See* the French Authorities' Application Annex 1 category 2 at 95–98.

[84] The French Authorities' Application discusses French and EU requirements that address firms' obligations to perform securities counts. *See* the French Authorities' Application Annex 1 category 2 at 32–38.

[85] Rule 3a71–6 sets forth additional analytic considerations in connection with substituted compliance for the Commission's recordkeeping, reporting, notification, and securities count requirements. In particular, Exchange Act rule 3a71–6(d)(6) provides that the Commission intends to consider (in addition to any conditions imposed) ''whether the foreign financial regulatory system's required records and reports, the timeframes for recording or reporting information, the accounting standards governing the records and reports, and the required format of the records and reports'' are comparable to applicable provisions under the Exchange Act, and whether the foreign provisions ''would permit the Commission to examine and inspect regulated firms' compliance with the applicable securities laws.''

[86] Recordkeeping, reporting, and notification rules that are linked to other Exchange Act rules include provisions that address: (1) Unverified security-based swap transactions (Exchange Act rules 18a–5(a)(15) and (b)(11), and 18a–6(b)(1)(i) and (b)(2)(i)); (2) compliance with business conduct requirements (Exchange Act rules 18a–5(a)(16) and (17) and (b)(12) and (13), 18a–6(b)(1)(i), (b)(1)(xii), (b)(2)(i), and 18a–6(b)(2)(vii)); (3) preservation of records relating to certain risk mitigation requirements (Exchange Act rules 18a–6(d)(4) and (5); (4) segregation requirements (Exchange Act rules 18a–5(a)(13) and (14) and (b)(9) and (10), 18a–6(b)(1)(viii)(L) and (b)(2)(v), 18a–7(c)(3) and (4), and 18a–8(g)); (5) capital requirements (Exchange Act rules 18a–5(a)(9) and (b)(1)(v), 18a–7(a)(3), and 18a–8(b); and (6) margin requirements (Exchange Act rules 18a–5(a)(12) and (b)(1)(viii)).

[87] *See* para. (f)(1)(ii) to the proposed Order.

[88] *See* para. (f)(1)(iii) to the proposed Order.

requirements of Exchange Act rule 18a–4 and a record of the reserve computation required by Exchange Act rule 18a–4, respectively. Substituted compliance is not available with respect to Exchange Act rule 18a–4. Instead, provisions of the rule address cross-border transactions and provide exemptions from its requirements depending on the nature of the transaction.[89] For example, a security-based swap dealer that is a foreign bank is subject to the possession or control and reserve account requirements of Exchange Act rule 18a–4 with respect to a security-based swap customer that is a U.S. person or, in the case of a non-U.S. person, if the security-based swap dealer holds funds or other property arising out of a transaction had by such non-U.S. person with a branch or agency in the United States of the foreign security-based swap dealer. Further, Exchange Act rule 18a–4 contains a complete exemption from its requirements if the security-based swap dealer limits its business activities and meets certain conditions.[90] SBS Entities that are not subject to the requirements of Exchange Act rule 18a–4 will not need to make the records required by Exchange Act rules 18a–5(a)(13) and (14) (if not prudentially regulated) or Exchange Act rules 18a–5(b)(9) and (10) (if prudentially regulated) under this condition in the proposed Order. However, if a firm is subject to Exchange Act rule 18a–4, it will need to make these records under this condition of the Order.

Under the proposed Order, substituted compliance in connection with the recordmaking requirements of Exchange Act rule 18a–5 is subject to the condition that the prudentially regulated SBS Entity makes and keeps current the records required by Exchange Act rule 18a–5(a)(16) (if not prudentially regulated) or Exchange Act rule 18a–5(b)(12) (if prudentially regulated).[91] This rule requires the firm to document compliance with Exchange Act rule 15Fh–6, which imposes restrictions related to political contributions to municipal entities. The French Authorities have not requested substituted compliance with respect to Exchange Act rule 15Fh–6.

Finally, under the proposed Order, substituted compliance in connection with the recordmaking requirements of Exchange Act rule 18a–5 is subject to the condition that the SBS Entity makes and keeps current records documenting compliance with requirements referenced in Exchange Act rule 18a–5(a)(17) (if not prudentially regulated) or Exchange Act rule 18a–5(b)(13) (if prudentially regulated) for which substituted compliance is not available.[92] Exchange Act rules 18a–5(a)(17) and (b)(13) require the firm to document compliance with Exchange Act rules 15Fh–1 through 15Fh–5 and Exchange Act rule 15Fk–1—which, as discussed more fully in sections VI and VII of this notice, establish certain obligations with respect to diligent supervision, compliance, and counterparty protection. Under the proposed Order, when substituted compliance is available with respect to such an obligation, substituted compliance also would be available with respect to the corresponding recordmaking requirement of Exchange Act rule 18a–5(a)(17) or (b)(13). In circumstances where substituted compliance is not permitted,[93] has not been requested,[94] or is otherwise not available under the proposed Order, direct compliance with the relevant Exchange Act obligation would be required, and so, too, would direct compliance with the corresponding recordmaking requirement of Exchange Act rule 18a–5(a)(17) (if not prudentially regulated) or Exchange Act rule 18a–5(b)(13) (if prudentially regulated).

ii. Additional Conditions Applicable to Exchange Act Rule 18a–6

Under the proposed Order, substituted compliance in connection with the record preservation requirements of Exchange Act rule 18a–6 is subject to the condition that the SBS Entity preserves the records required by Exchange Act rule 18a–6(b)(1)(viii)(L) (if not prudentially regulated) or Exchange Act rule 18a–6(b)(2)(v) (if prudentially regulated) if the firm is not exempt from the requirements of Exchange Act rule 18a–4.[95] Exchange Act rules 18a–6(b)(1)(viii)(L) and (b)(2)(v) require the preservation of detail relating to information for the possession or control requirements of Exchange Act rule 18a–4. As discussed above, substituted compliance is not available for Exchange Act rule 18a–4. Consequently, under this condition, an SBS Entity will need to preserve the records required by Exchange Act rule 18a–6(b)(1)(viii)(L) (if not prudentially regulated) or Exchange Act rule 18a–6(b)(2)(v) (if prudentially regulated), but only if the firm is not exempt from Exchange Act rule 18a–4.

Under the proposed Order, substituted compliance in connection with the record preservation requirements of Exchange Act rule 18a–6 is subject to the condition that the SBS Entity preserves records with respect to requirements referenced in Exchange Act rule 18a–6(b)(1)(xii) (if not prudentially regulated) or Exchange Act rule 18a–6(b)(2)(vii) (if prudentially regulated) for which substituted compliance is not available.[96] Under Exchange Act rules 18a–6(b)(1)(xii) and (b)(2)(vii), the firm must preserve copies of documents, communications, disclosures, and notices required pursuant to Exchange Act rules 15Fh–1 through 15Fh–6 and Exchange Act rule 15Fk–1—which establish certain obligations with respect to diligent supervision, compliance, and counterparty protection. Under the proposed Order, when substituted compliance is available with respect to such an obligation, substituted compliance also would be available with respect to the corresponding record preservation requirement of Exchange Act rule 18a–6 (b)(1)(xii) or (b)(2)(vii). In circumstances where substituted compliance is not permitted, has not been requested, or is otherwise not available under the proposed Order, direct compliance with the relevant Exchange Act obligation would be required, and so, too, would direct compliance with the corresponding record preservation requirement of Exchange Act rule 18a–6(b)(1)(xii) (if not prudentially regulated) or Exchange Act rule 18a–6(b)(2)(vii) (if prudentially regulated).

Under the proposed Order, substituted compliance in connection with the record preservation requirements of Exchange Act rule 18a–6 is subject to the condition that the security-based swap dealer or major security-based swap participant, with respect to a security-based swap transaction, preserves the information required by Exchange Act rule 18a–6(b)(1)(xi) (if not prudentially regulated) or Exchange Act rule 18a–6(b)(2)(vi) (if prudentially regulated).[97] This condition is designed to ensure that the firm preserves information if the transaction is required to be reported to a registered security-based swap data

[89] *See* 17 CFR 240.18a–4(e).

[90] *See* 17 CFR 240.18a–4(f).

[91] *See* para. (f)(1)(iv) to the proposed Order.

[92] *See* para. (f)(1)(v) to the proposed Order.

[93] *See* Exchange Act rule 3a71–6(d)(1) (specifying that substituted compliance is not available in connection with the antifraud provisions of Exchange Act rule 15Fh–4(a)).

[94] The French Authorities have not requested substituted compliance in connection with the ECP verification requirements of Exchange Act rule 15Fh–3(a)(1)) or the ''special entity'' provisions of Exchange Act rules 15Fh–3(a)(2) and (3), 15Fh–4(b) and 15Fh–5.

[95] *See* para. (f)(2)(ii) to the proposed Order.

[96] *See* para. (f)(2)(iii) to the proposed Order.

[97] *See* para. (f)(2)(iv) to the proposed Order.

repository pursuant to Regulation SBSR,[98] because the French Authorities have not requested substituted compliance with respect to Regulation SBSR.

Under the proposed Order, substituted compliance in connection with the record preservation requirements of Exchange Act rule 18a–6 is subject to the condition that the SBS Entity preserves the records required by Exchange Act rule 18a–6(b)(1)(xiii) (if not prudentially regulated) or Exchange Act rule 18a–6(b)(2)(viii) (if prudentially regulated).[99] These rules require the preservation of documents used to make a reasonable determination with respect to special entities, including information relating to the financial status, the tax status, and the investment or financing objectives of the special entity as required under Exchange Act sections 15F(h)(4)(C) and (5)(A). The French Authorities are not seeking substituted compliance with respect to these Exchange Act requirements.

iii. Additional Conditions Applicable to Exchange Act Rule 18a–7

Under the proposed Order, substituted compliance with respect to the requirement in Exchange Act rule 18a–7 to file periodic unaudited financial and operational information on the FOCUS Report Part II and Part IIC is subject to the condition that the SBS Entity file with the Commission periodic unaudited financial and operational information in the manner and format specified by the Commission by order or rule and present the financial information in accordance with generally accepted accounting principles (''GAAP'') that the firm uses to prepare general purpose publicly available or available to be issued financial statements in France.[100] Rule 18a–7 requires SBS Entities, on a monthly basis (if not prudentially regulated) or on a quarterly basis (if prudentially regulated), to file an unaudited financial and operational report known as FOCUS Report Part II (if not prudentially regulated) or Part IIC (if prudentially regulated). The Commission will use the FOCUS Report to both monitor the financial and operational condition of individual SBS Entities and to perform comparisons across SBS Entities. The FOCUS Report Parts II and IIC are standardized forms that elicit specific information through numbered line items. This facilitates cross-firm analysis and comprehensive monitoring of all SBS Entities registered with the Commission. Further, the Commission has designated the Financial Industry Regulatory Authority, Inc. (''FINRA'') to receive the FOCUS reports from SBS Entities.[101] Broker-dealers registered with the Commission currently file their FOCUS reports with FINRA through the eFOCUS system it administers. FINRA's eFOCUS system will enable broker-dealers, security-based swap dealers, and major security-based swap participants to file FOCUS reports on the same platform using the same preexisting templates, software, and procedures.

The Commission preliminarily believes that it would be appropriate to condition substituted compliance with respect to Exchange Act rule 18a–7 on the SBS Entity filing unaudited financial and operational information in a manner and format that facilitates cross-firm analysis and comprehensive monitoring of all SBS Entities registered with the Commission.[102] For example, the Commission could by order or rule require SBS Entities to file the financial and operational information with FINRA using the FOCUS Report Part II (if not prudentially regulated) or Part IIC (if prudentially regulated) but permit the information input into the form to be the same information the SBS Entity reports to the French Authorities or other European supervisors.[103]

Under the proposed Order, substituted compliance in connection with the requirement for non-prudentially regulated SBS Entities to file audited annual reports under Exchange Act rule 18a–7 is subject to four conditions. The first condition is that the SBS Entity simultaneously transmits to the principal office of the Commission or to an email address provided on the Commission's website a copy of the financial statements the Covered Entity is required to file annually with French and/or European authorities, including a report of an independent public accountant covering the financial statements.[104] Because French or EU laws would not otherwise require the financial statements and report of the independent public accountant covering the financial statements to be filed with the Commission, the purpose of this condition is to ensure the Commission receives the financial statements and report to more effectively supervise and monitor SBS Entities.

The second condition is that the SBS Entity includes with the transmission of the annual financial statements and report the contact information of an individual who can provide further information about the financial statements and reports.[105] This would assist the Commission staff in promptly contacting an individual at the SBS Entity who can respond to questions that information on the financial statements or report may raise about the SBS Entity's financial or operational condition.

The third condition is that the SBS Entity includes with the transmission the report of an independent public accountant required by Exchange Act rule 18a–7(c)(1)(i)(C) covering the annual financial statements if French or EU laws do not require the Covered Entity to engage an independent public accountant to prepare a report covering the annual financial statements.[106] The third condition further provides that the report of the independent public accountant may be prepared in accordance with generally accepted auditing standards (''GAAS'') in France or the EU that are used to perform audit and attestation services. According to the French Authorities' Application, French or EU laws only require certain investment firms (depending on their size) to have their financial statements audited, so this condition ensures that all SBS Entities subject to the requirement in rule 18a–7 to file audited

[98] *See* 17 CFR 242.900–909.

[99] *See* para. (f)(2)(iv) to the proposed Order.

[100] *See* para. (f)(3)(ii) to the proposed Order. Under this approach, SBS Entities would be permitted to present the information reported in the FOCUS Report in accordance with GAAP that the SBS Entity uses to prepare publicly available or available to be issued general purpose financial statements in its home jurisdiction instead of U.S. GAAP if other GAAP, such as International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB), is used by the SBS Entity in preparing publicly available or available to be issued general purpose financial statements in France.

[101] *See* Order Designating Financial Industry Regulatory Authority, Inc., to Receive Form X–17A–5 (FOCUS Report) from Certain Security-Based Swap Dealers and Major Security-Based Swap Participants, Exchange Release No. 34–88866 (May 14, 2020).

[102] *See* para. (f)(3)(ii) to the proposed Order.

[103] The Commission anticipates that it would be appropriate to tailor the line items required to be reported pursuant to this condition and is requesting comment on which, if any, line items in FOCUS Report Part II (if not prudentially regulated) and Part IIC (if prudentially regulated) the SBS Entity does not otherwise report or record pursuant to applicable laws or regulations. Further, the Commission is requesting comment on whether it would be appropriate as a condition to substituted compliance for SBS Entities to file a FOCUS Report Part II (if not prudentially regulated) or Part IIC (if prudentially regulated) with a limited number of the required line items filled out for two years. During this time, the Commission could further evaluate the scope of information SBS Entities should file.

[104] *See* para. (f)(3)(iii)(A) to the proposed Order.

[105] *See* para. (f)(3)(iii)(B) to the proposed Order.

[106] *See* para. (f)(3)(iii)(C) to the proposed Order.

annual reports are required to have their financial statements audited.

The fourth condition is that the SBS Entity files the reports required by Exchange Act rule 18a–7(c)(1)(i)(B) and (C) addressing the statements identified in Exchange Act rule 18a–7(c)(3) or (c)(4), as applicable, that relate to Exchange Act rule 18a–4.[107] These reports are designed to provide the Commission with information about an SBS Entity's compliance with Rule 18a–4. As discussed above, substituted compliance is not available for Exchange Act rule 18a–4 and, therefore, this condition is designed to provide the Commission with similar compliance information. Under this condition, SBS Entities will need to file a limited compliance report that includes the statements relating to Rule 18a–4 [108] or exemption report if the SBS Entity claims an exemption from Rule 18a–4. The SBS Entity also will need to file the report of an independent public accountant covering the limited compliance report or exemption report. The fourth condition further provides that the report of the independent public accountant may be prepared in accordance with GAAS in France or the EU that are used to perform audit and attestation services.

iv. Additional Conditions Applicable to Exchange Act Rule 18a–8

Under the proposed Order, substituted compliance in connection with the notification requirements of Exchange Act rule 18a–8 is subject to the condition that the SBS Entity: (1) Simultaneously transmits to the principal office of the Commission or to an email address provided on the Commission's website a copy of any notice required to be sent by the French notification laws; and (2) includes with the transmission the contact information of an individual who can provide further information about the matter that is the subject of the notice.[109] The purpose of this condition is to alert the Commission to financial or operational problems that could adversely affect the firm—the objective of Exchange Act rule 18a–8.

In addition, under the proposed Order, substituted compliance in connection with the notification requirements of Exchange Act rule 18a–8 is subject to the conditions that if the firm is not exempt from Exchange Act rule 18a–4, the SBS Entity complies with the notification requirements of Exchange Act rules 18a–8(e) and 18a–8(g) that relate to Exchange Act rule 18a–4.[110] Exchange Act rule 18a–8(e) requires notification if the firm discovers or is notified by an independent public accountant the existence of any material weakness that relates to Exchange Act rule 18a–4. Exchange Act rule 18a–8(g) requires notification if the firm fails to make in its special reserve account for the exclusive benefit of security-based swap customers a deposit, as required by Exchange Act rule 18a–4(c). As discussed above, substituted compliance is not available for Exchange Act rule 18a–4.

3. Examination and Production of Records

Every SBS Entity registered with the Commission, whether complying directly with Exchange Act requirements or relying on substituted compliance as a means of complying with the Exchange Act, is required to satisfy the inspection and production requirements imposed on such entities under the Exchange Act.[111] Covered entities may make, keep, and preserve records, subject to the conditions described above, in a manner prescribed by applicable European and French requirements. The Commission notes that as an element of its substituted compliance application, the French Authorities have provided the Commission with adequate assurances that no law or policy would impede the ability of any entity that is directly supervised by the authority and that may register with the Commission ''to provide prompt access to the Commission to such entity's books and records or to submit to onsite inspection or examination by the Commission.'' Consistent with those assurances and the requirements that apply to all registered SBS Entities under the Exchange Act, SBS Entities will need to keep books and records open to inspection by any representative of the Commission and to furnish promptly to a representative of the Commission legible, true, complete, and current copies of those records of the firm that these entities are required to preserve under Exchange Act rule 18a–6 (which would include records for which a positive substituted compliance determination is being made with respect to Exchange Act rule 18a–6 under this order), or any other records of the firm that are subject to examination or required to be made or maintained pursuant to Exchange Act section 15F that are requested by a representative of the Commission.[112]

IX. Additional Considerations Regarding Supervisory and Enforcement Effectiveness in France

A. General Considerations

As noted above, Exchange Act rule 3a71–6 provides that the Commission's assessment of the comparability of the requirements of the foreign financial regulatory system must account for ''the effectiveness of the supervisory program administered, and the enforcement authority exercised'' by the foreign financial regulatory authority. This prerequisite accounts for the understanding that substituted compliance determinations should reflect the reality of the foreign regulatory framework, in that rules that appear high-quality on paper nonetheless should not form the basis for substituted compliance if—in practice—market participants are permitted to fall short of their regulatory obligations. This prerequisite, however, also recognizes that differences among the supervisory and enforcement regimes should not be assumed to reflect flaws in one regime or another.[113]

In connection with these considerations, the French Authorities' Application includes information regarding the French supervisory and enforcement framework applicable to derivatives markets and market participants. This includes information regarding the supervisory and enforcement authority afforded to the AMF and the ACPR to promote compliance with applicable requirements, applicable supervisory and enforcement tools and capabilities, consequences of non-compliance, and the application of the AMF's and ACPR's supervisory and enforcement practices in the cross-border context. After review of this information, the Commission preliminarily believes that the framework is reasonably designed to promote compliance with the laws where substituted compliance has been requested.

B. Supervisory Framework in France

Supervision of credit institutions located in France is conducted by the AMF, the ACPR, and the ECB. Supervision of investment firms located in France is conducted by the AMF and

[107] *See* para. (f)(3)(iii)(D) to the proposed Order.

[108] The limited compliance report would not need to address Exchange Act rules 18a–1, 18a–9, or 17a–13.

[109] *See* para. (f)(4)(ii) to the proposed Order.

[110] *See* para. (f)(4)(iii) and (iv) to the proposed Order.

[111] *See* Exchange Act section 15F(f); Exchange Act rule 18a–6(g).

[112] *See* para. (f)(6) to the proposed Order.

[113] *See generally* Business Conduct Adopting Release, 81 FR at 30079.

the ACPR (together, credit institutions and investment firms are referred to as ''firms'').[114] The day-to-day supervision of the firms' security-based swap activities is conducted by the AMF; the ACPR's supervisory powers pertain to licensing matters and prudential requirements. The ACPR is the primary supervisor for margin and AML requirements. The AMF and the ACPR cooperate closely and have frequent communications regarding the supervision of firms to accomplish their respective missions. The ECB, through joint supervisory teams (''JSTs''), supervises firms for compliance with the CRD and CRR, including all capital requirements. The AMF, the ACPR, and the ECB have the ability to request records needed for supervision from firms through the supervisory process. In addition, the AMF, the ACPR, and the ECB set annual priorities and conduct thematic reviews, which are used to enhance supervision in specific regulatory areas. The results of these thematic reviews are made public to provide transparency to the industry.

The AMF uses a risk-based approach to supervision whereby investment firms are categorized within four Tiers. Tier 1 firms receive the most supervisory attention and the staff has been told that all firms that use substituted compliance will be treated as Tier 1 firms. The AMF's supervisory team maintains a constant dialogue with Tier 1 firms, including weekly calls with compliance officers and regular in-person meetings with senior operational management. The AMF assigns two portfolio managers to each firm that provides investment services.[115] One portfolio manager covers market activity and one portfolio manager covers the retail, private banking, depository activities, and marketing activities of the firm.

The AMF's supervision of a Tier 1 firm focuses in part on review and analysis of numerous types of data that is submitted by firms to the AMF or the ACPR. The portfolio manager in charge of monitoring market activity works closely with the data driven supervision (''DDS'') team, a group that analyzes the regulatory reporting data submitted by each firm to understand changes at the firm. The portfolio managers also review the annual compliance report submitted by the firms each year. The report covers numerous topics at the firm including compliance with the recordkeeping requirements, the best execution requirements, the anti-market abuse regulations, and how conflicts of interest are handled and controlled. In addition, the ACPR requires firms to file an internal control report each year, and the parts of the report that are applicable to the AMF's remit are shared with the AMF. The portfolio manager reviews these reports and compares the reports from one year to the next. Where inconsistencies are noted, the portfolio manager will compare them against other internal AMF information about the firm, as well as complaints that have been submitted and significant incidents that are reported to the AMF.

If the AMF identifies an issue at a Tier 1 firm, the AMF will follow up with the firm in a variety of ways. The AMF may schedule a follow-up meeting or request additional information. The AMF may also send the firm a letter from the General Secretary of the AMF or one of the AMF directors describing the violation of law. In addition, the AMF may ask the firm to carry out an internal or external audit on the topic, or request that the firm undertake specific corrective measures and report back with details on corrective action taken. The AMF could also start an onsite inspection of the firm. Inspections are carried out through an inspection division separate and apart from the supervisory team.

The ACPR also uses a risk-based approach to supervision, assessing the size, business model, complexity, and risk profile of the supervised entity. Supervisors are assigned based on this risk profile ranging in number from two supervisors for the least complex investment firms to up to twenty supervisors for the most significant banks. At least two supervisors for each Tier 1 firm focus on AML issues. All supervisors interact with the firm on a daily basis through phone calls and meetings, and review the annual report on internal controls, which includes information on capital and liquidity as well as the AML control framework of the firm. The ACPR also uses onsite inspectors to investigate areas of concern, conduct a general review of the firm, or validate a specific risk methodology. The ACPR allocates about a quarter of its onsite inspectors to AML inspections every year.

Where the ACPR detects issues at a firm, it will take corrective measures that its staff believe are proportional to the conduct. For example, the first step may be asking the firm, in writing, to take corrective measures, which is accompanied by enhanced monitoring and communication with the ACPR on the matter. The ACPR may also conduct on onsite inspections. When these corrective measures fail, the ACPR may open an enforcement proceeding.

Supervision of the CRD and CRR, which includes a firm's capital requirements, is conducted through the ECB's single supervisory mechanism and executed by JSTs comprising of ECB staff, ACPR staff, and staff from other countries in the EU where the significant institution has a subsidiary or branch. The ACPR assigns multiple supervisors to the JST for a significant institution headquartered in France. The head of the JST is from the ECB and generally is not from the country where the significant institution is located. As part of its day-to-day supervision, the JST analyzes the supervisory reporting, financial statements, and internal documentation of supervised entities. The JSTs hold regular and ad hoc meetings with the supervised entities at various levels of staff seniority. They conduct ongoing risk analyses of approved risk models, and analyze and assess the recovery plans of supervised entities. The various supervisory activities typically result in supervisory measures addressed to the supervised institution. Supervisory activities and decisions result in a number of routine steps such as the monitoring of compliance by the JST and, if necessary, enforcement measures and sanctions. In addition to ongoing supervision, the JST may conduct in-depth reviews on certain topics by organizing a dedicated onsite mission (*e.g.,* an inspection or an internal model investigation). The onsite inspections are carried out by an independent inspection team, which works in close cooperation with the respective JST.

For each firm, the JST conducts a Supervisory Review and Evaluation Process (''SREP''), which measures the risks for each bank. The SREP shows where a firm stands in terms of capital requirements and the way it handles risks. To develop the SREP, supervisors review the sustainability of each firm's business model, governance and risk management at the firm, capital risks, and liquidity and funding risks. Once the SREP is developed, the firm will receive a letter setting forth specific measures that must be implemented the following year based on the firm's individual profile. For example, the SREP may ask the firm to hold additional capital or set forth qualitative requirements related to the firm's governance structure or management.

C. Enforcement Authority in France

The MFC and SSM Regulations are applicable to the distribution of

[114] Starting in 2021, the ECB will also supervise significant investment firms under the framework described in this section.

[115] The staff was told that all firms applying to be a security-based swap dealer with the SEC provide investment services.

enforcement authority relating to security-based swaps in France. With respect to regulated entities, the AMF is primarily responsible for enforcement of recordkeeping and reporting requirements. ACPR is primarily responsible for the enforcement of prudential recordkeeping and reporting requirements regarding investment firms; and the ECB is primarily responsible for the enforcement of prudential recordkeeping and reporting requirements regarding credit institutions.

i. The AMF

The AMF's investigations may arise from information gathered during market supervision, monitoring of listed companies, alerts raised by the AMF's Market Surveillance Directorate or other AMF divisions, and information sent to the AMF by foreign authorities. AMF's investigative powers include, but are not limited to, obtaining hard copy and electronic documents, interviewing external experts, accessing business premises, and summoning persons likely to provide useful information for interviews.

The Enforcement Committee is the body empowered to determine sanctions in an enforcement matter. Sanctions available to the Enforcement Committee include freezing assets, banning a person from certain professional activity, imposing a monetary penalty, withdrawing the authorization of an asset management company or the status of a market operator, and requiring corrective statements to be published. The AMF also has the power to enter into settlements with respondents and as part of a settlement may require the respondent to cease all ongoing violations. Settlements may also include the payment of compensation to harmed investors. French law imposes a five year statute of limitations for AMF matters.

ii. The ECB and the ACPR

As noted above, the ACPR conducts supervisory inspections relating to prudential recordkeeping and reporting requirements for investment firms. When breaches of the requirements occur, the Supervisory Board of the ACPR is empowered to decide on the appropriate measures whether administrative, enforcement or disciplinary. These measures may include injunctions, ''mesures de police administrative'' (including warnings, formal notices, conservative measures and the appointment of a provisional administrator), and coercive fines. Additionally, the Supervisory Board may decide to introduce disciplinary proceedings for anti-money laundering and counter terrorist financing. The decision-making body in charge of the decision to sanction is a separate body, the Sanctions Committee, to which the Supervisory Board refers the case.

With respect to credit institutions, the ACPR conducts supervisory activity through JSTs, under the SSM Regulation. Where it identifies a failure to comply with obligations under applicable regulations, a JST may decide effective, proportionate and dissuasive sanctions. Misconduct detected by the JSTs is addressed primarily by the ECB. Under the SSM Regulations, the ECB is empowered to address issues of noncompliance with applicable European Union law by directly imposing enforcement measures on supervised entities or requiring the ACPR to use its national enforcement powers. It also may choose to impose administrative penalties or request that the ACPR open sanctioning proceedings. In particular, the ECB may impose administrative pecuniary penalties, and may impose fines and periodic penalty payments per day of infringement. Where appropriate, the ECB may exercise its enforcement authority in parallel with supervisory measures.

X. Request for Comment

Commenters are invited to address all aspects of the application, the Commission's preliminary views and the proposed Order.

A. General Aspects of the Comparability Assessments and Proposed Order

The Commission requests comment regarding the preliminary views and proposed Order in connection with each of the general ''regulatory outcome'' categories addressed above. Commenters particularly are invited to address, among other issues, whether the relevant French and EU provisions generally are sufficient to produce regulatory outcomes that are comparable to the outcomes associated with requirements under the Exchange Act, and whether the conditions and limitations of the proposed Order would adequately address potential gaps in the relevant regulatory outcomes.

Commenters also are invited to address any differences between French regulatory requirements and frameworks and the German requirements and frameworks that formed the basis for the Commission's grant of substituted compliance in connection with Germany.[116] Given the Commission's substituted compliance determination with respect to Germany, should the Commission allow German branches of French Covered Entities to use substituted compliance in circumstances where responsibility for ensuring compliance with any provision of MiFID, MAR or any other EU requirement adopted pursuant to MiFID or MAR listed in paragraphs (b) through (f) of this Order is allocated to the Bundesanstalt für Finanzdienstleistungsaufsicht (''BaFin''), the German financial authority? If so, should such reliance be conditioned on the MOU between the SEC and BaFin addressing substituted compliance under those circumstances? Similarly, should the Commission allow French branches of German Covered Entities to use substituted compliance in circumstances where responsibility for ensuring compliance with any provision of MiFID, MAR or any other EU requirement adopted pursuant to MiFID or MAR listed in paragraphs (b) through (e) of the German Substituted Compliance Order is allocated to the AMF and/or the ACPR? If so, should such reliance be conditioned on the MOU between the SEC and the French Authorities addressing substituted compliance under those circumstances?

B. Risk Control Requirements

The Commission further requests comment regarding the proposed grant of substituted compliance in connection with requirements under the Exchange Act related to risk management systems, trade acknowledgement and verification, portfolio reconciliation and dispute reporting, portfolio reconciliation and trading relationship documentation. Commenters particularly are invited to address the basis for substituted compliance in connection with those risk control requirements, and the proposed conditions and limitations connected to substituted compliance for those requirements.

Commenters further are invited to address any differences between French regulatory requirements and frameworks and the German requirements and frameworks that formed the basis for the Commission's conditional grant of substituted compliance in connection with Germany for those risk control requirements.[117]

C. Capital and Margin Requirements

The Commission further requests comment regarding the comparability analysis of French and EU capital requirements with Exchange Act capital

[116] *See* note 1, *supra.*

[117] *See generally* German Notice and Proposed Order, 85 FR at 72730–32.

requirements for non-prudentially regulated security-based swap dealers. Are there any conditions that should be applied to substituted compliance for these capital requirements to promote comparable regulatory outcomes? For example, given the objectives of Rule 18a–1, should the Commission consider including a condition that requires a non-prudentially regulated security-based swap dealer to maintain a minimum amount of liquid assets, such a minimum ratio of liquid assets to illiquid assets? If so, should the ratio of liquid assets to illiquid assets be 80% to 20%, 70% to 30%, 60% to 40% or some other ratio? In terms of defining liquid and illiquid assets, should the Commission consider assets that are allowable as capital under Exchange Act rule 18a–1 as liquid and assets that are not allowable as capital under that rule as illiquid?

In addition, should the Commission consider including a condition that would require non-prudentially regulated security-based swap dealers to be subject to a specific liquidity requirement, such as a requirement to maintain a pool of highly liquid assets to cover cash outflows during a 30-day period of stress?

The Commission further requests comment on whether it should consider including a condition that non-prudentially regulated security-based swap dealers must maintain equity capital equal or Tier 1 capital at least equal to the minimum fixed-dollar capital requirements under Exchange Act rule 18a–1? For example, should there be a condition that that firm maintain equity capital or Tier 1 capital of at least $20 million?

The Commission further requests comment on what specific types of non-prudentially regulated security-based swap dealers in France would be relying on a substituted compliance determination with respect to capital requirements under Exchange Act rule 18a–1. For example, what are the primary business lines engaged in by these entities and what types of assets and liabilities do they typically carry on their balance sheets? Are the balance sheets of these entities primarily composed of liquid or illiquid assets?

The Commission notes that the comparability analysis for capital for France focuses on Covered Entities that are subject to the prudential capital regime under CRR and CRD. The Commission requests comment on how the Commission should consider the effects of subsequent amendments to the capital requirements of the CRR and CRD on Covered Entities in the context of the proposed order, particularly with respect to amendments to the CRD (*e.g.,* CRD V), which would require changes to implementing French laws.

The Commission further requests comment on whether any investment firms that may be relying on the Commission's proposed substituted compliance determination would be covered under the new capital regime under the EU's IFR. If so, should these capital requirements be included in any Commission final order regarding the determination of substituted compliance with respect to the capital requirements of the Commission and the EU and France? If so, explain how they are comparable to the capital requirements for non-prudentially regulated security-based swap dealers under the Exchange Act.

The Commission further requests comment on whether there would be any non-prudentially regulated major security-based swap participants that would be seeking substituted compliance with respect to Exchange Act rule 18a–2.

The Commission further requests comment regarding the Commission's preliminary view that French and EU margin requirements are comparable to the Exchange Act margin requirements for non-prudentially regulated security-based swap dealers and major security-based swap participants. Are there any conditions that should be applied to substituted compliance for the margin requirements to promote comparable regulatory outcomes?

D. Internal Supervision, Chief Compliance Officer and Additional Exchange Act Section 15F(j) Requirements

The Commission requests comment regarding the proposed grant of substituted compliance in connection with requirements under the Exchange Act related to internal supervision and chief compliance officers, as well as additional Exchange Act section 15F(j) requirements. Commenters particularly are invited to address the basis for substituted compliance in connection with those risk control requirements, and the proposed conditions and limitations connected to substituted compliance for those requirements.

Commenters further are invited to address any differences between French regulatory requirements and frameworks and the German requirements and frameworks that formed the basis for the Commission's conditional grant of substituted compliance in connection with Germany for those internal supervision and chief compliance officers requirements, as well as additional Exchange Act section 15F(j) requirements.[118]

E. Counterparty Protection Requirements

The Commission requests comment regarding the proposed grant of substituted compliance in connection with counterparty protection requirements under the Exchange Act. Commenters particularly are invited to address the basis for substituted compliance in connection with the counterparty protection requirements, and the proposed conditions and limitations connected to substituted compliance for those requirements.

Commenters further are invited to address any differences between French regulatory requirements and frameworks and the German requirements and frameworks that formed the basis for the Commission's conditional grant of substituted compliance in connection with Germany for certain of those counterparty protection requirements. Would the responses to any of the questions about counterparty protection requirements that the Commission asked in connection with the German substituted compliance request differ if those questions applied to French regulatory requirements and frameworks?

F. Recordkeeping, Reporting, Notification, and Securities Count

The Commission requests comment regarding the proposed grant of substituted compliance in connection with requirements under the Exchange Act related to recordkeeping, reporting, notification, and securities counts, as well as additional Exchange Act section 15F(f) requirements. Commenters particularly are invited to address the basis for substituted compliance in connection with those requirements, and the proposed conditions and limitations connected to substituted compliance for those requirements. Do French and EU law taken as a whole produce regulatory outcomes that are comparable to those of Exchange Act section 15(f) and Exchange Act rules 18a–5, 18a–6, 18a–7, 18a–8, and 18a–9 thereunder?

Commenters further are invited to address any differences between French regulatory requirements and frameworks and the German requirements and frameworks that formed the basis for the Commission's conditional grant of substituted compliance in connection with Germany for recordkeeping, reporting, notification, and securities

[118] *See* generally German Notice and Proposed Order, 85 FR at 72732–34.

count requirements, as well as additional Exchange Act section 15F(f) requirements

Commenters particularly are invited to address the proposed condition with respect to Exchange Act rule 18a–5 that the SBS Entity: (a) Preserve all of the data elements necessary to create the records required by Exchange Act rules 18a–5(a)(1), (2), (3), (4), and (7) (if not prudentially regulated) or Exchange Act rules 18a–5(b)(1), (2), (3), and (7) (if prudentially regulated); and (b) upon request furnish promptly to representatives of the Commission the records required by those rules. Do the relevant French and EU laws require SBS Entities to retain the data elements necessary to create the records required by these rules? If not, please identify which data elements are not preserved pursuant to the relevant French and EU laws. Further, how burdensome would it be for an SBS Entity to format the data elements into the records required by these rules (*e.g.,* a blotter, ledger, or securities record, as applicable) if the firm was requested to do so? In what formats do SBS Entities in France produce this information to the French Authorities or other European authorities? How do those formats differ from the formats required by Exchange Act rules 18a–5(a)(1), (2), (3), (4), and (7) (if not prudentially regulated) or Exchange Act rules 18a–5(b)(1), (2), (3), and (7) (if prudentially regulated)?

Commenters also are invited to address the proposal that a positive substituted compliance determination with respect to Exchange Act rule 18a–7 would be conditioned on the SBS Entity filing financial and operational information with the Commission in the manner and format specified by the Commission by order or rule. With respect to FOCUS Report Part II, not all of the line items on the report may be as pertinent to a non-prudentially regulated SBS Entity if a positive substituted compliance determination is made with respect to capital or margin. With respect to FOCUS Report Part IIC, because the Commission does not have responsibility to administer capital and margin requirements for prudentially regulated SBS Entities, the FOCUS Report Part IIC elicits much less information than the FOCUS Report Part II or the financial reports SBS Entities file with the French Authorities and/or other European authorities. Should the Commission require SBS Entities to file the financial and operational information using the FOCUS Report Part II (if not prudentially regulated) or Part IIC (if prudentially regulated)? Are there line items on the FOCUS Report Part II or Part IIC that elicit information that is not included in the reports SBS Entities file with the French Authorities and/or other European authorities? If so, do SBS Entities record that information in their required books and records? Please identify any information that is elicited in the FOCUS Report Part II (if not prudentially regulated) or Part IIC (if prudentially regulated) that is not: (1) Included in the financial reports filed by SBS Entities with the French Authorities and/or other European authorities; or (2) recorded in the books and records required of SBS Entities. With respect to FOCUS Report Part IIC, would the answer to these questions change if references to FFIEC Form 031 were not included in the FOCUS Report Part IIC? If so, how? As a preliminary matter, as a condition of substituted compliance should SBS Entities file a limited amount of financial and operational information on the FOCUS Report Part II (if not prudentially regulated) or Part IIC (if prudentially regulated) for a period of two years to further evaluate the burden of requiring all applicable line items to be filled out? If so, which line items should be required? To the extent that SBS Entities otherwise report or record information that is responsive to the FOCUS Report Part II or Part IIC, how could the information on these reports be integrated into a database of filings the Commission or its designee will maintain for filers of the FOCUS Report Parts II and IIC (*e.g.,* the eFOCUS system) to achieve the objective of being able to perform cross-form analysis of information entered into the uniquely numbered line items on the forms?

Commenters also are invited to address the proposal that a positive substituted compliance determination with respect to the requirement to file annual audited reports pursuant to Exchange Act rule 18a–7 would be subject to four conditions. For example, comment is sought on the element of the third and fourth conditions that would permit the reports of the independent public accountant to be prepared in accordance with GAAS in France or the EU. How do those standards compare to U.S. GAAS? In addition, should the Commission include a condition in the final order that the independent public accountant must meet the Commission's independence standards for public accountants? Further, the third condition would require SBS Entities that are not required under French or EU laws to file a report of an independent public accountant covering their financial statements to file such an accountant's report. This condition is based on the fact that French or EU laws only require certain investment firms (depending on their size) to have their financial statements audited. Do the firms in France that are not subject to the requirement to file audited financial reports engage in security-based swap activities? If so, are they likely to register with the Commission as a non-prudentially regulated security-based swap dealer or major security-based swap participant?

Further, if the Commission makes a positive substituted compliance determination with respect to a substantive requirement, should the Commission make a positive substituted compliance determination with respect to the linked record making and record preservation requirement? In particular, in this circumstance, should a positive substituted compliance determination be made with respect to the recordkeeping, reporting, and notification rules that are linked to other Exchange Act rules which include provisions that address: (1) Unverified security-based swap transactions (Exchange Act rules 18a–5(a)(15) and (b)(11), and 18a–6(b)(1)(i) and (b)(2)(i)); (2) compliance with business conduct requirements (Exchange Act rules 18a–5(a)(16) and (17), and (b)(12) and (13), 18a–6(b)(1)(i), (b)(1)(xii), (b)(2)(i), and 18a–6(b)(2)(vii)); (3) preservation of records relating to certain risk mitigation requirements (Exchange Act rules 18a–6(d)(4) and (5); (4) segregation requirements (Exchange Act rules 18a–5(a)(13) and (14), and (b)(9) and (10), 18a–6(b)(1)(viii)(L) and (b)(2)(v), 18a–7(c)(3) and (4), and 18a–8(g)); (5) capital requirements (Exchange Act rules 18a–5(a)(9) and (b)(1)(v), 18a–7(a)(3), and 18a–8(b); and (6) margin requirements (Exchange Act rules 18a–5(a)(12) and (b)(1)(viii))? If so, explain why.

Finally, commenters are invited to address whether the French substituted compliance order should be conditioned on the SBS Entity furnishing to a representative of the Commission upon request an English translation of any record, report, or notification of the SBS Entity that is required to be made, preserved, filed, or subject to examination pursuant to Exchange Act section 15F or the French substituted compliance order. Should this condition be included in any substituted compliance order addressing a jurisdiction where SBS Entities' records, reports, or notifications are not required to use the English language? Should the German substituted compliance order be amended to include such a condition?

Are there any French SBS Entities that are not expected to be exempt from Exchange Act rule 18a–4? If so, should the final Order include a condition

requiring SBS Entities to file with the Commission the supporting schedules required by Exchange Act rule 18a–7(c)(2)(ii) that relate to Exchange Act rule 18a–4 (*i.e.,* Computation for Determination of Security-Based Swap Customer Reserve Requirements and Information Relating to the Possession or Control Requirements for Security-Based Swap Customers) if the SBS Entity is not exempt from Exchange Act rule 18a–4?

G. Supervisory and Enforcement Issues

The Commission further requests comment regarding how to weigh considerations regarding supervisory and enforcement effectiveness in France as part of the comparability assessments. Commenters particularly are invited to address relevant issues regarding the effectiveness of French supervision and enforcement over firms that may register with the Commission as SBS Entities, including but not limited to issues regarding:

- French supervisory and enforcement authority, supervisory inspection practices and the use of alternative supervisory tools, and enforcement tools and practices;
- French supervisory and enforcement effectiveness with respect to derivatives such as security-based swaps; and
- French supervision and enforcement in the cross-border context (*e.g.,* any differences between the oversight of firms' businesses within France and the oversight of activities and branches outside of France, including within the United States).

By the Commission.

Dated: December 22, 2020.

Vanessa A. Countryman,

Secretary.

Attachment A

It is hereby determined and ordered, pursuant to rule 3a71–6 under the Exchange Act, that a Covered Entity (as defined in paragraph (g)(1) of this Order) may satisfy the requirements under the Exchange Act that are addressed in paragraphs (b) through (f) of this Order so long as the Covered Entity is subject to and complies with relevant requirements of the French Republic and the European Union and with the conditions to this Order, as amended or superseded from time to time.

(a) General conditions.

This Order is subject to the following general conditions, in addition to the conditions specified in paragraphs (b) through (f):

(1) *Activities as ''investment services or activities.''* For each condition in paragraphs (b) through (f) of this Order that requires the application of, and the Covered Entity's compliance with, provisions of MiFID, provisions of MFC that implement MiFID and/or other EU and French requirements adopted pursuant to those provisions, the Covered Entity's relevant security-based swap activities constitute ''investment services'' or ''investment activities,'' as defined in MiFID article 4(1)(2) and in MFC L.321–1, and fall within the scope of the Covered Entity's authorization from the AMF or from the ACPR after approval by the AMF of the Covered Firm's program of operations to provide investment services and/or perform investment activities in the French Republic.

(2) *Counterparties as ''clients.''* For each condition in paragraphs (b) through (f) of this Order that requires the application of, and the Covered Entity's compliance with, provisions of MiFID, provisions of MFC that implement MiFID and/or other EU and French requirements adopted pursuant to those provisions, the relevant counterparty (or potential counterparty) to the Covered Entity is a ''client'' (or potential ''client''), as defined in MiFID article 4(1)(9) and as used in the relevant provision of MFC.

(3) *Security-based swaps as ''financial instruments.''* For each condition in paragraphs (b) through (f) of this Order that requires the application of, and the Covered Entity's compliance with, provisions of MiFID, provisions of MFC that implement MiFID and/or other EU and French requirements adopted pursuant to those provisions, the relevant security-based swap is a ''financial instrument,'' as defined in MiFID article 4(1)(15) and in MFC L.211–1 and D.211–1A.

(4) *Covered Entity as ''institution.''* For each condition in paragraph (b) through (f) of this Order that requires the application of, and the Covered Entity's compliance with, the provisions of CRD, provisions of MFC that implement CRD, CRR and/or other EU and French requirements adopted pursuant to those provisions, the Covered Entity is an ''institution,'' as defined in CRD article 3(1)(3) and CRR article 4(1)(3), and is either a credit institution or finance company, each as defined in MFC L.511–1.

(5) *Memorandum of Understanding with the French Authorities.* The Commission and the AMF and the ACPR have a supervisory and enforcement memorandum of understanding and/or other arrangement addressing cooperation with respect to this Order at the time the Covered Entity complies with the relevant requirements under the Exchange Act via compliance with one or more provisions of this Order.

(6) *Memorandum of Understanding Regarding ECB-Owned Information.* The Commission and the ECB and/or the AMF and/or the ACPR have a supervisory and enforcement memorandum of understanding and/or other arrangement addressing cooperation with respect to this Order as it pertains to information owned by the ECB at the time the Covered Entity complies with the relevant requirements under the Exchange Act via compliance with one or more provisions of this Order.

(7) *Notice to Commission.* A Covered Entity relying on this Order must provide notice of its intent to rely on this Order by notifying the Commission in writing. Such notice must be sent to an email address provided on the Commission's website. The notice must include the contact information of an individual who can provide further information about the matter that is the subject of the notice.

(8) *European Union Cross-Border Matters.* If, in relation to a particular service provided by a Covered Entity, responsibility for ensuring compliance with any provision of MiFID or any other EU or French requirement adopted pursuant to MiFID listed in paragraphs (b) through (f) of this Order is allocated to an authority of the Member State of the European Union in whose territory a Covered Entity provides the service, the AMF or the ACPR must be the authority responsible for supervision and enforcement of that provision or requirement in relation to the particular service. If responsibility for ensuring compliance with any provision of MAR or any other EU requirement adopted pursuant to MAR listed in paragraphs (b) through (f) of this Order is allocated to one or more authorities of a Member State of the European Union, one of such authorities must be the AMF or the ACPR.

(b) Substituted compliance in connection with risk control requirements.

This Order extends to the following provisions related to risk control:

(1) *Internal risk management.* The requirements of Exchange Act section 15F(j)(2) and related aspects of Exchange Act rule 15Fh–3(h)(2)(iii)(I), provided that the Covered Entity is subject to and complies with the requirements of: MiFID articles 16(4) and 16(5); MFC L. 533–10.II (4) and (5); MiFID Org Reg articles 21–24; CRD articles 74, 76 and 79–87; MFC L. 511–41–1–B and L. 511–41–1–C, L. 511–55 through L. 511–57, L. 511–60 through L.

511–66, L. 511–89 through L. 511–97; Internal Control Order articles 106, 111, 114–15, 121–22, 130–34, 146–86, 211–12, 214–15; Prudential Supervision and Risk Assessment Order article 7; CRR articles 286–88 and 293; and EMIR Margin RTS article 2.

(2) *Trade acknowledgement and verification.* The requirements of Exchange Act rule 15Fi–2, provided that the Covered Entity is subject to and complies with the requirements of MiFID article 25(6), MFC article L. 533–15, MiFID Org Reg articles 59–61, EMIR article 11(1)(a) and EMIR RTS article 12.

(3) *Portfolio reconciliation and dispute reporting.* The requirements of Exchange Act rule 15Fi–3, provided that:

(i) The Covered Entity is subject to and complies with the requirements of EMIR article 11(1)(b) and EMIR RTS article 13 and 15;

(ii) The Covered Entity provides the Commission with reports regarding disputes between counterparties on the same basis as it provides those reports to competent authorities pursuant to EMIR RTS article 15(2).

(4) *Portfolio compression.* The requirements of Exchange Act rule 15Fi–4, provided that the Covered Entity is subject to and complies with the requirements of EMIR RTS article 14.

(5) *Trading relationship documentation.* The requirements of Exchange Act rule 15Fi–5, other than paragraph (b)(5) to that rule when the counterparty is a U.S. person, provided that:

(i) The Covered Entity is subject to and complies with the requirements of MiFID article 25(5), MFC article L. 533–15, MiFID Org Reg articles 24, 58, 73 and applicable parts of Annex I, and EMIR Margin RTS article 2; and

(ii) The Covered Entity does not treat the applicable counterparty as an ''eligible counterparty'' for purposes of MiFID article 30 and MFC article L. 533–14, in relation to the MiFID and MFC provisions specified in paragraph (b)(5)(i).

(c) Substituted compliance in connection with capital and margin.

(1) *Capital.* The requirements of Exchange Act section 15F(e) and Exchange Act rules 18a–1 through 18a–1d, provided that the Covered Entity is subject to and complies with the capital requirements of the CRR, including recitals 40, 43 and 87, and articles 26, 28, 50–52, 61–63, 92, 111, 113(1), 114–122, 143, 153(8), 177(2), 283, 290, 300–311, 312(2), 362–377, 382–383, 412(1), 413(1), 416(1), 427(1), 413, 429, 430, and 499; MiFid Org. Reg., article 23(1); BRRD, articles 27(1), 31(2), 31(1)(a) and (5), 32(5), 45(6) and 81(1); CRD, articles 73, 79, 86, 97, 98(1)(e), 98(6), 99, 100(1), 102(1), 104, 104(1), 105, 129, 129(1), 130, 130(1), 130(5), 131, 133, 133(1), 133(4), 141, 142, 142(2), and 142(4); MFC articles L. 511–13, L. 511–15, 511–41–1 A, 511–41–1 A(XIV), L. 511–41–1 B, L. 511–41–1 C, L. 511–41–3, L. 511–41–3.II, L. 511–41–3.III, L. 511–41–3.IV, L. 511–41–4, L. 511–41–5, L. 511–42, L. 532–6, L. 533–2–1, L. 533–2–2, L. 533–2–3, L. 612–24, R. 612–30, L. 612–32, R. 612–32, L. 612–33.I, L. 612–33.II, L. 612–40, L. 613–44, L. 613–49. L. 613–49.II, L. 613–50.I, L. 631–2–1; Decree of 3 November 2014 on internal control, articles 10, 94–197, and 211–230; Ministerial Order on the Supervisory Review and Evaluation Process, articles 6–10; Decree of 3 November 2014 relating to capital buffers, articles 2, 16, 23, 37, 38, 56–64; and EMIR Margin RTS, recital 31, articles 2, 3(b), 7, and 19(1)(d)–(e), (3) and (8).

(2) *Margin.* The requirements of Exchange Act section 15F(e) and Exchange Act rule 18a–3, provided that the Covered Entity is subject to and complies with the requirements of: EMIR article 11; EMIR Margin RTS; CRR articles 103, 105(3); 105(10); 111(2), 224, 285, 286, 286(7), 290, 295, 296(2)(b), 297(1), 297(3), and 298(1); MiFID Org Reg. article 23(1); CRD articles 74 and 79(b); MFC articles L.511–41–1–B, L.533–2–2, L.533–29, I al. 1, and L. 511–55 al. 1; and Decree of 3 November 2014 on internal control, article 114.

(d) Substituted compliance in connection with internal supervision and compliance requirements and certain Exchange Act section 15F(j) requirements.

This Order extends to the following provisions related to internal supervision and compliance and Exchange Act section 15F(j) requirements:

(1) *Internal supervision.* The requirements of Exchange Act rule 15Fh–3(h) and Exchange Act sections 15F(j)(4)(A) and (j)(5), provided that:

(i) The Covered Entity is subject to and complies with the requirements identified in paragraph (d)(3);

(ii) The Covered Entity complies with paragraph (d)(4) to this Order; and

(iii) This paragraph (d) does not extend to the requirements of paragraph (h)(2)(iii)(I) to rule 15Fh–3 to the extent those requirements pertain to compliance with Exchange Act sections 15F(j)(2), (j)(3), (j)(4)(B) and (j)(6), or to the general and supporting provisions of paragraph (h) to rule 15Fh–3 in connection with those Exchange Act sections.

(2) *Chief compliance officers.* The requirements of Exchange Act section 15F(k) and Exchange Act rule 15Fk–1, provided that:

(i) The Covered Entity is subject to and complies with the requirements identified in paragraph (d)(3) to this Order;

(ii) All reports required pursuant to MiFID Org Reg article 22(2)(c) must also:

(A) Be provided to the Commission at least annually, and in the English language;

(B) Include a certification that, under penalty of law, the report is accurate and complete; and

(C) Address the firm's compliance with other applicable conditions to this Order in connection with requirements for which the Covered Entity is relying on this Order.

(3) *Applicable supervisory and compliance requirements.* Paragraphs (d)(1) and (d)(2) are conditioned on the Covered Entity being subject to and complying with the following requirements: MiFID articles 16 and 23; MFC articles L. 533–2, L.533–10.II and III, L. 533–24 and L. 533–24–1; MiFID Org Reg articles 21–37, 72–76 and Annex IV; CRD articles 74, 76, 79–87, 88(1), 91(1)–(2), 91(7)–(9) and 92–95; and MFC L. 511–41–1–B and L. 511–41–1–C, L. 511–51, L. 511–52.I, L. 511.53, L. 511–55 through L. 511–69, L. 511–71 through 86, L. 511–89 through L. 511–97, L. 511–102, R. 511–16–2 and R. 511–16–3; Internal Control Order articles 106, 111, 114, 115, 121–22, 130–34, 146–86, 211–12, 214–15; Prudential Supervision and Risk Assessment Order article 7.

(4) *Additional condition to paragraph (d)(1).* Paragraph (d)(1) further is conditioned on the requirement that Covered Entities comply with the provisions specified in paragraph (d)(3) as if those provisions also require compliance with:

(i) Applicable requirements under the Exchange Act; and

(ii) The other applicable conditions to this Order in connection with requirements for which the Covered Entity is relying on this Order.

(e) Substituted compliance in connection with counterparty protection requirements.

This Order extends to the following provisions related to counterparty protection:

(1) *Disclosure of information regarding material risks and characteristics.* The requirements of Exchange Act rule 15Fh–3(b) relating to disclosure of material risks and characteristics of a security-based swap, provided that the Covered Entity is subject to and complies with the requirements of MiFID article 24(4);

MFC L. 533–12.II and D. 533–15; and MiFID Org Reg articles 48–50, in each case in relation to that security-based swap.

(2) *Disclosure of information regarding material incentives or conflicts of interest.* The requirements of Exchange Act rule 15Fh–3(b) relating to disclosure of material incentives or conflicts of interest that a Covered Entity may have in connection with a security-based swap, provided that the Covered Entity, in relation to that security-based swap, is subject to and complies with the requirements of either:

(i) MiFID article 23(2)–(3); MFC L. 533–10.II(3); and MiFID Org Reg articles 33–35;

(ii) MiFID article 24(9); MFC L. 533–12–4; MiFID Delegated Directive article 11(5); and AMF General Regulation article 314–17; or

(iii) MAR article 20(1).

(3) ''*Know your counterparty.*'' The requirements of Exchange Act rule 15Fh–3(e), provided that the Covered Entity is subject to and complies with the requirements of MiFID article 16(2); MFC L 533–10.II(2); MiFID Org Reg articles 21–22, 25–26 and applicable parts of Annex I; CRD articles 74(1) and 85(1); MFC L. 511–55 and L. 511–41–1–B; MLD articles 11 and 13; MFC L. 561–5, L. 561–5–1, L. 561–6, L. 561–10, L. 561–4–1, R. 561–5, R. 561–5–1, R. 561–5–2, R. 561–5–4, R. 561–7, R. 561–10–3, R. 561–11–1 and R. 561–12; MLD articles 8(3) and 8(4)(a) as applied to internal policies, controls and procedures regarding recordkeeping of customer due diligence activities; and MFC L. 561–4–1 as applied to vigilance measures regarding recordkeeping of customer due diligence activities, in each case in relation to that security-based swap.

(4) *Suitability.* The requirements of Exchange Act rule 15Fh–3(f), provided that:

(i) The Covered Entity is subject to and complies with the requirements of MiFID articles 24(2)–(3) and 25(1)–(2); MFC L. 533–24, L. 533–24–1, L. 533–12(I), L. 533–12–6 and L. 533–13(I); and MiFID Org Reg articles 21(1)(b) and (d), 54 and 55, in each case in relation to the recommendation of a security-based swap or trading strategy involving a security-based swap that is provided by or on behalf of the Covered Entity; and

(ii) The counterparty to which the Covered Entity makes the recommendation is a ''professional client'' mentioned in MiFID Annex II section I and MFC D. 533–11 and is not a ''special entity'' as defined in Exchange Act section 15F(h)(2)(C) and Exchange Act rule 15Fh–2(d).

(5) *Fair and balanced communications.* The requirements of Exchange Act rule 15Fh–3(g), provided that the Covered Entity, in relation to the relevant communication, is subject to and complies with the requirements of:

(i) Either MiFID articles 24(1), (3) and MFC L. 533–11 and L. 533–12.I or MiFID article 30(1) and MFC L. 533–20; and

(ii) MiFID articles 24(4)–(5); MFC L. 533–12(II)–(III) and D. 533–15; MiFID Org Reg articles 46–48; MAR articles 12(1)(c) and 15; and MAR Investment Recommendations Regulation article 5.

(6) *Daily mark disclosure.* The requirements of Exchange Act rule 15Fh–3(c), provided that the Covered Entity is required to reconcile, and does reconcile, the portfolio containing the relevant security-based swap on each business day pursuant to EMIR articles 11(1)(b) and 11(2) and EMIR RTS article 13.

(f) Substituted compliance in connection with recordkeeping, reporting, notification, and securities count requirements.

This Order extends to the following provisions related to Commission requirements to:

(1) *Make and keep current certain records.* The requirements to make and keep current records of Exchange Act rule 18a–5 applicable to security-based swap dealers and major security-based swap participants; provided that:

(i) The Covered Entity is subject to and complies with the following requirements: CRR articles 103 and 105; EMIR articles 9(2), 11(1), and 39(4)–(5); EMIR RTS 148/2013; MiFID articles 9(1), 16(3), 16(6)–16(9), 25(1), 25(2), 25(5), and 25(6); MiFID Delegated Directive articles 2 and 8; MiFID Org Reg. articles 16(7), 21(1)(a), 35, 59, 72, 73, 74, 75, 76, Annex I, and Annex IV; MiFIR article 25; MLD4 articles 11 and 13; EBA/ESMA Guidelines on Management Suitability guidelines 74, 75, and 172, and Annex III; CRD articles 73, 88, 91(1), and 91(8); MFC articles L. 511–41–1–B, L. 511–51 through L. 511–103, L. 533–2–2, L. 533–10 II and III, L. 533–13, L. 533–14, L. 533–15, L. 533–25, L. 561–4–1, L. 561–5, L. 561–5–1, L. 561–6, R. 561–5, R. 561–5–1, R. 561–5–2, R. 561–5–3, R. 561–7, R. 561–10 II, R. 561–10–3, R. 561–11–1, R. 561–12, R. 561–15, R. 561–16, R. 561–18, R. 561–19; Internal Control Order; Decree of 6 September 2017 articles 3 and 10; Ministerial Order on the Supervisory Review and Evaluation Process; and AMF General Regulation article 312–6;

(ii)(A) The Covered Entity preserves all of the data elements necessary to create the records required by Exchange Act rules 18a–5(a)(1), (2), (3), (4), and (7) (if not prudentially regulated) or Exchange Act rules 18a–5(b)(1), (2), (3), and (7) (if prudentially regulated); and

(B) The Covered Entity upon request furnishes promptly to representatives of the Commission the records required by those rules;

(iii) The Covered Entity makes and keeps current the records required by Exchange Act rules 18a–5(a)(13) and (14) (if not prudentially regulated) or Exchange Act rules 18a–5(b)(9) and (10) (if prudentially regulated) if the Covered Entity is not exempt from the requirements of Exchange Act rule 18a–4;

(iv) The Covered Entity makes and keeps current the records required by Exchange Act rule 18a–5(a)(16) (if not prudentially regulated) or Exchange Act rule 18a–5(b)(12) (if prudentially regulated); and

(v) Except with respect to requirements of Exchange Act rules 15Fh–3 and 15Fk–1 to which this Order extends pursuant paragraphs (d)(2) and (e), the Covered Entity makes and keeps current the records required by Exchange Act rule 18a–5(a)(17) (if not prudentially regulated) or Exchange Act rule 18a–5(b)(13) (if prudentially regulated).

(2) *Preserve records.* The record preservation requirements of Exchange Act rule 18a–6 applicable to security-based swap dealers and major security-based swap participants; provided that:

(i) The Covered Entity is subject to and complies with the following requirements: CRD articles 73, 75–88, 91(1), and 91(8); CRR articles 99, 104(1)(j), 176, 286, 293(1)(d), 294, 394, 415–428, and 430; CRR Reporting ITS article 14 and Annexes I–V, VIII–XIII; EMIR articles 9(1), 9(2), and 11; MiFID articles 9(1), 16(2), 16(3), 16(5), 16(6) 24(9), 25(5), 25(6), and 69(2); MiFID Org Reg. articles 21(1)(a), 21(2), 22(3)(c), 23, 24, 25(2), 26, 29(2)(c), 31(1), 35, 58, 59, 72(1), 72(3), 73, and 76; MiFIR articles 16(2), 16(5), 16(6), 16(7), 25(1), 25(5), 31(1) and 72; MLD4 articles 11 and 13; EMIR RTS; EBA/ESMA Guidelines on Management Suitability guidelines 74, 75, and 172, and Annex III; EBA/GL/2016/10 on ICAAP/ILAAP; EBA Guidelines on Outsourcing section 13.3; MiFID Delegated Directive article 11; MFC articles L. 321–8–4, L. 511–41–1–B, L. 511–51 through L. 511–88, L. 533–2, L. 533–10, L. 533–14, L. 533–15, L. 561–4–1, L. 561–5, L. 561–5–1, L. 561–6, L. 621–8–4, L. 621–9, L. 621–10, R. 561–5, R. 561–5–1, R. 561–5–2, R. 561–5–3, R. 561–7, R. 561–10 II, R. 561–10–3, R. 561–11–1, R. 561–12, R. 561–15, R. 561–16, R. 561–18, R. 561–19; AMF General Regulation articles 314–16 and

314–17; Internal Control Order article 258; Ministerial Order on the Supervisory Review and Evaluation Process; and ACPR Instruction no. 2017–I–24, as amended or superseded from time to time;

(ii) The Covered Entity preserves the records required by Exchange Act rule 18a–6(b)(1)(viii)(L) (if not prudentially regulated) or Exchange Act rule 18a–6(b)(2)(v) (if prudentially regulated) if the Covered Entity is not exempt from the requirements of Exchange Act rule 18a–4;

(iii) Except with respect to requirements of Exchange Act rules 15Fh–3 and 15Fk–1 to which this Order extends pursuant to paragraphs (d)(2) and (e), the Covered Entity preserves the records required by Exchange Act rule 18a–6(b)(1)(xii) (if not prudentially regulated) or Exchange Act rule 18a–6(b)(2)(vii) (if prudentially regulated); and

(iv) The Covered Entity preserves the records required by Exchange Act rule 18a–6(b)(1)(xi) and (b)(1)(xiii) (if not prudentially regulated) or Exchange Act rule 18a–6(b)(2)(vi) and (b)(2)(viii) (if prudentially regulated).

(3) *File Reports.* The reporting requirements of Exchange Act rule 18a–7 applicable to security-based swap dealers and major security-based swap participants; provided that:

(i) The Covered Entity is subject to and complies with the following requirements: CRR articles 26(2), 99, 104(1)(j), 132(5), 154, 191, 321, 325bi, 350, 353, 368, 394, 415–428, 430, and 431–455; CRR Reporting ITS chapter 2 and Annexes I–V and VII–XIII; CRD article 89; MiFID article 16(8)–(10); MiFID Delegated Directive articles 2, 8, 72(2), Annex I; Commission Delegated Regulation (EU) 2017/1443, as amended or superseded from time to time; MFC articles L. 511–45 and L. 533–10; Accounting Directive article 34; Decree of 6 September 2017 articles 3 and 10; French Commerce Code articles L. 232–1, R. 232–1 through R. 232–8, and L. 823–1 through L. 823–8–1; and AMF General Regulation articles 312–6 and 312–7;

(ii) The Covered Entity files periodic unaudited financial and operational information with the Commission or its designee in the manner and format required by Commission rule or order and presents the financial information in the filing in accordance with generally accepted accounting principles that the Covered Entity uses to prepare general purpose publicly available or available to be issued financial statements in France;

(iii) With respect to financial statements the Covered Entity is required to file annually with French and/or European authorities, including a report of an independent public accountant covering the financial statements, the Covered Entity (if not prudentially regulated):

(A) Simultaneously transmits to the principal office of the Commission or to an email address provided on the Commission's website a copy of such annual financial statements and the report of the independent public accountant covering the annual financial statements;

(B) Includes with the transmission the contact information of an individual who can provide further information about the annual financial statements and report;

(C) Includes with the transmission the report of an independent public accountant required by Exchange Act rule 18a–7(c)(1)(i)(C) covering the annual financial statements if French or EU laws do not require the Covered Entity to engage an independent public accountant to prepare a report covering the annual financial statements; provided, however, that such report of the independent public accountant may be prepared in accordance with generally accepted auditing standards in France or the EU that the independent public accountant uses to perform audit and attestation services; and

(D) Includes with the transmission the reports required by Exchange Act rule 18a–7(c)(1)(i)(B) and (C) addressing the statements identified in Exchange Act rule 18a–7(c)(3) or (c)(4), as applicable, that relate to Exchange Act rule 18a–4; provided, however, that the report of the independent public accountant required by Exchange Act Rule 18a–7(c)(1)(i)(C) may be prepared in accordance with generally accepted auditing standards in France or the EU that the independent public accountant uses to perform audit and attestation services.

(4) *Provide Notification.* The notification requirements of Exchange Act rule 18a–8 applicable to security-based swap dealers and major security-based swap participants; provided that:

(i) The Covered Entity is subject to and complies with the following requirements: CRD IV article 71; MiFID article 73; MFC articles L. 511–33 II, L. 634–1, and L. 634–2;

(ii) The Covered Entity:

(A) Simultaneously transmits to the principal office of the Commission or to an email address provided on the Commission's website a copy of any notice required to be sent by the French and EU laws referenced in paragraph (f)(3)(i) of this order; and

(B) Includes with the transmission the contact information of an individual who can provide further information about the matter that is the subject of the notice;

(iii) The Covered Entity complies with notification requirements of Exchange Act rule 18a–8(e) that relate to Exchange Act rule 18a–4 if the Covered Entity is not exempt from Exchange Act rule 18a–4; and

(iv) The Covered Entity complies with notification requirements of Exchange Act rule 18a–8(g) if the Covered Entity is not exempt from Exchange Act rule 18a–4.

(5) *Perform Securities Count.* The securities count requirements of Exchange Act rule 18a–9 applicable to non-prudentially regulated security-based swap dealers and major security-based swap participants; provided that:

(i) The Covered Entity is subject to and complies with the following requirements: MiFID Delegated Directive articles 2 and 8; MiFID Org Reg. articles 74 and 75; EMIR article 11(1)(b); Decree of 6 September 2017 articles 3 and 10; AMF General Regulation articles 312–6 and 312–7.

(6) *Examination and Production of Records.* Notwithstanding the forgoing provisions of paragraph (f) of this Order, security-based swap dealers and major security-based swap participants remains subject to the requirement of Exchange Act section 15F(f) to keep books and records open to inspection by any representative of the Commission and the requirement of Exchange Act rule 18a–6(g) to furnish promptly to a representative of the Commission legible, true, complete, and current copies of those records of the Covered Entity that are required to be preserved under Exchange Act rule 18a–6, or any other records of the Covered Entity that are subject to examination or required to be made or maintained pursuant to Exchange Act section 15F that are requested by a representative of the Commission.

(g) Definitions.

(1) ''Covered Entity'' means an entity that:

(i) Is a security-based swap dealer or major security-based swap participant registered with the Commission;

(ii) Is not a ''U.S. person,'' as that term is defined in rule 3a71–3(a)(4) under the Exchange Act; and

(iii) Is an investment firm authorized by the AMF to provide investment services or perform investment activities in the French Republic or a credit institution authorized by the ACPR after approval by the AMF of the credit institution's program of operations to provide investment services or perform investment activities in the French Republic.

(2) ''MiFID'' means the ''Markets in Financial Instruments Directive,'' Directive 2014/65/EU, as amended or superseded from time to time.

(3) ''MFC'' means France's ''Code monétaire et financier,'' as amended or superseded from time to time.

(4) ''Internal Control Order'' means the French AMF's Arrêté of 3 November 2014 on Internal Control of Companies in the Banking, Payment Services and Investment Services Sector Subject to the Supervision of the Authorité de Contrôle Prudentiel et de Résolution, as amended or superseded from time to time.

(5) ''Prudential Supervision and Risk Assessment Order'' means the French ministerial order on prudential supervision and risk assessment, as amended or superseded from time to time.

(6) ''MiFID Org Reg'' means Commission Delegated Regulation (EU) 2017/565, as amended or superseded from time to time.

(5) ''MiFID Delegated Directive'' means Commission Delegated Directive (EU) 2017/593, as amended or superseded from time to time.

(6) ''MLD'' means Directive (EU) 2015/849, as amended or superseded from time to time.

(7) ''MiFIR'' means Regulation (EU) 600/2014, as amended or superseded from time to time.

(8) ''EMIR'' means the ''European Market Infrastructure Regulation,'' Regulation (EU) 648/2012, as amended or superseded from time to time.

(9) ''EMIR RTS'' means Commission Delegated Regulation (EU) 149/2013, as amended or superseded from time to time.

(10) ''EMIR Margin RTS'' means Commission Delegated Regulation (EU) 2016/2251, as amended or superseded from time to time.

(11) ''CRR Reporting ITS'' means Commission Implementing Regulation (EU) 680/2014, as amended or superseded from time to time.

(12) ''CRD'' means Directive 2013/36/EU, as amended or superseded from time to time.

(13) ''CRR'' means Regulation (EU) 575/2013, as amended or superseded from time to time.

(14) ''MAR'' means the ''Market Abuse Regulation,'' Regulation (EU) 596/2014, as amended or superseded from time to time.

(15) ''MAR Investment Recommendations Regulation'' means Commission Delegated Regulation (EU) 2016/958, as amended or superseded from time to time.

(16) ''AMF'' means the French Autorité des Marchés Financiers.

(17) ''ACPR'' means the French Authorité de Contrôle Prudentiel et de Résolution.

(18) ''ECB'' means the European Central Bank.

(19) ''Accounting Directive'' means Directive 2013/34/EU of the European Parliament and of the Council of 26 June 2013, as amended or superseded from time to time.

(20) ''Decree of 6 September 2017'' means France's Decree number 2017–1324 of 6 September 2017, as amended or superseded from time to time.

(21) ''AMF General Regulation'' means France's ''Règlement Général de L'Autorité des Marchés Financiers,'' as amended or superseded from time to time.

(22) ''Ministerial Order on the Supervisory Review and Evaluation Process'' means France's Arrêté of 3 November 2014 on the Process for Prudential Supervision and Risk Assessment of Banking Service Providers and Investment Firms Other than Portfolio Management Companies, as amended or superseded from time to time.

(23) ''French Commerce Code'' means the French Commercial Code, as amended or superseded from time to time.

(24) ''Prudentially regulated'' means a Covered Entity that has a ''prudential regulator'' as that term is defined in Exchange Act section 3(a)(74).

(25) ''Decree of 3 November 2014 on internal control'' means Arrêté of 3 November 2014 on internal control of companies in the banking, payment services and investment services sector subject to the supervision of the ACPR.

(26) ''Decree of 3 November 2014 relating to capital buffers'' means *Arrêté* of 3 November 2014 relating to the capital buffers of banking service providers and investment firms other than portfolio management companies.

(27) ''BRRD'' means Bank Recovery and Resolution Directive 2014/59/EU of the European Parliament and of the Council of 15 May 2014, as amended or superseded from time to time.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90736; File No. SR–FICC–2020–803]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing of Advance Notice To Include Same-Day Settling Trades in the Risk Management, Novation, Guarantee, and Settlement Services of the Government Securities Division's Delivery-Versus-Payment Service, and Make Other Changes

December 21, 2020.

Pursuant to Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act entitled the Payment, Clearing, and Settlement Supervision Act of 2010 (''Clearing Supervision Act'') [1] and Rule 19b–4(n)(1)(i) under the Securities Exchange Act of 1934 (''Act''),[2] notice is hereby given that on November 19, 2020, Fixed Income Clearing Corporation (''FICC'') filed with the Securities and Exchange Commission (''Commission'') the advance notice as described in Items I, II and III below, which Items have been prepared by the clearing agency.[3] The Commission is publishing this notice to solicit comments on the advance notice from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Advance Notice

This advance notice consists of amendments to the FICC Government Securities Division (''GSD'') Rulebook (the ''Rules'') [4] in order to (i) include Same-Day Settling Trades (as defined below) in the risk management, Novation, guarantee, and settlement services of GSD's delivery-versus-payment service (''DVP Service''), (ii) provide that FICC would attempt to settle, on a reasonable efforts basis, any Same-Day Settling Trades that are compared in the timeframe specified by FICC in notices made available to Members from time to time [5] to the

[1] 12 U.S.C. 5465(e)(1).

[2] 17 CFR 240.19b–4(n)(1)(i).

[3] On November 19, 2020, FICC filed this advance notice as a proposed rule change (SR–FICC–2020–015) with the Commission pursuant to Section 19(b)(1) of the Act, 15 U.S.C. 78s(b)(1), and Rule 19b–4 thereunder, 17 CFR 240.19b–4. A copy of the proposed rule change is *available at http://www.dtcc.com/legal/sec-rule-filings.aspx.*

[4] Capitalized terms not defined herein are defined in the Rules, *available at http://www.dtcc.com/legal/rules-and-procedures.*

[5] The initial timeframe would be after 3:01 p.m. If the FRB announces an extension of the Fedwire Securities Service, FICC would match the duration of the extension. All times herein are ET.

extent described below, (iii) introduce an optional service that would allow GSD to systematically pair-off certain Members' failed Securities Settlement Obligations between approximately 3:32 p.m. and 4:00 p.m., (iv) change the time of intraday funds-only settlement (''FOS'') processing from 3:15 p.m. to 4:30 p.m., and (v) make certain technical changes, as described in further detail below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Advance Notice

In its filing with the Commission, the clearing agency included statements concerning the purpose of and basis for the advance notice and discussed any comments it received on the advance notice. The text of these statements may be examined at the places specified in Item IV below. The clearing agency has prepared summaries, set forth in sections A and B below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement on Comments on the Advance Notice Received From Members, Participants, or Others

FICC has not received or solicited any written comments relating to this proposal. FICC will notify the Commission of any written comments received by FICC.

(B) Advance Notice Filed Pursuant to Section 806(e) of the Clearing Supervision Act

Nature of the Proposed Change

The proposed rule change would amend the Rules in order to (i) include Same-Day Settling Trades (as defined below) in the risk management, Novation, guarantee, and settlement services of GSD's DVP Service, (ii) provide that FICC would attempt to settle, on a reasonable efforts basis, any Same-Day Settling Trades that are compared in the timeframe specified by FICC in notices made available to Members from time to time to the extent described below, (iii) introduce an optional service that would allow GSD to systematically pair-off certain Members' failed Securities Settlement Obligations between approximately 3:32 p.m. and 4:00 p.m., (iv) change the time of intraday FOS processing from 3:15 p.m. to 4:30 p.m., and (v) make certain technical changes, as described in further detail below.

(i) Proposed Change To Include Same-Day Settling Trades in the Risk Management, Novation, Guarantee, and Settlement Services of GSD's DVP Service

GSD provides comparison, risk management, Novation, netting, guarantee, and settlement of netting-eligible trades executed by its Netting Members and Sponsored Members in the U.S. government securities market. In GSD's DVP Service, GSD provides these services for Repo Transactions.[6] The DVP Service encompasses all non-GCF Repo activity (both repo and buy-sell activity). All delivery obligations are made against full payment.

Currently, with respect to same-day starting Repo Transactions, GSD only risk manages, novates, nets, and settles the End Leg, except in instances where GSD assumes the fail on the Start Leg of a Brokered Repo Transaction.[7] If a same-day starting Repo Transaction is a Brokered Repo Transaction and the Start Leg of such transaction fails to settle on its original Scheduled Settlement Date, FICC will assume responsibility for settlement of such Start Leg from the Repo Broker on the evening of the day the Start Leg was due to settle. This may involve the receipt of securities from the repo dealer for redelivery to the reverse dealer, or the settlement of the Start Leg may be effected by netting of the settlement obligations arising from the Start Leg against the settlement obligations arising from the End Leg of the same or another repo. FICC does so in these instances (and has been doing so since the inception of its blind brokered repo service) in order to decrease settlement risk by centralizing the settlement of these failed Start Legs and including them in the netting process with the End Legs (which already settle at FICC). The Repo Broker acts as an intermediary and expects to net out of every transaction and not have a settlement position from the settlement process. By assuming the fail, FICC replaces the Repo Broker so that FICC becomes the central counterparty for settlement of these transactions and thereby, FICC decreases settlement risk. In all cases where FICC assumes a fail from a Repo Broker, the counterparty remains responsible to FICC for its obligations with respect to the transaction.

The DVP Service did not include settlement of the Start Leg of same-day starting Repo Transactions at its inception, and these transactions have always been settled between the parties (*i.e.,* outside of FICC). Recently, participants have expressed an interest in being able to settle the Start Leg of their same-day starting Repo Transactions through GSD. FICC believes that expanding its DVP Service in this way (hereinafter, ''Same-Day Settling Service'') could reduce market risk because the Start Legs as well as the End Legs of eligible Repo Transactions would be risk managed, novated, guaranteed, and settled through FICC. FICC also believes that the expansion of its DVP Service in this way could potentially reduce fails in the market by centralizing the settlement of the applicable Start Legs with FICC. FICC believes that this expansion of its DVP Service could increase settlement efficiencies and decrease settlement risk in the market and decrease operational risk with respect to Members. FICC believes that the Same-Day Settling Service could increase settlement efficiencies and decrease settlement risk because it would reduce the number of securities movements between Members by centralizing the settlement of the Start Legs with FICC even though the Start Legs are not netted. It would eliminate the number of bilateral movements because the Start Legs would settle through FICC. FICC also believes that the Same-Day Settling Service could decrease operational risk because FICC believes it could decrease the number of fails of the Start Legs as there would be fewer counterparties involved in the settlement of the Start Legs.

For example, assuming the following two Brokered Repo Transactions are executed on the same day: (i) Broker 1 executes an overnight same-day starting repo transaction with Dealer A and Dealer B (''Brokered Repo 1'') and (ii) Broker 2 executes an overnight same-day starting repo transaction with Dealer A and Dealer B (''Brokered Repo 2'').

- Brokered Repo 1 involves: (a) A repo transaction in CUSIP XYZ with a

[6] In addition to the DVP Service, GSD also provides such services in its GCF Repo® Service and CCIT Service. The GCF Repo Service and the CCIT Service are not part of this proposal. The GCF Repo Service is primarily governed by Rule 20 and enables Netting Members to trade general collateral finance repurchase agreement transactions based on rate, term, and underlying product throughout the day with Repo Brokers on a blind basis. The CCIT Service is governed by Rule 3B and enables tri-party repurchase agreement transactions in GCF Repo Securities between Netting Members that participate in the GCF Repo Service and institutional cash lenders (other than investment companies registered under the Investment Company Act of 1940, as amended). Rule 20 and Rule 3B, *supra* note 4.

[7] *See* Rule 19, Section 5, *supra* note 4. A same-day starting Repo Transaction consists of a Start Leg and End Leg where the initial Scheduled Settlement Date of the Start Leg is scheduled to settle on the Business Day on which it is submitted to GSD (typically referred to in the industry as a same-day settling start leg).

par and principal of $50 million with Dealer A and (b) a reverse repo transaction in the same CUSIP with a par and principal of $50 million with Dealer B.

• Brokered Repo 2 involves: (a) A repo transaction in CUSIP XYZ with a par of $50 million and principal of $51 million with Dealer B and (b) a reverse repo transaction in CUSIP XYZ with a par of $50 million and principal of $51 million with Dealer A.

Today, the Start Leg of both Transactions would settle away from FICC. Specifically, with respect to Brokered Repo 1, today, Dealer A would deliver securities with a par of $50 million to Broker 1, and Dealer A would receive $50 million in principal (cash) from the Broker 1. Broker 1 would then deliver securities with a par of $50 million to Dealer B, and Broker 1 would receive from Dealer B $50 million in principal (cash). With respect to Brokered Repo 2, today, Dealer B would deliver to Broker 2 securities with a par of $50 million and Dealer B would receive $51 million in principal (cash). Broker 2 would then deliver securities with a par of $50 million to Dealer A, and Broker 2 would receive $51 million in principal (cash) from Dealer A.

Today, Brokered Repo 1 and Brokered Repo 2 are submitted to FICC upon execution. The Start Leg and the End Leg of each of Brokered Repo 1 and Brokered Repo 2 are submitted for Demand Comparison to FICC by the Repo Brokers, who are considered Demand Trade Sources. Upon receipt of the trade data from the Demand Trade Source, FICC deems the trades compared. The dealer counterparties also submit matching trade data to FICC.

Today, on the Start Date, settlement of the Start Leg would occur over Fedwire (or on the books of the Clearing Bank(s) between the four counterparties referenced above). This has the potential to cause fails in the marketplace if one or more counterparties fail to meet their settlement obligations at any point in the process. As previously stated, on the evening of the day the Start Leg was due to settle, FICC would assume the Start Leg(s) if they failed versus the Repo Broker. These broker fails would go into that night's netting cycle and be marked-to-market. Because both Brokered Repo Transactions are overnight trades, the Close Leg of each trade would also be included in that night's netting cycle.

With this proposed expansion of the DVP Service, on Start Date, the Start Leg of each Brokered Repo Transaction would settle versus FICC upon submission of the trade data from the Demand Trade Source. The Repo Brokers would be removed from the settlement process. The settlement of the Start Leg of each Brokered Repo Transaction would settle over Fedwire (or on the books of FICC's Clearing Agent Bank (The Bank of New York Mellon) between the two dealer counterparties and FICC (acting as the central counterparty)).

Specifically, with the proposed expansion of the DVP Service, with respect to Brokered Repo 1, Dealer A would deliver securities in CUSIP XYZ of $50 million par to FICC, and Dealer A would receive $50 million in principal (cash) from FICC. FICC would then deliver to Dealer B securities in CUSIP XYZ of $50 million par, and FICC would receive $50 million in principal (cash) from Dealer B. With respect to Brokered Repo 2, Dealer B would deliver securities in CUSIP XYZ with a par of $50 million to FICC, and Dealer B would receive $51 million in principal (cash) from FICC. FICC would then deliver to Dealer A securities in CUSIP XYZ with a par of $50 million, and FICC would receive from Dealer A principal (cash) of $51 million.

If these same-day settling Securities Settlement Obligations failed to settle on their original Scheduled Settlement Date, and Dealer A and Dealer B have chosen to opt into the proposed Pair-Off Service (as described below), FICC would pair-down the failed Securities Settlement Obligations, resulting in a net money difference of $1 million debit to Dealer A and $1 million credit to Dealer B. To complete the settlement process on the same day that the Same-Day Settling Trade is executed, the money differences would settle through intraday funds-only settlement (FOS). If the dealer parties have not opted into the proposed Pair-Off Service, the failed same-day settling Securities Settlement Obligations would go into the night's net and the collection of any money differences would occur on the following Business Day through the start of day FOS.

Under Section 7 of Rule 12, if FICC has delivered Eligible Netting Securities to a Netting Member with a Net Long Position (Dealer B in our example), such Member shall be obligated to accept delivery of all such securities at the Settlement Value for the Receive Obligation or Receive Obligations that comprise such Position. If such Member fails to do so, it shall be obligated to pay, or to reimburse FICC for, all costs, expenses, and charges incurred by FICC as the result thereof, and it may be subject to a fine by FICC if FICC, in its sole discretion, determines that such failure to accept securities was done without good cause.[8]

In addition, in the event Dealer B's failure to pay the principal amount is due to financial difficulties, FICC would also have the right to suspend a Member from any service provided by FICC either with respect to a particular transaction or transactions or with respect to transactions generally, or prohibit or limit such Member with respect to access to services offered by FICC and/or to cease to act for such Member.[9]

FICC proposes to include the following transactions in the risk management, Novation, guarantee, and settlement services of GSD's DVP Service: (i) A Start Leg of a Netting Member's Repo Transaction where the Scheduled Settlement Date of the Start Leg is the current Business Day, (ii) an As-Of Trade of a Netting Member where the Scheduled Settlement Date of the Start Leg is the previous Business Day and the End Leg is the current Business Day or thereafter,[10] and (iii) a Sponsored

[8] Rule 12, Section 7, *supra* note 4.

[9] Rule 21 and Rule 22A, *supra* note 4.

[10] FICC has added As-Of Trades in this proposal in order to reasonably include as many variations of Same-Day Settling Trades as possible. This addition of As-Of Trades in this proposal covers scenarios in which a Member submits a DVP repo transaction for comparison on the day after the Scheduled Settlement Date for the Start Leg (*i.e.,* where a trade compares on the day after the Scheduled Settlement Date of the Start Leg). Members may occasionally need to submit As-Of Trades due to human or operational errors.

Although this scenario is not frequently observed, FICC believes that inclusion of these transactions in the Novation and settlement process under this proposal would provide Members with consistent processing in terms of settlement of their FICC-cleared DVP Repo Transactions, irrespective of whether those transactions are submitted as As-Of Trades or Same-Day Settling Trades.

Under this proposal, from an operational and risk management perspective, As-Of Trades would be risk managed and settled in the same manner as all other eligible Same-Day Settling Trades. FICC would settle both the Start Leg and the End Leg of an As-Of Trade on a bilateral basis between FICC and the Member that submitted the trade. The End Leg of an As-Of Trade would not be netted unless the Scheduled Settlement Date of the End Leg is later than the current Business Day that the trade was submitted.

For purposes of clarity, Securities Settlement Obligations generated for the purposes of settlement of the Start Leg and End Leg of an As-Of Trade that is eligible for settlement under this proposal would be generated based on the Scheduled Settlement Date (*i.e.* contractual settlement date) for each leg of the As-Of Trade. However, the generation of such obligation(s) on the Scheduled Settlement Date for each leg of an As-Of Trade does not mean that such obligation(s) would actually settle on such date.

Today, the Start Leg of an As-Of Trade settles outside of FICC, and if the Scheduled Settlement Date of the End Leg is the current Business Day, the End Leg would also settle outside of FICC.

Under this proposal, if an As-Of Trade is an overnight repo that is submitted on the current Business Day (so the Start Date would be as of the

Continued

Member Trade within the meaning of section (b) of that definition that meets the requirements of either (i) or (ii) above (hereinafter, collectively, ''Same-Day Settling Trades''). Same-Day Settling Trades would not go through FICC's netting process. This is because GSD netting occurs the night before the Scheduled Settlement Date for such transactions, and these Same-Day Settling Trades would not be submitted for settlement until after this time.

Same-Day Settling Trades would settle on a trade-for-trade basis at Contract Value unless such Same-Day Settling Trades fail to settle. Because Same-Day Settling Trades are not netted, they would settle at Contract Value (not at System Value). In the event that such Same-Day Settling Trades fail to settle, they would be netted for settlement on the next Business Day as is the case for current Securities Settlement Obligations that fail to settle. If such Same-Day Settling Trades fail to settle, the trade would be netted at Contract Value versus System Value, which all other Fail Deliver Obligations and Fail Receive Obligations would be netted at. Same-Day Settling Trades that fail to settle are netted with other transactions that fail in that security (*i.e.,* the process for netting fails of Same-Day Settling Trades would remain the same). Those obligations that fail to settle would be subject to the fails charge (either a debit or a credit), the accrual of which would be included in the Member's monthly invoice.[11]

The Start Leg of an As-Of Trade (overnight and term) and a same-day starting repo (overnight and term) would settle at Contract Value. The End Leg of an As-Of Trade that is an overnight repo would settle at Contract Value. Both the Start Leg and End Leg of an As-Of Trade that is an overnight repo are Same-Day Settling Trades and, therefore, would settle at the Contract Value. Similarly, the Start Leg of a same-day starting repo (overnight or term) is also a Same-Day Settling Trade and would settle at Contract Value.

The End Leg of an As-Of Trade that is a term repo, same-day starting repo that is an overnight repo, and same-day starting repo that is a term repo would settle at System Value. The End Leg of an As-Of Trade that is a term repo, the End Legs of a same-day starting repo (overnight and term), and the Start Legs and End Legs of a forward starting repo (overnight and term) would settle at System Value because these legs would go through FICC's netting process.

Below is a chart that describes whether the Start Legs and End Legs of As-Of Trades, same-day starting repos, and forward starting repos would settle at Contract Value or System Value:

Trade type	Start leg settles at:	End leg settles at:
As-Of Overnight Trade	Contract Value	Contract Value.
As-Of Term Trade	Contract Value	System Value.
Same-Day Starting Overnight Repo	Contract Value	System Value.
Same-Day Starting Term Repo	Contract Value	System Value.
Forward Starting Overnight Repo	System Value	System Value.
Forward Starting Term Repo	System Value	System Value.

The proposed Same-Day Settling Service would be voluntary for Inter-Dealer Broker Netting Members and Non-IDB Repo Brokers with Segregated Repo Accounts (collectively, ''Repo Brokers''). Because Repo Brokers tend to provide a suite of services to their clients where facilitating the settlement of a Same-Day Settling Trade is one of those services, FICC did not want to cause any disruption to Repo Brokers and their clients by bifurcating the existing set of services whereby FICC does the settlement of the Same-Day Settling Trade and the Repo Broker continues to provide the rest of their existing services to their clients. FICC believes that providing optionality will allow Repo Brokers and their clients to determine how and when a Repo Broker should participate in the proposed Same-Day Settling Service. GSD would discontinue assuming fails for Repo Brokers who choose to participate in this proposed Same-Day Settling Service, because such assumption would be replaced by the FICC Novation that would occur upon comparison of the Same-Day Settling Trades. As described above, today, FICC assumes the fails for Repo Brokers (and has been doing so since the inception of its blind brokered repo service) in order to decrease risk. By assuming the fail, FICC removes the Repo Broker, who acts as an intermediary and who expects to net out of every transaction and not have a settlement position, from the settlement process. In all cases where FICC assumes a fail from a Repo Broker, the counterparty remains responsible for its obligations with respect to the transaction.

The proposed Same-Day Settling Service would be mandatory for all other Netting Members and for Sponsored Members who execute transactions with Netting Members other than their Sponsoring Member because GSD must have a balanced set (both a Repo and a Reverse Repo) on all transactions. Specifically, if a Member (other than a Repo Broker[12]) that is a party to a Same-Day Settling Trade could choose to opt out of the Same-Day Settling Service, FICC would not be able to create equal and opposite Securities Settlement Obligations for the two counterparties, which would require them to settle away from FICC. This would create uncertainty among Members as to who to settle their transactions with (*i.e.,* FICC or bilaterally outside of FICC). By requiring these Members to participate, Members would have certainty that their compared transactions would settle with FICC as their settlement counterparty.

To implement these changes, FICC is proposing to revise Rule 1 by: (1) Adding a new definition for ''Same-Day Settling Trade'' and (2) revising the definitions of ''Deliver Obligation,'' ''Receive Obligation,'' ''Settlement Value,'' and ''System Value.''

''Same-Day Settling Trade'' would mean (i) a Start Leg of a Netting

prior Business Day) and the Scheduled Settlement Date of its End Leg is the current Business Day, then FICC would settle each leg independently at Contract Value with the Member.

If an As-Of Trade is a term repo that is submitted on the current Business Day (so the Start Leg would be as of the prior Business Day) and the Scheduled Settlement Date of the End Leg is the next Business Day or thereafter, then the End Leg would go into the netting process and would settle at System Value. For As-Of Trades that are term repos, FICC would settle the Start Legs at Contract Value.

[11] Rule 11, Section 14, *supra* note 4.

[12] Repo Brokers submit a side for each of their two counterparties. Therefore, if a Repo Broker participates in the proposed Same-Day Settling Service, then FICC would settle the two trades (*i.e.,* a Receive Obligation and a Deliver Obligation with the two counterparties). However, if a Repo Broker does not participate in the proposed Same-Day Settling Service, the two trades would settle away from FICC as they do today (except in the instance of a broker fail where FICC would assume the broker fails).

Member's Repo Transaction where the Scheduled Settlement Date of the Start Leg is the current Business Day, (ii) an As-Of Trade of a Netting Member where the Scheduled Settlement Date of the Start Leg is the previous Business Day and the End Leg is the current Business Day or thereafter, or (iii) a Sponsored Member Trade within the meaning of subsection (b) of that definition [13] that meets the requirements of either (i) or (ii) above.

The definitions of Deliver Obligation and Receive Obligation would be amended to include references to Same-Day Settling Trades. Similarly, the definition of Settlement Value would be amended to specify that, with respect to a Deliver Obligation or a Receive Obligation for a Same-Day Settling Trade, Settlement Value means the Contract Value for such obligation. In addition, FICC would amend the definition of System Value to exclude Same-Day Settling Trades because Same-Day Settling Trades would settle at the Contract Value (not the System Value). Members are currently settling their Same-Day Settling Trades at the Contract Value, so FICC would not be changing the way such Members are settling these transactions, consistent with what is occurring today.

FICC would revise Section 8(c) of Rule 3A to reference new Section 11 of Rule 12 (described below).

In addition, FICC would amend Section 5 of Rule 5 to provide that settlement of Same-Day Settling Trades would be processed as per new Section 11 of Rule 12. This proposed addition is needed in that provision of Rule 5 because the prior sentence (that is, the current last sentence of that section) addresses the current process where trades that are not netted and settled with FICC are settled between the parties to the trades; with this proposal, Same-Day Settling Trades would be settled with FICC even though they are not netted.

FICC would revise Section 8 of Rule 5 to address the Novation and guaranty of Same-Day Settling Trades in a new subsection (b). Specifically, language would be added that each Same-Day Settling Trade that becomes a Compared Trade and was entered into in good faith would be novated to FICC, and that FICC would guarantee the settlement of each such Compared Trade at the time at which the comparison of such trade occurs pursuant to Rules 6A and 6B, as applicable. Such Novation would consist of the termination of the deliver, receive, and related payment obligations between the Netting Members and their replacement with identical obligations to and from FICC in accordance with the Rules.

FICC would amend Section 2 of Rule 11 to state that Same-Day Settling Trades would not be netted. As explained above, in GSD's DVP Service netting takes place the night before the Scheduled Settlement Date; Same-Day Settling Trades would settle after the net is run (unless a settlement fail occurs). Because they will not be netted, Same-Day Settling Trades would settle on a trade-for-trade basis at Contract Value with FICC on their Scheduled Settlement Date unless such Same-Day Settling Trades fail to settle. If a Same-Day Settling Trade fails to settle, such Same-Day Settling Trade would be netted for settlement on the next Business Day as is the current process for Securities Settlement Obligations that fail to settle. Those that fail to settle would be subject to the fails charge.

FICC would amend Rule 11B to add a new subsection that would describe that FICC would guarantee the settlement of any Same-Day Settling Trade provided that certain requirements are met. Specifically, the data on such Same-Day Settling Trade must be submitted for Bilateral or Demand Comparison at the time that the comparison of such trade occurs pursuant to Rules 6A or 6B, respectively. Rules 6A and 6B discuss Bilateral Comparison and Demand Comparison, respectively. In order for FICC to settle the trades, the trades must be novated. In order to novate the trades, they must first be compared.

FICC would amend Rule 12 to add a section (new Section 11) stating that Same-Day Settling Trades must also meet the requirements of new Section 11(ii) of Rule 12 (which is a proposed section pursuant to this filing) and the trade must have been entered into in good faith. Proposed Section 11(ii) would state that a Same-Day Settling Trade would be eligible for settlement with FICC if it meets all of the following requirements: (a) The Same-Day Settling Trade is a Compared Trade, (b) the data on the Same-Day Settling Trade are listed on a Report that has been made available to Netting Members, (c) (i) the End Leg of the Same-Day Settling Trade meets the eligibility requirements for netting in Rule 11, or (ii) the Repo Transaction is an As-Of Trade and its End Leg settles on the current Business Day or thereafter, and (d) the underlying securities are Eligible Netting Securities.

In addition, notwithstanding the above, a Same-Day Settling Trade eligible for settlement to which an Executing Firm is a party, the data on which has been submitted to FICC on behalf of such Executing Firm by a Submitting Member that is a Netting Member, would not be settled if the Submitting Member has provided FICC with notice that it does not wish to have trades submitted by it on behalf of that Executing Firm be settled through the Comparison System. Also notwithstanding the above, a trade would not be settled if either Submitting Member had submitted data on a side of the trade on behalf of an Executing Firm whose trades it had provided FICC with notice pursuant to the Rules that it did not wish to be settled. Pursuant to Section 1 of Rule 8, a Submitting Member must submit to FICC for comparison and/or netting data on any transaction calling for the delivery of Eligible Securities between an Executing Firm on whose behalf it is acting pursuant to these Rules and either another Member of the Netting System, Comparison System or another Executing Firm on whose behalf it or another Member is acting pursuant to these Rules. Therefore, a Same-Day Settling Trade submitted by such Submitting Member will be eligible to settle through the proposed Same-Day Settling Service unless the Submitting Member has provided notice to FICC in advance that it does not wish to have such trades settled through the Comparison System. This provision in proposed Section 11 of Rule 12 that discusses the eligibility for settlement through the Same-Day Settling Service would also align with FICC's current rule on the eligibility for netting in Section 2 of Rule 11.[14]

Proposed Section 11 of Rule 12 would also state that, notwithstanding the above, FICC may, in its sole discretion, exclude any Same-Day Settling Trade or Same-Day Settling Trades from the Comparison System, by Netting Member or by Eligible Netting Security. For example, if a trade was submitted to the Comparison System because of an operational error or technological error and the client is unable to delete such trade, then FICC may exclude such trade from the Comparison System. In addition, with respect to Repo Transactions, if the Start Leg is excluded, then the corresponding End Leg would also be excluded. This provision of the new Section 11 of Rule 12 that discusses the eligibility for settlement through the Same-Day Settling Service would also align with

[13] "Sponsored Member Trade" means a transaction that satisfies the requirements of Section 5 of Rule 3A and that is (a) between a Sponsored Member and its Sponsoring Member or (b) between a Sponsored Member and a Netting Member. Rule 1, *supra* note 4.

[14] Rule 8, Section 1, *supra* note 4.

FICC's current rule on the eligibility for netting in Section 2 of Rule 11.

In addition to the above, in the new Section 11 of Rule 12, FICC would describe the settlement of Same-Day Settling Trades with FICC, including eligibility requirements for settlement and how the Deliver Obligations and Receive Obligations related to such transactions must be satisfied. FICC would also describe that if a novated Same-Day Settling Trade becomes uncompared or is cancelled pursuant to the Rules, the Novation and FICC's guaranty of settlement of such transaction would no longer apply, cancelling the deliver, receive, and related payment obligations between FICC and the applicable Members, created by such Novation. Furthermore, FICC would state that in the event that such transaction is cancelled after the satisfaction of the deliver, receive, and related payment obligations between FICC and the applicable Netting Members, FICC would establish reverse Securities Settlement Obligations in the form of a Receive Obligation or a Deliver Obligation for the amount of the Contract Value of the Same-Day Settling Trades that have become uncompared or cancelled between FICC and the applicable Members. If such Receive Obligation or Deliver Obligation fails to settle, then such obligations would be netted at Contract Value for settlement on the next Business Day. Those that fail to settle would be subject to the fails charge (either a debit or credit), the accrual of which would be included in the Member's monthly invoice.

FICC would make clear that Sections 6 (Finance Costs), 7 (Obligation to Receive Securities), 8 (Obligation to Facilitate Financing) and 9 (Relationship with Clearing Banks) of Rule 12 would be applicable in connection with the settlement of Same-Day Settling Trades with FICC.[15] These sections are part of GSD's securities settlement rule and do not require any changes to accommodate the settlement of Same-Day Settling Trades.

Furthermore, because the proposed Same-Day Settling Service would be voluntary for Repo Brokers, FICC would amend Section 5 of Rule 19 and Sections IV.A.5, IV.A.6, and IV.B.3 of the Fee Structure to state that the applicable section would only apply to Repo Brokers that do not elect to settle Same-Day Settling Trades with FICC. This is because these sections address the assumption of certain Start Legs by GSD that would be replaced by GSD's Novation, guaranty, and settlement of Same-Day Settling Trades of those Repo Brokers that elect to participate in the proposed service.

(ii) Proposed Change To Provide That FICC Would Attempt To Settle Same-Day Settling Trades That Are Compared in the Timeframe Specified by FICC in Notices Made Available to Members From Time to Time on a Reasonable Efforts Basis

Today, Members occasionally execute Same-Day Settling Trades after the close of the Fedwire Securities Service. These Same-Day Settling Trades are settled between the Members (outside of FICC) as long as both parties to the trade settle such trades within the same Clearing Bank.

In order to accommodate this practice, FICC proposes to provide the proposed Same-Day Settling Service to late-day compared Same-Day Settling Trades (*i.e.,* those Same-Day Settling Trades that are compared after 3:01 p.m.[16]). FICC would attempt to settle, on a reasonable efforts basis, such trades that are compared in the timeframe specified by FICC in notices made available to Members from time to time, provided (i) FICC is able to contact the counterparties to the trade and FICC's Clearing Agent Bank and (ii) FICC's Clearing Agent Bank and the counterparties to the trade agree to settle such trade. The foregoing sentence would only apply to Same-Day Settling Trades of Members that clear at FICC's Clearing Agent Bank. Reasonable efforts basis would mean that FICC would attempt to contact the counterparties to the trade and FICC's Clearing Agent Bank to confirm they agree to settle such trade. Specifically, FICC would continue to process securities movements between FICC's account at FICC's Clearing Agent Bank and Members' accounts at FICC's Clearing Agent Bank, on a reasonable efforts basis, in the timeframe specified by FICC in notices made available to Members from time to time, provided that (i) FICC is able to contact FICC's Clearing Agent Bank and (ii) FICC's Clearing Agent Bank and the counterparties to the trade agree to settle such trade.[17]

For those Members that do not have accounts at FICC's Clearing Agent Bank, FICC would attempt to settle, on a reasonable efforts basis, Same-Day Settling Trades that are compared after the time specified by FICC in notices made available to Members from time to time during the reversal period of the Fedwire Securities Service,[18] provided (i) FICC is able to contact FICC's Clearing Agent Bank, (ii) FICC is able to contact the counterparties to the trade to confirm that they agree to settle the trade, and (iii) FICC's Clearing Agent Bank, the Member's Clearing Agent Bank, and the Federal Reserve Bank of New York each permit settlement of the trade (Fedwire must be open for settlement). Reasonable efforts basis would mean that FICC would attempt to contact the counterparties to the trade and FICC's Clearing Agent Bank to confirm that they agree to settle such trade.

To implement this proposed rule change, FICC would include provisions in newly added Section 11 of Rule 12.

(iii) Proposed Change To Introduce an Optional Service That Would Allow GSD To Systematically Pair-Off Certain Members' Failed Securities Settlement Obligations Between Approximately 3:32 p.m. and 4:00 p.m.

FICC also proposes to introduce an optional service for Netting Members (other than Repo Brokers) and for Sponsored Member Trades (other than those between the Sponsored Member and its Sponsoring Member) whereby GSD would systematically pair-off such Members' failed Securities Settlement Obligations between approximately 3:32 p.m. and 4:00 p.m.

[15] Section 6 (Financing Costs) addresses situations where if a Netting Member with a Net Short Position delivers eligible Netting Securities to FICC and FICC is unable, because the delivery was made near the close of Fedwire or for any other reason, to redeliver such securities on the same Business Day to a Netting Member or Members with Net Long Positions in such securities and, as a result, FICC incurs costs, expenses, or charges related to financing such securities (the ''financing costs''), then the Netting Members, as a group, shall be obligated to pay, or to reimburse FICC, for such financing costs. Section 7 (Obligation to Receive Securities) covers the obligation of Members to accept delivery of securities regarding their Receive Obligations. Section 8 (Obligation to Facilitate Financing) sets forth FICC's ability to obtain financing necessary for the provision of securities settlement services contemplated by the Rules. Section 9 (Relationship with Clearing Banks) makes clear that no improper or unauthorized action, or failure to act, by a clearing bank acting on behalf of a Netting Member shall excuse or otherwise affect the obligations of a Netting Member to FICC pursuant to the Rules. Rule 12, *supra* note 4.

[16] As described above, if the FRB announces an extension of the Fedwire Securities Service, FICC would match the duration of the extension.

[17] Initially, this would apply to Same-Day Settling Trades that are compared after 3:01 p.m. until 5 p.m.

[18] Initially, this time would be after 3:01 p.m. until 3:30 p.m. If the FRB announces an extension for the reversal period of the Fedwire Securities Service, FICC would match the duration of the extension for the reversal period. The Fedwire Securities Services closes at 3:30 p.m. for transfer reversals. *See Fedwire® and National Securities Service,* Federal Reserve Bank of New York (March 2015), *available at https://www.newyorkfed.org/aboutthefed/fedpoint/fed43.html* and *Fedwire Securities Service,* Board of Governors of the Federal Reserve System (July 31, 2014), *available at https://www.federalreserve.gov/paymentsystems/fedsecs_about.htm.*

The failed Securities Settlement Obligations could include (i) Receive Obligations and Deliver Obligations resulting from the previous night's net and (ii) obligations that were created intraday in order to settle a Right of Substitution or a Same-Day Settling Trade. Fails that occur go into the net that evening.[19]

GSD would look at each Member's failing activity on a per CUSIP basis and pair-off their Receive Obligations and Deliver Obligations irrespective of the settlement amounts on those obligations; this could result in money differences. This proposed process would be structured so that the net par result of the pair-offs would be zero. Specifically, the proposed pair-off process (''Pair-Off Service'') would consist of the matching and the offset of a participating Member's Fail Deliver Obligations and Fail Receive Obligations in equal par amounts of the same Eligible Netting Security. The participating Member would receive a debit or credit Pair-Off Adjustment Amount (which FICC may initially collect as a Miscellaneous Adjustment Amount), as applicable, of the difference in the Settlement Values of the applicable Fail Deliver Obligations and Fail Receive Obligations in the intraday funds-only settlement process. The proposed Pair-Off Service would start at approximately 3:32 p.m. The proposed rule change would provide FICC with the discretion to suspend or delay the Pair-Off Service in the event of an operational or market event. For example, FICC may delay the Pair-Off Service if the FRB extends Fedwire because extending the Fedwire would enable trades to potentially settle instead of fail. FICC believes that suspending the Pair-Off Service would not adversely affect Members because failed obligations would go into the net as they do today, and would continue to be risk-managed.

The proposed Pair-Off Service would allow the participating Member to settle their cash obligations today; the settlement process would be completed on the same day (via intraday FOS) rather than on the next day (via start of day FOS). As noted in the example in Item II(B)(i) above, if these obligations failed to settle, and Dealer A and Dealer B have chosen to opt into the proposed Pair-Off Service, FICC would pair-down the failed obligations, resulting in a net money difference of $1 million debit to Dealer A and $1 million credit to Dealer B. To complete the settlement process on the same day that the trade is executed, the money differences would settle through intraday funds-only settlement. The alternative to the proposed Pair-Off Service is to let the failed obligations go into the net and collect any money differences on the following Business Day through the start of day FOS.

To implement the proposed Pair-Off Service, FICC would revise Rules 1, 3A, and 12. Specifically, FICC would amend Rule 1 by adding two definitions, ''Pair-Off Service'' and ''Pair-Off Adjustment Payment.'' FICC would initially collect this amount as a Miscellaneous Adjustment Amount. Then, following development by FICC, this amount would be collected as a ''Pair-Off Adjustment Payment.''

FICC would also revise Rule 12 to describe the proposed Pair-Off Service, which would be a voluntary automated process. The proposed Pair-Off Service would consist of the matching and offset of a participating Netting Member's Fail Deliver Obligations and Fail Receive Obligations in equal par amounts in the same Eligible Netting Security. The participating Netting Member would receive either a debit or credit Pair-Off Adjustment Payment, as applicable, of the difference in the Settlement Values of the applicable Fail Deliver Obligations and Fail Receive Obligations in the FOS process under Rule 13. Any Securities Settlement Obligations remaining after the pair-off of eligible obligations would constitute a Fail Net Settlement Position.

Rule 12 would also state that FICC would have the discretion to suspend the Pair-Off Service on any Business Day due to FRB extensions and/or system or operational issues. FICC would notify Members of any such extension.

FICC would also revise Section 8 of Rule 3A to state that with respect to Section 1 of Rule 12, the optional Pair-Off Service would be available to Sponsored Member Trades within the meaning of section (b) of that definition.

(iv) Proposed Change To Change the Time of Intraday FOS Processing From 3:15 p.m. to 4:30 p.m.

FICC proposes to change the time of intraday FOS processing from 3:15 p.m. to 4:30 p.m. because FICC proposes to start the proposed Pair-Off Service at approximately 3:32 p.m. and would provide Funds-Only Settling Banks with their intraday net FOS figures by 4:00 p.m. for acknowledgment by 4:30 p.m. The proposed rule change would also provide that such time may be extended due to FRB extensions and/or system or operational issues. Moving this processing time from 3:15 p.m. to 4:30 p.m. would enable FICC to settle any net money differences that arise from the proposed Pair-Off Service.

To implement this change, FICC would amend the Schedule of Timeframes by deleting the 3:15 p.m. time and the related description, and adding a 4:30 p.m. time and a description that would state that intraday FOS debits and credits would be executed via the FRB's National Settlement Service for Netting Members.

(v) Proposed Technical Changes

FICC also proposes to make certain technical changes. Because a subsection would be added to Section 8 of Rule 5 to describe the comparison, Novation, and guarantee of Same-Day Settling Trades (as described in detail above), FICC would also renumber subsections that follow the proposed section for consistency and accuracy.

Implementation Timeframe

FICC would implement the proposed rule changes within 90 days after the later of the no objection to the advance notice and approval of the related proposed rule change[20] by the Commission. FICC would announce the effective date of the proposed changes by Important Notice posted to its website.

Expected Effect on Risks to the Clearing Agency, Its Participants and the Market

FICC believes that the proposed changes in Items II(B)(i) through II(B)(iv) above could increase settlement efficiencies in most instances and decrease settlement and operational risk because participants would have one settlement counterparty, FICC, for this activity. FICC believes that the proposed changes described in Items II(B)(i) and II(B)(ii) above could potentially reduce settlement fails by centralizing the settlement of the Same-Day Settling Trades with FICC.

FICC also believes that the proposed changes described in Items II(B)(iii) and II(B)(iv) above could provide FICC with the ability to potentially complete securities movements after the close of the Fedwire Securities Service. FICC believes these proposals could improve market risk to FICC because the settlement process would be completed on the same day rather than on the next Business Day.

Management of Identified Risks

The Same-Day Settling Trades that are the subject of the proposed rule changes in Items II(B)(i) and II(B)(ii) above are

[19] Fails occur because one party does not have the inventory to settle with the other party on the scheduled date.

[20] *Supra* note 3.

currently being submitted to FICC today. To the extent that they are unsettled during the times at which FICC runs its risk management processes, they are margined accordingly. Such Same-Day Settling Trades are also captured in FICC's liquidity risk processes today.

As such, FICC is not proposing any changes to its risk management processes in order to accommodate the activity that would be submitted to FICC in connection with the proposed rule changes described in Items II(B)(i) and II(B)(ii) above. The risk management is based on the outstanding settlement obligations regardless of where the Start-Leg cash payments are exchanged. The activity would be measured, monitored, margined and provisioned for potential market and liquidity exposure in the same way as netting eligible trades are currently.

In order to risk manage the proposed changes described in Item II(B)(iii) above, FICC is proposing in this filing the changes discussed in Item II(B)(iv) above. Specifically, FICC would move the intraday FOS processing time to later in the day in order to include the results of the proposed Pair-Off Service in the FOS process.

Consistency With the Clearing Supervision Act

FICC believes that the proposed rule change would be consistent with Section 805(b) of the Clearing Supervision Act.[21] The objectives and principles of Section 805(b) of the Clearing Supervision Act are to promote robust risk management, promote safety and soundness, reduce systemic risks, and support the stability of the broader financial system.[22]

FICC believes that the proposed changes described in Items II(B)(i) and II(B)(ii) above would promote robust risk management and promote safety and soundness. This is because the proposed changes would enable Members' Same-Day Settling Trades in Eligible Netting Securities, including Brokered Repo Transactions, to be included in the risk management, Novation, guarantee, and settlement services of the DVP Service. FICC does not settle such trades today (with the exception of assumed Broker fails). These proposed changes would enable the settlement of these trades to be centralized with FICC. FICC believes these proposed changes could increase settlement efficiencies and decrease settlement risk in the market and operational risk with respect to its Members because the participants would have one settlement counterparty, FICC, for this activity. As such, FICC believes that the proposed changes described in Items II(B)(i) and II(B)(ii) above would promote robust risk management and promote safety and soundness, consistent with the objectives and principles of Section 805(b) of the Clearing Supervision Act cited above.

FICC believes the proposed changes described in Items II(B)(iii) and II(B)(iv) above are designed to promote robust risk management and promote safety and soundness. Specifically, the proposed changes described in Items II(B)(iii) and II(B)(iv) above could reduce market risk to FICC because additional settlements would be completed on the same day rather than on the next Business Day. As such, FICC believes that the proposed changes described in Items II(B)(iii) and II(B)(iv) above, taken together, would promote robust risk management and promote safety and soundness, consistent with the objectives and principles of Section 805(b) of the Clearing Supervision Act cited above.

FICC believes the proposed technical changes described in Item II(B)(v) above are designed to provide clear and coherent Rules regarding the proposed expanded DVP Service described above for Members. FICC believes that clear and coherent Rules would enhance the ability of FICC and its Members to more effectively plan for, manage, and address the risks related to the proposed expanded DVP Service. As such, FICC believes that the technical changes would promote robust risk management, consistent with the objectives and principles of Section 805(b) of the Clearing Supervision Act cited above.

III. Date of Effectiveness of the Advance Notice, and Timing for Commission Action

The proposed change may be implemented if the Commission does not object to the proposed change within 60 days of the later of (i) the date that the proposed change was filed with the Commission or (ii) the date that any additional information requested by the Commission is received. The clearing agency shall not implement the proposed change if the Commission has any objection to the proposed change.

The Commission may extend the period for review by an additional 60 days if the proposed change raises novel or complex issues, subject to the Commission providing the clearing agency with prompt written notice of the extension. A proposed change may be implemented in less than 60 days from the date the advance notice is filed, or the date further information requested by the Commission is received, if the Commission notifies the clearing agency in writing that it does not object to the proposed change and authorizes the clearing agency to implement the proposed change on an earlier date, subject to any conditions imposed by the Commission.

The clearing agency shall post notice on its website of proposed changes that are implemented.

The proposal shall not take effect until all regulatory actions required with respect to the proposal are completed.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the advance notice is consistent with the Clearing Supervision 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–FICC–2020–803 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–FICC–2020–803. 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 advance notice that are filed with the Commission, and all written communications relating to the advance notice 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

[21] 12 U.S.C. 5464(b).

[22] *Id.*

office of FICC and on DTCC's website (*http://dtcc.com/legal/sec-rule-filings.aspx*). 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–FICC–2020–803 and should be submitted on or before January 13, 2021.

By the Commission.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28652 Filed 12–28–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–135, OMB Control No. 3235–0176]

Proposed Collection; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rules 8b–1 to 8b–33

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rules 8b–1 to 8b–33 (17 CFR 270.8b–1 to 8b–33) under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) (''Investment Company Act'') set forth the procedures for preparing and filing a registration statement under the Investment Company Act. These procedures are intended to facilitate the registration process. These rules generally do not require respondents to report information.[1]

The Commission believes that it is appropriate to estimate the total respondent burden associated with preparing each registration statement form rather than attempt to isolate the impact of the procedural instructions under Section 8(b) of the Investment Company Act, which impose burdens only in the context of the preparation of the various registration statement forms. Accordingly, the Commission is not submitting a separate burden estimate for rules 8b–1 through 8b–33, but instead will include the burden for these rules in its estimates of burden for each of the registration forms under the Investment Company Act. The Commission is, however, submitting an hourly burden estimate of one hour for administrative purposes.

The collection of information under rules 8b–1 to 8b–33 is mandatory. The information provided under rules 8b–1 to 8b–33 is not kept confidential. 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.

Written comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information has practical utility; (b) the accuracy of the Commission's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, C/O Cynthia Roscoe, 100 F Street NE, Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: December 22, 2020.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2020–28772 Filed 12–28–20; 8:45 am]

BILLING CODE 8011–01–P

[1] Although the rules under Section 8(b) of the Investment Company Act are generally procedural in nature, two of the rules require respondents to disclose some limited information. Rule 8b–3 (17 CFR 270.8b–3) provides that whenever a registration form requires the title of securities to be stated, the registrant must indicate the type and general character of the securities to be issued. Rule 8b–22 (17 CFR 270.8b–22) provides that if the existence of control is open to reasonable doubt, the registrant may disclaim the existence of control, but it must state the material facts pertinent to the possible existence of control. The information required by both of these rules is necessary to insure that investors have clear and complete information upon which to base an investment decision.

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–361, OMB Control No. 3235–0411]

Proposed Collection; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 489 and Form F–N

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (''Paperwork Reduction Act''), the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 489 (17 CFR 230.489) under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) requires foreign banks and foreign insurance companies and holding companies and finance subsidiaries of foreign banks and foreign insurance companies that are exempted from the definition of ''investment company'' by virtue of rules 3a–1 (17 CFR 270.3a–1), 3a–5 (17 CFR 270.3a–5), and 3a–6 (17 CFR 270.3a–6) under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) to file Form F–N (17 CFR 239.43) to appoint an agent for service of process when making a public offering of securities in the United States. The information is collected so that the Commission and private plaintiffs may serve process on foreign entities in actions and administrative proceedings arising out of or based on the offer or sales of securities in the United States by such foreign entities.

The Commission received an average of 27 Form F–N filings from 18 unique filers each year for the last three years (2017–2019). The Commission has previously estimated that the total annual burden associated with information collection and Form F–N preparation and submission is one hour per filing. Based on the Commission's experience with disclosure documents generally, the Commission continues to believe that this estimate is appropriate. Thus the estimated total annual burden for rule 489 and Form F–N is 27 hours.[1]

Estimates of average burden hours are made solely for the purposes of the

[1] 27 responses × 1 hour per response = 27 hours per year.

Paperwork Reduction Act and are not derived from a comprehensive or even representative survey or study of the costs of Commission rules and forms. Compliance with the collection of information requirements of rule 489 and Form F–N is mandatory to obtain the benefit of the exemption. Responses to the collection of information will not be kept confidential. 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.

Written comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information has practical utility; (b) the accuracy of the Commission's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, C/O Cynthia Roscoe, 100 F Street NE, Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: December 22, 2020.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2020–28771 Filed 12–28–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–267, OMB Control No. 3235–0272]

Proposed Collection; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 11a–2

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Rule 11a–2 (17 CFR 270.11a–2) under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) permits certain registered insurance company separate accounts, subject to certain conditions, to make exchange offers without prior approval by the Commission of the terms of those offers. Rule 11a–2 requires disclosure, in certain registration statements filed pursuant to the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) of any administrative fee or sales load imposed in connection with an exchange offer.

There are currently 676 registrants governed by Rule 11a–2. The Commission includes the estimated burden of complying with the information collection required by Rule 11a–2 in the total number of burden hours estimated for completing the relevant registration statements and reports the burden of Rule 11a–2 in the separate Paperwork Reduction Act (''PRA'') submissions for those registration statements (see the separate PRA submissions for Form N–3 (17 CFR 274.11b), Form N–4 (17 CFR 274.11c) and Form N–6 (17 CFR 274.11d). The Commission is requesting a burden of one hour for Rule 11a–2 for administrative purposes.

The estimate of average burden hours is made solely for the purposes of the PRA, and is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules or forms. With regard to Rule 11a–2, the Commission includes the estimate of burden hours in the total number of burden hours estimated for completing the relevant registration statements and reported on the separate PRA submissions for those statements (see the separate PRA submissions for Form N–3, Form N–4 and Form N–6). The information collection requirements imposed by Rule 11a–2 are mandatory. Responses to the collection of information will not be kept confidential.

Written comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information has practical utility; (b) the accuracy of the Commission's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, C/O Cynthia Roscoe, 100 F Street NE, Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: December 22, 2020.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2020–28770 Filed 12–28–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90749; File No. SR–CBOE–2020–116]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Add Options on the Mini-Russell 2000 Index (''Mini-RUT'' or ''MRUT'') to Its P.M. Pilot Program

December 21, 2020.

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 December 18, 2020, Cboe Exchange, Inc. (''Exchange'' or ''Cboe Options'') 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 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

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to add options on the Mini-Russell 2000 Index (''Mini-RUT'' or ''MRUT'') to its P.M. Pilot Program. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 purpose of this proposed rule change is to amend the Exchange's pilot program for P.M.-settled options on standard third-Friday-of-the-month (''Expiration Friday'') in connection with the Exchange's plans to list and trade MRUT options.[3] MRUT options are options on the Mini-RUT Index, the value of which is 1/10th the value of the Russell 2000 (''RUT'') Index. Currently, the Exchange has in place a pilot program under Interpretation and Policy .13 to Rule 4.13 that allows the Exchange to list Mini-SPX (''XSP'') options[4] that expire on Expiration Friday, for which the exercise settlement value is based on the index value derived from the closing prices of the component (*i.e.,* P.M.-settled) (the ''P.M. Pilot Program'').[5] The Exchange proposes to add Mini-RUT options to the existing P.M. Pilot Program and to permit it to list P.M.-settled Mini-RUT options, for which the exercise settlement value will be based on the index value derived from the closing prices of the on the last trading day prior to expiration, on a pilot basis (currently set to expire on May 3, 2021).[6] The Exchange notes that, like proposed MRUT options, XSP options are reduced-value options (1/10th) compared to SPX options that offer individual investors lower cost options to obtain the potential benefits of options on a broad-based index (the S&P 500 Index), and are likewise designed to provide options overlying the higher-valued SPX Index more readily available as an investing tool and at more affordable prices for the average retail investor. Therefore, the Exchange believes that because both mini-index options are intended for the same investor-base, providing the same P.M.-settlement opportunities for both XSP and MRUT options is appropriate. The Exchange believes permitting the trading of MRUT options on a P.M.-settled basis will encourage greater trading in MRUT options once listed and traded on the Exchange.[7]

The Exchange proposes to abide by the same reporting requirements for the trading of P.M.-settled MRUT options that it does for the trading of P.M.-settled XSP options.[8] The Exchange proposes to include data regarding P.M.-settled MRUT options as it does for P.M.-settled XSP options in the pilot program report that it submits to the Commission at least two months prior to the expiration date of the P.M. Pilot Program (the ''annual report'').[9] Specifically, the Exchange submits annual reports to the Commission that contain an analysis of volume, open interest, and trading patterns in connection with products in the P.M. Pilot Program. The analysis examines trading in products in the P.M. Pilot Program, as well as trading in the securities that comprise the underlying index. Additionally, for series that exceed certain minimum open interest parameters, the annual reports provide analysis of index price volatility and share trading activity.

Going forward, the Exchange will include the same analysis of P.M.-settled MRUT options, as well as trading in securities that comprise the RUT Index (as MRUT options are based on 1/10th the value of the RUT Index), in the annual reports. Also, like it currently does for P.M.-settled XSP options, the Exchange will submit periodic interim reports for P.M.-settled MRUT options that contain some, but not all, of the information contained in the annual reports.

The pilot reports will both contain the following volume and open interest data:

(1) Monthly volume aggregated for all trades;

(2) monthly volume aggregated by expiration date;

(3) monthly volume for each individual series;

(4) month-end open interest aggregated for all series;

(5) month-end open interest for all series aggregated by expiration date; and

(6) month-end open interest for each individual series.

The annual reports will also contain the information noted in Items (1) through (6) above for Expiration Friday, A.M.-settled, RUT index options traded on Cboe Options, as well as the following analysis of trading patterns in P.M.-settled MRUT options series in the Pilot Program:

(1) A time series analysis of open interest; and

(2) an analysis of the distribution of trade sizes.

Finally, for series that exceed certain minimum parameters, the annual reports will contain the following analysis related to index price changes and underlying share trading volume at the close on Expiration Fridays:

(1) A comparison of index price changes at the close of trading on a given Expiration Friday with comparable price changes from a control sample. The data includes a calculation of percentage price changes for various time intervals and compare that information to the respective control sample. Raw percentage price change data as well as percentage price change data normalized for prevailing market volatility, as measured by the Cboe Volatility Index (VIX), is provided; and

(2) a calculation of share volume for a sample set of the component securities representing an upper limit on share trading that could be attributable to expiring in-the-money series. The data includes a comparison of the calculated share volume for securities in the sample set to the average daily trading volumes of those securities over a sample period.

The minimum open interest parameters, control sample, time intervals, method for randomly selecting the component securities, and sample

[3] The Exchange plans to, simultaneously with this proposal, submit a proposal to list and trade Mini-RUT options on the Exchange. The Exchange plans to list Mini-RUT options as part of the Nonstandard Expiration Pilot Program and as a Quarterly Index Expiration (''QIX'') option. The Exchange intends to list and trade Mini-RUT options at the end of January 2021. The Exchange notes that trading in P.M.-settled MRUT options will operate in the same manner as provided in the proposal to list and trade Mini-RUT options on the Exchange. That is, P.M.-settled MRUT options will have the same European-style exercise, same number of permissible expirations, same exercise interval prices and limitations, same position and exercise limits, and will trade in the same minimum price increment.

[4] As well as SPX options (''SPXPM'').

[5] *See* Interpretation and Policy .13 to Rule 4.13.

[6] The proposed rule change also makes a nonsubstantive update to Interpretation and Policy .13 to Rule 4.13 by adding a reference to the defined term ''SPX'' after S&P 500 Stock Index and using that defined term within the provision in order to provide greater clarity and consistency with the language throughout Interpretation and Policy .13 to Rule 4.13.

[7] *See supra* note 3.

[8] *See* Securities Exchange Act Release No. 70087 (July 31, 2013), 78 FR 47809 (August 6, 2013) (SR–CBOE–2013–055) (the ''P.M.-settled XSP Approval Order''). The reporting requirements are also the same for SPXPM. *See* Securities and Exchange Act Release No. 68888 (February 8, 2013), 78 FR 10668 (February 14, 2013) (SR–CBOE–2012–120) (the ''SPXPM Approval Order'').

[9] *See* P.M.-settled XSP Approval Order.

periods are determined by the Exchange and the Commission. In proposing to add MRUT options to the P.M. Pilot Program, the Exchange will abide by the reporting requirements described herein, the same reporting requirements described in the P.M.-settled XSP Approval Order.[10] Additionally, the Exchange will provide the Commission with any additional data or analyses the Commission requests because it deems such data or analyses necessary to determine whether the P.M. Pilot Program, including P.M.-settled MRUT options as proposed, is consistent with the Exchange Act. As it does for current P.M. Pilot products, the Exchange will make public any data and analyses in connection with P.M.-settled MRUT options it submits to the Commission under the Pilot Program.[11]

Overall, the Exchange believes that permitting the trading of MRUT options on a P.M.-settled basis will encourage greater trading in MRUT options. The Exchange anticipates high customer demand for P.M.-settled MRUT options as they will provide market participants, particularly smaller-sized investors and retail customers, an opportunity to benefit from exposure to the broad-based RUT Index market with a manageably sized contract that has the flexibility of a P.M.-settlement.

Additionally, the Exchange proposes to amend Rule 5.1, which governs trading days and hours, in conjunction with the proposed addition of MRUT options to the P.M.-settled Pilot Program. Rule 5.1(b)(2)(C) currently provides that on their last trading day, Regular Trading Hours for P.M.-settled XSP options [12] may be effected on the Exchange between 9:30 a.m. and 4:00 p.m. Eastern Time [13] (as opposed to the 9:30 a.m. to 4:15 p.m. Regular Trading Hours for options with those expirations that are non-expiring). The proposed rule change amends Rule 5.1(b)(2)(C) to include P.M.-settled MRUT options. The Exchange expects that MRUT options, like SPX, XSP and RUT options (with Nonstandard Expirations, *i.e.,* P.M.-settled Weekly and End of Month (''EOM'') RUT options),[14] will typically be priced in the market based on corresponding futures values. The primary listing markets for the component securities that comprise the RUT Index (and thus, Mini-RUT Index) close trading in those securities at 4:00 p.m., just as the primary listing markets for the component securities that comprise the SPX Index (on which SPX and XSP options are based) close trading at 4:00 p.m. The primary listing exchanges for the component securities disseminate closing prices for the component securities, which are used to calculate the exercise settlement value of the RUT Index. The Exchange believes that, under normal trading circumstances, the primary listing markets have sufficient bandwidth to prevent any data queuing that may cause any trades that are executed prior to the closing time from being reported after 4:00 p.m. If trading in expiring P.M.-settled MRUT options continued an additional fifteen minutes until 4:15 p.m. on their last trading day, expiring MRUT options could not be priced on corresponding futures values, but rather would have to be priced on the known cash value. At the same time, the prices of non-expiring P.M.-settled MRUT options series would continue to move and likely be priced in response to changes in corresponding futures prices. As a result, a potential pricing divergence could occur between 4:00 p.m. and 4:15 p.m. on the final trading day in expiring P.M.-settled MRUT options (*e.g.,* a switch from pricing off of futures to cash). The Exchange understands that the switch from pricing off of futures to cash can be a difficult and risky crossover for liquidity providers. As a result, if expiring P.M.-settled contracts closed at 4:15 p.m., Market-Makers may react by widening spreads in order to compensate for the additional risk. Therefore, in order to mitigate potential investor confusion and the potential for increased costs to investors, the Exchange believes that it is appropriate to cease trading in the expiring P.M.-settled MRUT options at 4:00 p.m., as it already does for expiring P.M.-settled XSP options and RUT options with Nonstandard Expirations for the same aforementioned reasons.[15] The Exchange does not believe that the proposed rule change will impact volatility on the underlying cash market comprising the RUT Index at the close on Expiration Fridays, as it already closes trading on the last trading day for expiring P.M.-settled options at 4:00 p.m. (such as P.M.-settled XSP options and P.M.-settled Weekly and EOM RUT options), which the Exchange does not believe has had an adverse impact on fair and orderly markets on Expiration Fridays for the underlying stocks comprising the corresponding indexes.[16]

With regard to the impact of this proposal on system capacity, the Exchange has analyzed its capacity and represents that it believes that the Exchange and OPRA have the necessary systems capacity to handle any potential additional traffic associated with trading of P.M.-settled MRUT options. The Exchange does not believe that its Trading Permit Holders (''TPHs'') will experience any capacity issues as a result of this proposal and represents that it will monitor the trading volume associated with any possible additional options series listed as a result of this proposal and the effect (if any) of these additional series on market fragmentation and on the capacity of the Exchange's automated systems.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[17] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [18] requirements that the rules of an 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 regulating, clearing, settling, processing information with respect to, and 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [19] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange does not believe that the addition of MRUT options to the P.M. Pilot Program will raise any prohibitive regulatory concerns, nor adversely impact fair and orderly markets on Expiration Fridays for the underlying stocks comprising the

[10] *See also* SPXPM Approval Order.

[11] P.M. Pilot products data and analyses are made available at *https://www.cboe.com/aboutcboe/legal-regulatory/national-market-system-plans/pm-settlement-spxpm-data.*

[12] This same rule will apply to MRUT options with Nonstandard Expirations and QIXs, as proposed in the rule filing to list and trade MRUT options.

[13] *See* Rule 1.6, which states that unless otherwise specified, all times in the Rules are Eastern Time.

[14] *See* Rule 4.13(e).

[15] *See* Securities Exchange Act Release No. 69638 (May 24, 2013), 78 FR 32524 (May 30, 2013) (SR–CBOE–2013–055); *and* P.M.-settled XSP Approval Order.

[16] *See* Securities Exchange Act Release No. 90263 (October 23, 2020), 85 FR 68611 (October 29, 2020) (SR–CBOE–2020–100).

[17] 15 U.S.C. 78f(b).

[18] 15 U.S.C. 78f(b)(5).

[19] *Id.*

RUT Index. The Exchange has not experienced any meaningful regulatory concerns, nor adverse impact on fair and orderly markets, in connection with the P.M. Pilot Program that has permitted trading of P.M.-settled XSP since 2013, which have a similar purpose and likely similar investor base as MRUT options.[20] Additionally, the proposed rule change will provide investors with an opportunity to trade MRUT options with a P.M.-settlement feature on the Exchange subject to transparent exchange-based rules as well as price discovery and liquidity, as opposed to alternatively trading these products in the over-the-counter market. Investors will benefit from the opportunity to trade in association with this product on Expiration Fridays. Indeed, market participants, particularly smaller-sized investors and retail customers, will benefit from exposure to the broad-based RUT Index market with a manageably sized contract that has the flexibility of a P.M.-settlement, thereby removing impediments to a free and open market consistent with the Act.

In addition, the Exchange believes that the proposal to end trading at 4:00 p.m. on the last trading day for transactions in expiring P.M.-settled MRUT options will prevent continued trading on a product after the exercise settlement value has been fixed, thereby mitigating potential investor confusion and the potential for increased costs to investors as a result of potential pricing divergence at the end of the trading day. Given the significant changes in the closing procedures of the primary markets in recent decades, the Exchange does not believe that the proposed P.M.-settled MRUT options and 4:00 p.m. closing time on Expiration Fridays will adversely impact the maintenance of a fair and orderly market or the protection of investors because the risks of potential impact of P.M.-, cash-settled index derivatives on the underlying cash markets are greatly reduced today by the enhanced closing procedures currently in place at the primary equity markets. The Exchange notes also that it will include analysis in connection with P.M.-settled MRUT options, in the same manner that it currently does for other P.M.-settled options, in the pilot reports it submits to the Commission, and will provide the Commission with any additional data or analyses the it may request because it deems such data or analyses necessary to determine whether the Pilot Program, including P.M.-settled MRUT options as proposed, is consistent with the Exchange Act. The Exchange represents that it believes that it has the necessary systems capacity to support any additional traffic associated with trading of P.M.-settled MRUT and does not believe that its TPHs will experience any capacity issues as a result of this proposal. The Exchange will monitor the trading volume associated with any possible additional options series listed and the effect (if any) of these additional series on market fragmentation and on the capacity of the Exchange's automated systems.

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 does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because P.M.-settled MRUT options will be available to all market participants and the proposed 4:00 p.m. closing time on Expiration Fridays will apply equally to all market participants trading in MRUT options.

The Exchange does not believe that the proposal to list and trade options on the Mini-RUT Index, and the proposed rules governing the trading of MRUT options on the Exchange, will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because options on the RUT Index, including reduced-value options as proposed, are proprietary Exchange products. To the extent that the advent of P.M.-settled MRUT options trading on the Exchange may make the Exchange a more attractive marketplace to market participants at other exchanges, such market participants are free to elect to become market participants on the Exchange. As stated above, the listing and trading of P.M.-settled MRUT options on the Exchange will subject such options to transparent exchange-based rules as well as price discovery and liquidity, as opposed to alternatively trading these products in the over-the-counter market.

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

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. By order approve or disapprove such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be 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–CBOE–2020–116 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–CBOE–2020–116. 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

[20] Trading in SPXPM has been permitted since 2013, as well. The Exchange notes too that for roughly five years (1987 to 1992) it listed and traded an A.M.-settled S&P 500 index option (called NSX) at the same time it listed and traded a P.M.-settled S&P 500 index option (called SPX) and did not observe any market disruptions as a result of offering both products.

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–CBOE–2020–116, and should be submitted on or before January 19, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28655 Filed 12–28–20; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90762; File No. SR–NYSECHX–2020–33]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Effective Date in Interpretation and Policy .10 Under NYSE Chicago Article 6, Rule 13

December 21, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 15, 2020, the NYSE Chicago, Inc. (''NYSE Chicago'' or the ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II 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 proposes a rule change to extend the effective date in Interpretation and Policy .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE Chicago Article 6, Rule 13 (Registration Requirements) applicable to Participants, from December 31, 2020 to April 30, 2021. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, 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 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 Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend the effective date in Interpretation and Policy .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE Chicago Article 6, Rule 13 (Registration Requirements) applicable to Participants,[3] from December 31, 2020 to April 30, 2021. The proposed rule change would extend the 120-day period that certain individuals can function as a principal without having successfully passed an appropriate qualification examination through April 30, 2021,[4] and would apply only to those individuals who were designated to function as a principal prior to January 1, 2021. This proposed rule change is based on a filing recently submitted by the Financial Regulatory Authority, Inc. (''FINRA'')[5] and is intended to harmonize the Exchange's registration rules with those of FINRA so as to promote uniform standards across the securities industry.

The COVID–19 pandemic is an unpredictable, exogenous event that has resulted in unavoidable disruptions to the securities industry and impacted member firms, regulators, investors and other stakeholders. In response to COVID–19, earlier this year FINRA began providing temporary relief by way of frequently asked questions (''FAQs'')[6] to address disruptions to the administration of FINRA qualification examinations caused by the pandemic that have significantly limited the ability of individuals to sit for examinations due to Prometric test center capacity issues.[7]

FINRA published the first FAQ on March 20, 2020, providing that individuals who were designated to function as principals under FINRA Rule 1210.04[8] prior to February 2, 2020, would be given until May 31, 2020, to pass the appropriate principal qualification examination.[9] On May 19, 2020, FINRA extended the relief to pass the appropriate examination until June 30, 2020. On June 29, 2020, FINRA again extended the temporary relief providing that individuals who were designated to function as principals under FINRA Rule 1210.04 prior to May 4, 2020, would be given until August 31,

[21] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''Participant'' means any Participant Firm that holds a valid Trading Permit and any person associated with a Participant Firm who is registered with the Exchange. A Participant shall be considered a ''member'' of the Exchange for purposes of the Exchange Act. *See* Article 1, Rule 1(s).

[4] If NYSE Chicago seeks to provide additional temporary relief from the rule requirements identified in this proposed rule change beyond April 30, 2021, NYSE Chicago will submit a separate rule filing to further extend the temporary extension of time.

[5] *See* Exchange Act Release No. 90617 (December 9, 2020), 85 FR 81258 (December 15, 2020) (SR–FINRA–2020–043) (the ''FINRA Filing''). The Exchange notes that the FINRA Filing also provides temporary relief to individuals registered with FINRA as Operations Professionals under FINRA Rule 1220. The Exchange does not have a registration category for Operations Professionals and therefore, the Exchange is not proposing to adopt that aspect of the FINRA Filing.

[6] *See https://www.finra.org/rules-guidance/key-topics/covid-19/faq#qe.*

[7] At the outset of the COVID–19 pandemic, all FINRA qualification examinations were administered at test centers operated by Prometric. Based on the health and welfare concerns resulting from COVID–19, in March Prometric closed all of its test centers in the United States and Canada and began to slowly reopen some of them at limited capacity in May. Currently, Prometric has resumed testing in many of its United States and Canada test centers, at either full or limited occupancy, based on local and government mandates.

[8] Interpretation and Policy .03 under NYSE Chicago Article 6, Rule 13 is the corresponding rule to FINRA Rule 1210.04.

[9] FINRA Rule 1210.04 (Requirements for Registered Persons Functioning as Principals for a Limited Period) allows a member firm to designate certain individuals to function in a principal capacity for 120 calendar days before having to pass an appropriate principal qualification examination. Interpretation and Policy .03 under NYSE Chicago Article 6, Rule 13 provides the same allowance to Participants.

2020, to pass the appropriate principal qualification examination.

On September 25, 2020, NYSE Chicago filed with the Commission a proposed rule change for immediate effectiveness to extend the temporary relief provided via the FAQ by adopting temporary Interpretation and Policy .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE Chicago Article 6, Rule 13 (Registration Requirements).[10] Pursuant to this rule filing, individuals who were designated prior to September 3, 2020, to function as a principal under Interpretation and Policy .10 of NYSE Chicago Article 6, Rule 13 have until December 31, 2020, to pass the appropriate qualification examination.

The COVID–19 conditions necessitating the extension of relief provided in the FAQ and SR–NYSECHX–2020–28 persist and in fact appear to be worsening.[11] One of the impacts of COVID–19 continues to be serious interruptions in the administration of FINRA qualification examinations at Prometric test centers and the limited ability of individuals to sit for the examinations.[12] Although Prometric has been reopening its test centers, Prometric's safety practices mean that currently not all test centers are open, some of the open test centers are at limited capacity, and some open test centers are delivering only certain examinations that have been deemed essential by the local government.[13] Furthermore, Prometric has had to close some reopened test centers due to incidents of COVID–19 cases. The initial nationwide closure in March along with the inability to fully reopen all Prometric test centers due to COVID–19 have led to a significant backlog of individuals who are waiting to sit for FINRA examinations that are not available online, including the General Securities Principal Exam (Series 24).[14]

In addition, firms are continuing to experience operational challenges with much of their personnel working from home due to shelter-in-place orders, restrictions on businesses and social activity imposed in various states, and adherence to other social distancing guidelines consistent with the recommendations of public health officials.[15] As a result, firms continue to face potentially significant disruptions to their normal business operations that may include a limitation of in-person activities and staff absenteeism as a result of the health and welfare concerns stemming from COVID–19. Such potential disruptions may be further exacerbated and may even affect client services if firms cannot continue to keep principal positions filled as they may have difficulty finding other qualified individuals to transition into these roles or may need to reallocate employee time and resources away from other critical responsibilities at the firm.

These ongoing, extenuating circumstances make it impracticable for Participants to ensure that the individuals whom they have designated to function in a principal capacity, as set forth in Interpretation and Policy .03 under Article 6, Rule 13, are able to successfully sit for and pass an appropriate qualification examination within the 120-calendar day period required under the rule, or to find other qualified staff to fill this position. The ongoing circumstances also require individuals to be exposed to the health risks associated with taking an in-person examination, because the General Securities Principal examination is not available online. Therefore, NYSE Chicago is proposing to extend the effective date of the temporary relief provided through SR–NYSECHX–2020–28 until April 30, 2021. The proposed rule change would apply only to those individuals who were designated to function as a principal prior to January 1, 2021. Any individuals designated to function as a principal on or after January 1, 2021, would need to successfully pass an appropriate qualification examination within 120 days.

NYSE Chicago believes that this proposed continued extension of time is tailored to address the needs and constraints on a Participant's operations during the COVID–19 pandemic, without significantly compromising critical investor protection. The proposed extension of time will help to minimize the impact of COVID–19 on Participants by providing continued flexibility so that Participants can ensure that principal positions remain filled. The potential risks from the proposed extension of the 120-day period are mitigated by the Participant's continued requirement to supervise the activities of these designated individuals and ensure compliance with federal securities laws and regulations, as well as NYSE Chicago rules.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[16] in general, and furthers the objectives of Section 6(b)(5),[17] 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 proposed rule change is intended to minimize the impact of COVID–19 on Participant operations by extending the 120-day period certain individuals may function as a principal without having successfully passed an appropriate qualification examination pursuant to Interpretation and Policy .03 under Article 6, Rule 13 until April 30, 2021. The proposed rule change does not relieve Participants from maintaining, under the circumstances, a reasonably designed system to supervise the activities of their associated persons to achieve compliance with applicable securities laws and regulations, and with applicable NYSE Chicago rules that directly serve investor protection. In a time when faced with unique challenges resulting from the COVID–19 pandemic, NYSE Chicago believes that the proposed rule change is a sensible accommodation that will continue to afford Participants the ability to ensure that critical positions are filled and client services maintained, while continuing to serve and promote the protection of investors and the public interest in this unique environment.

[10] *See* Exchange Act Release No. 90114 (October 7, 2020), 85 FR 64556 (October 13, 2020) (Notice of Filing and Immediate Effectiveness of SR–NYSECHX–2020–28).

[11] *See, e.g.,* Meryl Kornfield, Jacqueline Dupree, Marisa Iati, Paulina Villegas, Siobhan O'Grady and Hamza Shaban, New daily coronavirus cases in U.S. rise to 145,000, latest all-time high, Wash. Post, November 11, 2020, *https://www.washingtonpost.com/nation/2020/11/11/coronavirus-covid-live-updates-us/.*

[12] Information about the continued impact of COVID–19 on FINRA-administered examinations is available at *https://www.finra.org/rules-guidance/key-topics/covid-19/exams.*

[13] Information from Prometric about its safety practices and the impact of COVID–19 on its operations is available at *https://www.prometric.com/corona-virus-update. See also supra* note 12.

[14] Earlier this year, an online test delivery service was launched for candidates seeking to take qualification examination remotely. Only certain qualification examinations are available online. *See supra* note 12. FINRA is considering making additional qualification examinations available remotely on a limited basis.

[15] *See, e.g.,* Centers for Disease Control and Prevention, How to Protect Yourself & Others, *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html.*

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

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. As set forth in SR–NYSECHX–2020–28, the proposed rule change is intended solely to extend temporary relief necessitated by the continued impacts of the COVID–19 pandemic and the related health and safety risks of conducting in-person activities. In its filing, FINRA notes that the proposed rule change is necessary to temporarily rebalance the attendant benefits and costs of the obligations under FINRA Rule 1210 in response to the impacts of the COVID–19 pandemic that would otherwise result if the temporary amendments were to expire on December 31, 2020.[18] The Exchange accordingly incorporates FINRA's abbreviated economic impact assessment by reference.

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. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[19] and Rule 19b–4(f)(6) thereunder.[20]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii), the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately upon filing. As noted above, the Exchange stated that the proposed extension of time will help minimize the impact of the COVID–19 outbreak on Participants' operations by allowing them to keep principal positions filled and minimizing disruptions to client services and other critical responsibilities. The Exchange further stated that the ongoing extenuating circumstances of the COVID–19 pandemic make it impractical to ensure that individuals designated to act in these capacities are able to take and pass the appropriate qualification examination during the 120-calendar day period required under the rules. The Exchange also explained that shelter-in-place orders, quarantining, restrictions on business and social activity and adherence to social distancing guidelines consistent with the recommendations of public officials remain in place in various states.[21] In addition, the Exchange observed that, following a nationwide closure of all test centers earlier in the year, some test centers have re-opened, but are operating at limited capacity or are only delivering certain examinations that have been deemed essential by the local government.[22] Although, as the Exchange noted, FINRA has launched an online test delivery service to help address this backlog, the General Securities Principal (Series 24) Examination is not available online.[23] Nevertheless, the Exchange explained that the proposed rule change will provide needed flexibility to ensure that these positions remain filled and is tailored to address the constraints on Participants' operations during the COVID–19 pandemic without significantly compromising critical investor protection.[24]

The Commission observes that the Exchange's proposal, like the FINRA Filing, provides only an extension to temporary relief from the requirement to pass certain qualification examinations within the 120-day period in the rules. As proposed, this relief would extend the 120-day period that certain individuals can function as principals through April 30, 2021. If a further extension of temporary relief from the rule requirements identified in this proposal beyond April 30, 2021 is required, the Exchange noted that it may submit a separate rule filing to extend the effectiveness of the temporary relief under these rules.[25] For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest.[26] Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[27]

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–NYSECHX–2020–33 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–2020–33. 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

[18] *See* FINRA Filing, 85 FR at 81260.

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[21] *See supra* note 15.

[22] *See supra* notes 12 and 13. The Exchange states that Prometric has also had to close some reopened test centers due to incidents of COVID–19 cases.

[23] *See supra* note 14. FINRA is considering making additional qualification examinations available remotely on a limited basis.

[24] The Exchange states that Participants remain subject to the continued requirement to supervise the activities of these designated individuals and ensure compliance with federal securities laws and regulations, as well as NYSE Chicago rules.

[25] *See supra* note 4.

[26] As noted above by NYSE Chicago, this proposal is an extension of temporary relief provided in a prior filing where NYSE Chicago also requested and the Commission granted a waiver of the 30-day operative delay. *See supra* note 10, 85 FR at 64558.

[27] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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–NYSECHX–2020–33 and should be submitted on or before January 19, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28666 Filed 12–28–20; 8:45 am]

BILLING CODE 8011–01–P

[28] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90739; File No. SR–NYSE–2020–90]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Amend the Requirement Applicable to Special Purpose Acquisition Companies Upon Consummation of a Business Combination Concerning Compliance With the Round Lot Shareholder Requirement

December 21, 2020.

On October 27, 2020, New York Stock Exchange LLC (''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 amend the requirement applicable to special purpose acquisition companies upon consummation of a business combination concerning compliance with the round lot shareholder requirement. The proposed rule change was published for comment in the **Federal Register** on November 16, 2020.[3] The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act [4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission will either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is December 31, 2020. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates February 14, 2021 as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSE–2020–90).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28654 Filed 12–28–20; 8:45 am]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 90382 (November 9, 2020), 85 FR 73121.

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90748; File No. SR–CBOE–2020–118]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To List and Trade Options That Overlie the Mini-Russell 2000 Index

December 21, 2020.

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 December 16, 2020, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''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 proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [3] and Rule 19b–4(f)(6) thereunder.[4] 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

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to list and trade options that overlie the Mini-Russell 2000 Index (''Mini-RUT'' or ''MRUT''). The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, 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

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

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 purpose of this proposed rule change is to amend certain rules in connection with the Exchange's plans to list and trade MRUT options.[5] MRUT options are options on the Mini-RUT Index, the value of which is 1/10th the value of the Russell 2000 (''RUT'') Index. The Russell 2000 Index measures the performance of small-cap segment of the U.S. equity universe. It is a subset of the Russell 3000 Index and includes approximately 2,000 U.S.-based securities based on a combination of their market cap and current index membership. The Russell 2000 Index is constructed to provide a comprehensive and unbiased small-cap barometer and is completely reconstituted annually to ensure larger stocks do not distort the performance and characteristics of the true small-cap opportunity set. The Russell 2000 Index is a commonly used benchmark for mutual funds that identify themselves as ''small-cap,'' and much like the S&P 500 Index (''SPX''), is used to benchmark large capitalization stocks. The Exchange understands that investors often use Russell 2000 Index-related products to diversify their portfolios and benefit from market trends. RUT options currently offer these benefits to investors but may be expensive given their larger notional value and are therefore primarily used by institutional market participants. By contrast, Mini-RUT options are a reduced-value options (1/10th) compared to RUT options that will offer individual investors lower cost options to obtain the potential benefits of options on the Russell 2000 Index. The Exchange believes that investors will benefit from the availability of Mini-RUT option contracts by making options overlying the higher-valued RUT Index more readily available as an investing tool and at more affordable prices for the average retail investor. The Exchange notes that it has previously listed and traded options on the Mini-RUT Index, which were delisted in 2010.[6]

Initial and Maintenance Listing Criteria

The Mini-RUT Index contains the same stocks with the same weightings as the RUT Index and will be calculated in the same manner as the RUT Index, with the exception of being 1/10th the value of the RUT Index. The RUT Index is a broad-based index currently authorized to list and trade on the Exchange, therefore the Mini-RUT Index also meets the definition of a broad-based index as set forth in Rule 4.11 (*i.e.,* an index designed to be representative of a stock market as a whole or of a range of companies in unrelated industries). The index reporting authority, Frank Russell Co., for the Mini-RUT Index is the same as for the RUT Index.[7] Additionally, the Mini-RUT Index (like the RUT Index) satisfies the initial listing criteria of a broad-based index, as set forth in Rule 4.10(f):[8]

(1) The index is broad-based, as defined in Rule 4.11;

(2) options will be A.M.-settled;

(3) the index is capitalization-weighted, modified capitalization-weighted, price-weighted, or equal dollar-weighted;[9]

(4) the index consists of 50 or more component securities;

(5) each component security that accounts for at least 95% of the weight of the index has a market capitalization of at least $75 million, except that for each component security that accounts for at least 65% of the weight of the index has a market capitalization of at least $100 million;

(6) component securities that account for at least 80% of the weight of the index satisfy the requirements of Rule 4.3 applicable to individual underlying securities;

(7) each component security that accounts for at least 1% of the weight of the index has an average daily trading volume of at least 90,000 shares during the last six-month period;

(8) no single component security accounts for more than 10% of the weight of the index, and the five highest weighted component securities in the index do not, in the aggregate, account for more than 33% of the weight of the index;

(9) each component security is an NMS stock;

(10) non-U.S. component securities (stocks or ADRs) that are not subject to comprehensive surveillance agreements do not, in the aggregate, represent more than 20% of the weight of the index;[10]

(11) the current index value is widely disseminated at least once every 15 seconds by the Options Price Reporting Authority, CTA/CQ, NIDS or one or more major market data vendors during the time options on the index are traded on the Exchange;

(12) The Exchange reasonably believes it has adequate system capacity to support the trading of options on the index, based on a calculation of the Exchange's current Independent System Capacity Advisor allocation and the number of new messages per second expected to be generated by options on such index;

(13) an equal dollar-weighted index is rebalanced at least once every calendar quarter;

(14) if an index is maintained by a broker-dealer, the index is calculated by a third-party who is not a broker-dealer, and the broker-dealer has erected an informational barrier around its personnel who have access to information concerning changes in, and adjustments to, the index;[11]

(15) The Exchange has written surveillance procedures in place with respect to surveillance of trading of options on the index.

Options on the Mini-RUT Index will also be subject to the maintenance listing standards set forth in Rule 4.10(g):

(1) The conditions stated in (1), (2), (3), (9), (10), (11), (12), (13), (14), and (15) above must continue to be satisfied and the conditions stated in (5), (6), (7), (8) above must be satisfied only as of the first day of January and July in each year;

(2) The total number of component securities in the index may not increase or decrease by more than 10% from the number of component securities in the index at the time of its initial listing.[12]

Expiration Months, Settlement, and Exercise Style

Consistent with existing rules for certain index options, including RUT options, the Exchange will allow up to six standard monthly expirations for MRUT options[13] as well as LEAPS.[14] The Exchange may list MRUT options as A.M.-, cash-settled contracts with European-style exercise.[15] A.M.-settlement is consistent with the generic

[5] The Exchange intends to file a Form 19b–4(e) with the Commission for Mini-Russell 2000 Index options pursuant to Rule 19b–4(e) of the Act.

[6] The Exchange notes that when it previously listed and traded reduced-value options on the RUT Index (at 1/10th and 1/5th the value), such options were multiply listed and available for trading on other options exchange. The Exchange now plans list and trade options on the Mini-RUT Index as a proprietary product.

[7] The proposed rule change adds the reporting authority for the Mini-RUT Index to Rule 4.12(c).

[8] The Exchange also notes that it may authorize for trading FLEX Options on Mini-RUT if it may authorize for trading a non-FLEX Options on Mini-RUT pursuant to Rule 4.10. See Rule 4.20.

[9] The Mini-RUT Index is capitalization-weighted.

[10] The Mini-RUT Index is comprised of only U.S. component securities.

[11] The index reporting authority, Frank Russell Co., is not a broker-dealer.

[12] As is the case with other index options authorized for listing and trading on Cboe Options, in the event the Mini-RUT Index fails to satisfy the maintenance listing standards, the Exchange will not open for trading any additional series of options of that class unless such failure is determined by the Exchange not to be significant and the Commission concurs in that determination, or unless the continued listing of that class of index options has been approved by the Securities and Exchange Commission (the ''Commission'') under Section 19(b)(2) of the Securities and Exchange Act (the ''Act'').

[13] *See* Rule 4.13(a).

[14] Pursuant to Rule 4.13(b), index LEAPS may expire 12–180 months from the date of issuance.

[15] *See* Rule 4.13(a)(3).

listing criteria for broad-based indexes.[16] The Exchange proposes to amend Rule 4.13(a)(4) to add Mini-RUT Index options to the list of other permissible A.M.-settled options, including RUT options. Also, European-style exercise is consistent with many index options, as set forth in Rule 4.13(a)(3). Standard third-Friday-of-the-month (''Expiration Friday'') RUT and MRUT options, as proposed, are typically A.M.-settled with European-style exercise. The Exchange proposes to amend Rule 4.13(a)(3) to add Mini-RUT Index options to the list of other European-style index options, including RUT options. As discussed above, the Mini-RUT Index consists of all components that are included in the RUT Index but is 1/10th the value of the RUT Index. Because of the relation between the Mini-RUT Index and the RUT Index, both of which market participants may use as a hedging vehicle to meet their investment needs in connection with RUT Index-related products and cash positions, the Exchange believes it is appropriate to permit the same number of monthly expirations for MRUT options as RUT options and to list MRUT options with the same standard settlement and exercise style as RUT options.

Quarterly and Nonstandard Expirations

In addition to this, pursuant to Rule 4.13(c), the Exchange may open for trading Quarterly Index Expirations (''QIXs'') on certain indexes, including the RUT Index. QIXs are index option contracts that expire on the last business day of a calendar quarter. The Exchange proposes to amend Rule 4.13(c) to include QIXs on the Mini-RUT Index. The Exchange notes that there may be there may be up to eight near-term QIXs open for trading in a class and that QIXs are P.M.-settled. Also, the Exchange's Nonstandard Expirations Pilot Program currently allows it to list Weekly Expirations and End of Month (''EOM'') Expirations on any broad-based index.[17] Weekly and EOM options are P.M., cash-settled and have European-style exercise. The Exchange intends to list MRUT options pursuant to the Nonstandard Expirations Pilot Program and notes that it currently lists RUT options with Nonstandard Expirations pursuant to the program. As stated above, due to the relation between the Mini-RUT Index and the RUT Index, the Exchange believes it is appropriate to list MRUT options with the same available expirations as RUT options. Further, the Exchange notes that Rule 5.1(b)(2)(C), which governs trading days and hours, currently provides that on their last trading day, Regular Trading Hours for index options with Nonstandard Expirations and QIXs, may be effected on the Exchange between 9:30 a.m. and 4:00 p.m. Eastern Time[18] (as opposed to the 9:30 a.m. to 4:15 p.m. Regular Trading Hours for options with those expirations that are non-expiring). Therefore, expiring MRUT options with Nonstandard Expirations and QIXs will also be opened for trading from 9:30 a.m. to 4:00 p.m. on their last trading day pursuant to Rule 5.1(b)(2)(C).

Minimum Increments

The Exchange also proposes to amend Rule 5.4 in connection with minimum increments for bids and offers for MRUT options. Currently, the minimum increments for bids and offers for options on the iShares Russell 2000 ETF (''IWM''), which is an exchange-traded fund (''ETF'') that tracks the performance of the RUT Index, is $0.01 regardless of whether option series is quoted above, at, or below $3. Because both Mini-RUT options and IWM options prices are based, overall, on 1/10th the value of the RUT Index, the Exchange believes that it is important that these products have the same minimum increments to promote consistency and competition. As such, the Exchange proposes that for so long as IWM options participate in the Penny Interval Program the minimum increment for MRUT options will be $0.01 at all prices. The Exchange notes that this is consistent with the minimum increment for Mini-XSP, which is likewise $0.01 so long as options on the SPDR S&P 500 ETF (''SPY''), an ETF that tracks the SPX Index, participate in the Penny Interval Program, as both Mini-XSP and SPY options are by and large based on 1/10th the value of the SPX Index.[19]

Exercise Prices

The Exchange also proposes to adopt rules regarding permissible exercise prices for Mini-RUT options. Specifically, the proposed rule change amends Interpretation and Policy .01(i)[20] to Rule 4.13 provide that, notwithstanding Interpretation and Policies .01(a),[21] .01(d)[22] and .04[23] to Rule 4.13, the exercise prices for new and additional series of Mini-RUT options shall be listed subject to the following:

(1) If the current value[24] of the Mini-RUT is less than or equal to 20, the Exchange shall not list series with an exercise price of more than 100% above or below the current value of the Mini-RUT;

(2) if the current value of the Mini-RUT is greater than 20, the Exchange shall not list series with an exercise

[16] *See* Rule 4.10(f)(2).

[17] *See* Rule 4.13(e). The Exchange notes that it will provide the Commission with the annual report analyzing volume and open interest of MRUT Weekly and EOM options, as well as information and analysis of Weekly and EOM trading patterns, and index price volatility and share trading activity for series that exceed minimum parameters, pursuant to the Nonstandard Expirations Pilot approval order. *See* Securities Exchange Act Release 62911 (September 14, 2010), 75 FR 57539 (September 21, 2010) (SR–CBOE–2009–075).

[18] *See* Rule 1.6, which states that unless otherwise specified, all times in the Rules are Eastern Time.

[19] *See* Securities Exchange Act Release No. 70087 (July 31, 2013), 78 FR 47809 (August 6, 2013) (SR–CBOE–2013–055).

[20] The Exchange notes that, currently, Interpretation and Policy .01(i) and Interpretation and Policy .01(a) houses the exercise price provisions applicable to Mini-RUT options that were in place when the Exchange prior listed and traded options on the Mini-RUT Index, which were multiply listed at the time, and thus based on the strike price interval rules of other options exchanges. *See* Securities Exchange Act Release No. 60977 (November 10, 2009), 74 FR 59592 (November 18, 2009) (SR–CBOE–2009–086). The Exchange proposes to remove these former strike interval price provisions and implement strike price interval provisions that are consistent with those that govern Mini-XSP options, a proprietary mini-index option like Mini-RUT options today.

[21] Interpretation and Policy .01(a) to Rule 4.13 provides that the interval between strike prices will be no less than $5.00; provided, the interval between strike prices will be no less than $2.50 for certain classes of index options.

[22] Interpretation and Policy .01(d) to Rule 4.13 provides that when new series of index options with a new expiration date are opened for trading, or when additional series of index options in an existing expiration date are opened for trading as the current value of the underlying index to which such series relate moves substantially from the exercise prices of series already opened, the exercise prices of such new or additional series shall be reasonably related to the current value of the underlying index at the time such series are first opened for trading.

[23] Interpretation and Policy .04 to Rule 4.13 provides that the Exchange may open for trading additional series of the same class of index options as the current index value of the underlying index moves substantially from the exercise price of those index options that already have been opened for trading on the Exchange. The exercise price of each series of index options opened for trading on the Exchange shall be reasonably related to the current index value of the underlying index to which such series relates at or about the time such series of options is first opened for trading on the Exchange. The term ''reasonably related to the current index value of the underlying index'' means that the exercise price is within 30% of the current index value. The Exchange may also open for trading additional series of index options that are more than 30% away from the current index value, provided that demonstrated customer interest exists for such series, as expressed by institutional, corporate, or individual customers or their brokers.

[24] The proposed rule change makes this value explicit by updating Interpretation and Policy .06 to Rule 4.13 to provide that the current index value current index value of reduced-value options on the S&P 500 Stock Index (''Mini-SPX options'') and reduced-value options on the Russell 2000 Index (''Mini-RUT options'') shall be one-tenth (1/10th) the value of the applicable underlying index reported by the Reporting Authority.

price of more than 50% above or below the current value of the Mini-RUT; and

(3) the lowest strike price interval that may be listed for standard Mini-RUT options, including LEAPS, is $1, and the lowest strike price interval that may be listed for series of Mini-RUT listed under the Nonstandard Expirations Pilot Program in Rule 4.13(e) and for QIX Mini-RUT options is $0.50.

Pursuant to current Interpretation and Policy .01(a) to Rule 4.13, index options have strike price intervals of $5 or greater. This includes strike price intervals for options on the RUT Index.[25] The Exchange believes that MRUT options, which have 1/10th the value of the RUT options, should therefore be permitted smaller strike price intervals than RUT options. As stated, MRUT options will allow smaller-scale investors to gain broad exposure to the RUT options market and hedge RUT Index-related positions with a manageably sized contract and the proposed finer strike prices for MRUT options will permit strike prices accordingly aligned with RUT options. For example, if the RUT Index value was 2700, then the Mini-RUT Index value would be 270. RUT options would be permitted to be listed with strikes of 2710, 2720, and 2730. Corresponding standard and QIX MRUT options strikes, as proposed, would be 271, 272, and 273; as opposed to strikes of only 270 and 275, as permitted under the current Rule. The proposed $1 strike interval for standard options will permit the listing of series with strikes that correspond to RUT option strikes. The Exchange, however, recognizes the proposed $1 strike approach for MRUT options alone does not achieve full harmonization between strikes in MRUT options and RUT options. For example, if there was a 2715 strike in RUT options, the $1 strike interval would not permit the Exchange to list a corresponding 271.5 strike in MRUT options. Therefore, the Exchange also proposes $0.50 strike price intervals for MRUT options with Nonstandard Expirations and for QIX MRUT options. The Exchange believes that smaller strike intervals for MRUT options with Nonstandard and QIX expirations (all of which are ''nonstandard'' expirations with P.M.-settlement, and, at times, have expirations that coincide)[26] will provide market participants with more efficient hedging and trading opportunities. The proposed $0.05 strike setting regime would permit strikes on a more refined scale that, at times, will more closely reflect values in the underlying RUT Index and allow market participants to roll open positions from a lower strike to a higher strike in conjunction with the price movement of the underlying.

The Exchange notes that the proposed strike interval prices for MRUT options are substantively the same as those for options on the Mini-SPX Index (which are 1/10th the value of SPX options).[27] The Exchange believes these permissible strike prices will permit the Exchange to list MRUT options with strikes that closely reflect the current values of the RUT Index, as they provide more flexibility and will allow the Exchange to better respond to customer demand for MRUT option strike prices that relate to current RUT Index values. In addition, the Exchange believes that because the number of strikes that may be listed will be contained by the percentages above and below the current Mini-RUT Index value (as further discussed below) there is no need to restrict the use of $1 or $0.50 strike price intervals based on the amount of the strike price. Rather, the Exchange may determine to list strikes in $1 or $0.50 intervals, as applicable, or higher based on the level of the Mini-RUT Index, customer demand and the need to list scaled strikes in reduced-value MRUT options that correspond to strikes in full-value RUT options. The Exchange believes the proposed strike price intervals for MRUT options will allow retail investors to better use MRUT options to gain exposure to the RUT options market, hedge their positions in RUT Index-related instruments and cash positions in the RUT Index, and tailor their investment strategies with the same precision as market participants in RUT options.

Additionally, the proposed strike price range limitations for MRUT options are closely aligned with the strike price range limitations for equity and ETF options pursuant to the Rule 4.7(b) and the Options Listing Procedure Plan (''OLPP'').[28] The OLPP and Rule 4.7(b) set forth exercise price range limitations for equity and ETF options which differ from the general exercise price range limitations for index options set forth in Interpretations and Policies .01(d) and .04 to Rule 4.13. The Exchange also notes that the exercise price range limitations currently in place for Mini-SPX options differ from the limitations in Interpretations and Policies .01(d) and .04 to Rule 4.13 and, instead, are consistent with the OLPP limitations.[29] Interpretation and Policy .01(d) requires the exercise price of each series of index options to be reasonably related to the current index value of the underlying index to which the series relates at time the series is first opened for trading on the Exchange. ''Reasonably related to the current index value of the underlying index'' means the exercise price must be within 30% of the current index value.[30] Pursuant to Interpretation and Policy .04 to Rule 4.13, the Exchange may also open for trading additional series of index options that are more than 30% away from the current index value, provided that demonstrated customer interest exists for the series. Therefore, if the value of the Mini-RUT Index is $200, under the current Rules providing general exercise price range limitations for index options, the Exchange may only list strikes ranging from $140 to $260 (*i.e.,* 30% above and below the current value). Pursuant to the OLPP and Rule 4.7(b) strike price limitations for equity and ETF options, however, if the underlying price of an equity or ETF option is $200, the Exchange is permitted to list strikes ranging from $100 through $300 (*i.e.,* 50% above and below the current value). Therefore, by applying the OLPP limitations, as proposed, if the value of the Mini-RUT Index is $200, the Exchange will be able to list strikes ranging 50% above and below the current value of the index. The Exchange believes the proposed exercise price limitations for MRUT options will put such options on equal standing with equity and ETF options, as well as Mini-SPX options, in connection with exercise price limitations and, as a result, will allow the Exchange to list strikes that more closely reflect the current values in the RUT Index and to better respond to customer demand for MRUT options strike prices that better relate to current RUT Index values.

Finally, the Exchange notes that the proposed rule change removes current Interpretation and Policy .01(i)(1) through (4) to Rule 4.13, as well as the

[25] Unless the strike price is $200 or less, then the intervals may be no less than $2.50. *See* Interpretation and Policy .01(a) to Rule 4.13.

[26] For example, every third EOM expiration corresponds to a quarterly expiration.

[27] *See* Interpretation and Policy .10 to Rule 4.13; *and see* Securities Exchange Act Release Nos. 72482 (June 26, 2014), 79 FR 37825 (July 2, 2014) (SR–CBOE–2014–051) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to Strike Settings for Mini-S&P 500 Index Options); and 72991 (September 4, 2014), 79 FR 53794 (September 10, 2014) (SR–CBOE–2014–069) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to XSP and DJX Strike Price Listings). The Exchange notes that it does not propose to add MRUT options to the Short Term Options Series Program, and therefore, does not include strike interval prices for these options in the proposed rule as it does for XSP options.

[28] *See* Rule 4.7(b)

[29] *See supra* note 27.

[30] *See supra* note 23.

references to reduced-value Russell 2000 Index options in Interpretation and Policy .01(a) to Rule 4.13, which contain the strike price provisions and delisting policy applicable to the multiply listed Mini-RUT options that were previously listed on the Exchange.[31] The Exchange notes that other exchanges that also listed Mini-RUT options at that time adopted substantially the same strike price rules and delisting policies for Mini-RUT options as provided in current Interpretation and Policy .01(i)(1) through (4).[32] For the reasons described above, the Exchange wishes to adopt strike price intervals and limitations that are consistent with those for Mini-SPX options, which is a proprietary product traded exclusively on the Exchange, as will be the case for the MRUT options that the Exchange now proposes to list and trade.[33] The Exchange notes that its general delisting policies provided in Rule 4.5 will apply to MRUT options in the same manner that they currently apply to other index options, including Mini-XSP, pursuant Interpretation and Policy .01 to Rule 4.13.[34]

Position and Exercise Limits

Rule 8.31 governs position limits for broad-based index options, and currently provides that there shall be no position limits for broad-based index option contracts (including reduced-value option contracts) on, among other broad-based index option contracts, the RUT Index. Rule 8.42 governs exercise limits and Rule 8.42(b) specifically provides that there shall be no exercise limits for broad-based index options (including reduced-value option contracts) on, among other broad-based index option contracts, the RUT Index. Therefore, there will be no position or exercise limits for Mini-RUT option contracts upon their listing and trading as they are reduced-value option contracts on the RUT Index. The Exchange notes that the Commission has previously approved the Exchange Rules codifying that there are no position or exercise limits on reduced-value option contracts, the filing of which specifically included reduced-value option contracts on the RUT Index.[35]

Appointment Weights

The Exchange proposes to add options on the Mini-RUT Index as a Tier AA class with a Market-Maker appointment weight of .001.[36] This is the same appointment weight as a majority of the other Tier AA options classes. The Exchange determines appointment weights of Tier AA classes based on several factors, including, but not limited to, competitive forces and trading volume. The Exchange believes the proposed initial appointment weight of .001 for Mini-RUT Index options will foster competition by incentivizing Market-Makers to obtain an appointment in these newly listed options, which may increase liquidity in the new class. The Exchange notes that it recently listed options on the S&P 500 ESG Index, to which it also assigned an appointment weight of .001 for the same reasons—to incentivize Market-Makers to obtain appointments and provide increased liquidity in a newly listed class.[37]

Capacity

The Exchange has analyzed its capacity and represents that it believes the Exchange and OPRA have the necessary systems capacity to handle the additional traffic associated with the listing of new series that may result from the introduction of the Mini-RUT Index options up to the proposed number of possible expirations. Because the proposal is limited to one class, the Exchange believes any additional traffic that may be generated from the introduction of Mini-RUT Index options will be manageable.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[38] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[39] requirements that the rules of an 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 regulating, clearing, settling, processing information with respect to, and 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[40] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that the proposal to list and trade options on the Mini-RUT Index will remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest, because the Exchange believes that the proposed rule change will further the Exchange's goal of introducing innovative products to the marketplace. The Exchange particularly believes that the proposed rule change will benefit investors, as the Exchange believes there is unmet market demand for exchange-listed security options that track the RUT Index. ETFs based on the RUT Index (*e.g.,* IWM and Vanguard Russell 2000 ETF (''VTWO'')) and E-mini RUT Index futures products are listed and traded on other exchanges. The Exchange believes that Mini-RUT Index options are designed to provide additional, relatively low-cost opportunities for investors, particularly retail investors, to hedge or speculate on the market risk and meet their investment needs associated with the RUT Index and RUT Index-linked products by listing an option on 1/10th the value of this index. More specifically, the lower cost of MRUT options is designed to allow investors to hedge their portfolios with a smaller

[31] These were delisted in 2010.

[32] *See e.g.,* Securities and Exchange Act Release Nos. 60977 (November 10, 2009), 74 FR 59592 (November 18, 2009) (SR–CBOE–2009–086); and 60637 (September 9, 2009), 74 FR 47634 (September 16, 2009) (SR–Phlx–2009–77).

[33] *See supra* note 6.

[34] The Exchange notes that the proposed rule change corrects the reference to Rule 4.5 in Interpretation and Policy .01 to Rule 4.13, which was a carry-over error as a result of the migration of the Exchange's Rulebook in 2019. *See* Securities and Exchange Act Release No. 87337 (October 17, 2020), 84 FR 56879 (October 23, 2019) (SR–CBOE–2019–092).

[35] *See* Securities Exchange Release No. 56350 (September 4, 2007), 72 FR 51878 (September 11, 2007) (SR–CBOE–2007–79) (Order Granting Accelerated Approval of Proposed Rule Change and Amendment No. 1 Thereto To Eliminate Position and Exercise Limits for Options on the Russell 2000 Index, and To Specify That Certain Reduced-Value Options on Broad-Based Security Indexes Have No Position and Exercise Limits).

[36] *See* Rule 5.50(g). RUT Index options and IWM options are also in Tier AA. While the appointment weights of Tier AA classes are not subject to quarterly rebalancing under Rule 5.50(g)(1), the Exchange regularly reviews the appointment weights of Tier AA classes to ensure that they continue to be appropriate. The Exchange determines appointment weights of Tier AA classes based on several factors, including, but not limited to, competitive forces and trading volume.

[37] *See* Securities Exchange Act Release No. 89749 (September 2, 2020), 85 FR 55723 (September 9, 2020) (SR–CBOE–2020–080) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To List and Trade Options That Overlie the S&P 500 ESG Index).

[38] 15 U.S.C. 78f(b).

[39] 15 U.S.C. 78f(b)(5).

[40] *Id.*

outlay of capital and may facilitate overall investor participation in the market for RUT options, which should, in turn, help to maintain the depth and liquidity of the market for RUT options, to the benefit of investors.

The Exchange believes the proposed rule change will remove impediments to and perfect the mechanism of a free and open market and a national market system, because it is consistent with current Rules, previously filed with the Commission. Particularly, the Mini-RUT Index options satisfy the initial listing standards for broad-based indexes in the Exchange's current Rules, which the Commission previously approved as consistent with Act.[41] The proposed rule change to add the Mini-RUT Index to the table regarding reporting authorities for indexes, to the list of European-style exercise index options, to the list of A.M.-settled index options and to the list of index options with QIXs, to add MRUT options to the Nonstandard Expiration Pilot Program,[42] to permit the standard number of expirations for MRUT options, and to allow for no position or exercise limits to apply to MRUT option contracts (as previously approved by the Commission specifically for reduced-value option contract on the RUT Index),[43] is consistent with existing Rules governing broad-based index options currently authorized and listed for trading on the Exchange. The Exchange notes that with respect to these changes, RUT options currently have the same reporting authority, number of permissible expirations, standard (A.M.) settlement and exercise style, may open QIXs for trading, are part of the Nonstandard Expiration Pilot Program, and are not subject to position or exercise limits.[44] The Exchange has observed no trading or capacity issues in RUT trading given the number and type of permissible expirations, standard settlement, European-style exercise and application of no position and exercise limits. Because the same components comprise the RUT Index and the Mini-RUT Index, market participants may use either as a hedging vehicle to meet their investment needs in connection with RUT Index-related products and cash positions, and, therefore, the Exchange believes it is appropriate to provide generally consistent features between the full- and reduced-value options on the RUT Index.

The Exchange believes that adopting a minimum increment of $0.01 for MRUT options, aligned with the minimum increment for IWM options (which is also 1/10th the value of the RUT Index), will remove impediments to and perfect the mechanism of a free and open market and national market system by promoting competition and providing consistency for market participants that participate in products that track the price of the RUT Index. The Exchange believes that aligning the minimum increments for MRUT options with those for IWM options will allow market participants to quote in smaller minimum increments of $0.01, which may provide the opportunity for reduced spreads, thereby lowering costs to investors.[45] This proposed rule change is also consistent with the minimum increments for Mini-XSP, which are $0.01 and likewise aligned with options on the ETF (SPY) that tracks the same underlying index (SPX) and is similarly 1/10th the value of the SPX Index.[46]

With respect to the proposed permissible exercise prices for MRUT options, the proposed rule change is designed to closely align MRUT option strike prices with those of RUT option strike prices. The proposed exercise price regime will provide the Exchange with the flexibility to respond to customer demand for MRUT option strike prices that relate to current RUT Index values and closely reflect values in the underlying RUT Index, which will allow investors to roll open positions from a lower strike to a higher strike in conjunction with the price movement of the underlying. The Exchange believes that the proposed strike prices will afford investors important hedging and trading opportunities by allowing investors (particularly, retail investors) to fine-tune their use of MRUT options to gain exposure to the RUT options market, hedge RUT-Index-related positions, and manage their portfolios. The proposed rule change will add consistency to the RUT Index options markets and will help ensure that investors in MRUT options are not at a disadvantage with respect to larger institutional investors in RUT options. The Exchange believes that because the number of strikes that may be listed will be contained by the percentages above and below the current Mini-RUT Index value, the number of MRUT strikes that may be listed will not be unbounded. The proposed MRUT strike prices and limitations are substantively identical to the strike prices and limitations for XSP options, a similar reduced-value contract on a broad-based index. The Exchange believes that the proposed strike price regime for MRUT options, like the current regime for XSP options, will benefit investors by giving them increased flexibility and the ability to more closely tailor their investment and hedging decisions to their needs.[47] Additionally, the Exchange believes that it is appropriate to delete the strike price and delisting provisions that were applicable to multiply listed Mini-RUT options, previously listed on multiple exchanges, including the Exchange, and, instead, adopt strike price intervals that are consistent with those for Mini-SPX options, which are listed exclusively on the Exchange, as will also be the case for MRUT options. The Exchange notes that its general delisting policies provided in Rule 4.5 will apply to MRUT options in the same manner that they currently apply to other index options, including Mini-XSP.

The Exchange also believes the proposed initial low appointment weight for Mini-RUT Index options promotes competition and efficiency by incentivizing more Market-Makers to obtain an appointment in the newly listed class. The Exchange believes this may result in liquidity and competitive pricing in this class, which ultimately benefits investors. The Exchange does not believe that the proposed rule change is unfairly discriminatory, as the appointment weight will apply to all Market-Makers in this class. Additionally, the proposed appointment weight is the same as the appointment weight for a majority of other Tier AA options classes, as well as a recently listed index option class to likewise promote Market-Maker appointment, liquidity and competitive pricing in that class.[48]

Finally, the Exchange represents that it has the necessary systems capacity to support the new option series given these proposed specifications. The Exchange believes that its existing surveillance and reporting safeguards are designed to deter and detect possible manipulative behavior which might arise from listing and trading Mini-RUT options. The Exchange further notes that current Exchange Rules that apply to the trading of other index options traded on the Exchange, such as RUT options, will also apply to the trading of Mini-RUT options, such as, for example, Exchange

[41] *See* Securities Exchange Act Release No. 34–53266 (February 9, 2006), 71 FR 8321 (February 16, 2006) (SR–CBOE–2005–59) (Order Approving Generic Listing Standards for Options on Broad-based Indexes).

[42] *See supra* note 17.

[43] *See supra* note 35.

[44] *See* Rules 4.12(c), 4.13(a)(2) through (4), 4.13(c), Rule 8.31, and Rule 8.42(b).

[45] *See supra* note 19.

[46] *See id.*

[47] *See supra* note 27.

[48] *See* Rule 5.50(g); *and see supra* note 37.

Rules governing customer accounts, margin requirements and trading halt procedures.

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 does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act as options on the Mini-RUT Index satisfy initial listing standards set forth in the Rules, and MRUT options will be equally available to all market participants who wish to trade such options. The proposed number and type of expirations (*i.e.,* standard, Nonstandard, and QIXs), settlement (standard A.M.), exercise style, application of no position and exercise limits, minimum increments, and strike price intervals and limitations will apply in the same manner to all options traded on the Mini-RUT Index. In addition to this, the Exchange notes that the proposed initial low Market-Maker appointment cost for Mini-RUT Index options will apply equally to all Market-Makers with an appointment in MRUT options and will promote competition by incentivizing more Market-Makers to obtain an appointment in the newly listed class, resulting in liquidity and competitive pricing within the class.

The Exchange does not believe that the proposal to list and trade options on the Mini-RUT Index, and the proposed rules governing the trading of MRUT options on the Exchange, will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because options on the RUT Index, including reduced-value options as proposed, are proprietary Exchange products. To the extent that the advent of MRUT options trading on the Exchange may make the Exchange a more attractive marketplace to market participants at other exchanges, such market participants are free to elect to become market participants on the Exchange. As noted above, other option products related to the RUT Index, such as ETFs based on the RUT Index (*e.g.,* IWM and VTWO) and E-mini RUT Index futures products, are listed for trading on other exchanges.

The Exchange believes that the proposal to list and trade MRUT options and the proposed rules that will govern the trading of MRUT options on the Exchange will promote competition by providing investors with a relatively low-cost means to hedge their portfolios with a smaller outlay of capital and may facilitate overall participation in the market for RUT options, which may help to maintain the depth and liquidity of the market for RUT options, to the benefit of all investors.

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

Because the foregoing proposed rule change does not:

A. Significantly affect the protection of investors or the public interest;

B. impose any significant burden on competition; and

C. become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [49] and Rule 19b–4(f)(6) [50] 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 will 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–CBOE–2020–118 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–CBOE–2020–118. 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–CBOE–2020–118 and should be submitted on or before January 19, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[51]

J. Matthew DeLesDernier,

Assistant Secretary.

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[49] 15 U.S.C. 78s(b)(3)(A).

[50] 17 CFR 240.19b–4(f)(6).

[51] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90747; File No. SR–DTC–2020–019]

Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing of Proposed Rule Change To Update the Distributions Service Guide

December 21, 2020.

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 December 9, 2020, The Depository Trust Company (''DTC'') 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 clearing agency. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change[3] consists of amendments to the DTC Corporate Actions Distributions Service Guide (''Distributions Guide'')[4] to (i) more clearly explain the interim accounting process, generally; (ii) provide an explanation for the interim accounting process for a security being delisted; (iii) change how DTC manages interim accounting when an ex-date[5] is changed due to an unscheduled closure of a stock exchange; (iv) remove the statements that (A) DTC's U.S. Tax Withholding (''UTW'') service is available to subaccounts of U.S. Participants, and (B) users of the UTW service must enter into a Withholding Agent Agreement; (v) update the copyright date in the Important Legal Information section; and (vi) make certain conforming and technical changes, as described in greater detail below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to update the Distributions Guide to (i) more clearly explain the interim accounting process, generally; (ii) provide an explanation for the interim accounting process for a security being delisted; (iii) change how DTC manages interim accounting when an ex-date is changed due to an unscheduled closure of a stock exchange; (iv) remove the statements that (A) the UTW service is available to subaccounts of U.S. Participants, and (B) users of the UTW service must enter into a Withholding Agent Agreement; (v) update the copyright date in the Important Legal Information section; and (vi) make certain conforming and technical changes.

Interim Accounting

Interim accounting is an important part of the entitlements and allocations process for distributions. The interim period (also referred to as the due bill period) is the period during which a settling trade has due bills attached to it. A due bill is an indication of a seller's obligation to deliver a pending distribution (*e.g.,* cash dividend, stock dividend, interest payment, etc.) to the buyer in a securities transaction. For distributions that are the subject of a due bill, the interim period extends from the Interim Accounting Start Date (*i.e.,* record date +1)[6] up to the Due Bill Redemption Date (which is typically ex-date +1 for equities and payable date −1 for debt).[7]

Normally, the registered holder of a security on the close of business on the record date is entitled to the distribution. There are times, however, when that is not the case. Such times generally fall into two categories. First, for equity issues, there are times when the listed exchange will declare an ex-date that is not one business day prior to the record date (*e.g.,* an ex-date that equals payable date +1). At such times, a buyer is entitled to the distribution when the registered holder of an equity issue sells the security prior to the ex-date. Second, for most bonds, the buyer of the security is entitled to the interest payment (*i.e.,* the distribution) on trades that settle up to and including the day before the payable date, even though the buyer is not the record date holder.

Without DTC's interim accounting process, due-bill processing can be more cumbersome. For example, trades that settle after the record date ''with distribution,'' thus entitling the buyer to the distribution, will have a due bill attached to them (*i.e.,* the seller owes the buyer the distribution). Without DTC's interim accounting process, the distribution will need to be handled between the seller and the buyer outside of DTC's distribution processing service, potentially in the form of a payment order, wire or postdated check equal to the amount of the distribution.

With DTC's interim accounting process, during a due bill period, DTC will track all settled activity, where the receiver (typically a buyer) is entitled to a distribution, and adjust Participants' record-date positions, crediting the receiver (typically a buyer) and debiting the deliverer (typically a seller) the distribution amount.[8] This process helps ensure accurate payment on the payable date and eliminate time-consuming, costly paper processing.

In order to provide a clearer understanding of the interim accounting process, generally, DTC proposes to update the Distributions Guide to better reflect the description provided here.

Interim Accounting on a Security Being Delisted

Listed exchanges are often unable to announce an ex-date that is on or after the date the corresponding security is being delisted. In these instances, if the listed exchange does not declare an ex-date, but it provides direction that trades in that security up to a specified date include the distribution, then DTC will capture interim accounting based on the exchange's direction.[9]

Following an exchange's direction in such circumstances has been a longstanding DTC practice; however, that practice is not clearly described in the Distributions Guide. As such, DTC proposes to update the Distributions Guide to reflect the description provided here.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Capitalized terms not defined herein are defined in the Rules, By-Laws and Organization Certificate of DTC (''Rules'') *available at http://www.dtcc.com/~/media/Files/Downloads/legal/rules/dtc_rules.pdf.*

[4] *Available at http://www.dtcc.com/~/media/Files/Downloads/legal/service-guides/Service%20Guide%20Distributions.pdf.*

[5] The ''ex-date'' or ''ex-dividend date'' is the day the stock starts trading without the value of its next dividend payment.

[6] The record date is the cut-off date used to determine which shareholders are entitled to a corporate dividend. The record date will usually be the day following the ex-date.

[7] The payable date refers to the date that any declared stock dividends are due to be paid out. Investors who purchased their stock before the ex-date are eligible to receive dividends on the payable date.

[8] It is important to note that the physical movement of securities (such as, deposits, withdrawals-by-transfer, and certificates-on-demand) are not transactions that are included in the interim accounting process; thus, they do not result in adjustments between Participants.

[9] Please note that on the rare occasion that a corporate action event (*e.g.,* a merger) would occur during an interim period, special processing arrangements with the industry may be required.

Interim Accounting for an Ex-Date Change Due to Unscheduled Closing of a Stock Exchange

Occasionally, there is an unscheduled closing of one or more stock exchanges (*e.g.,* a national day of mourning, an event causing significant market disruption or regional impact, etc.). During an unscheduled closing, a listed exchange will typically move ex-dates that were scheduled for that date to the next business day that the exchange is open, which is usually the record date. Such a move is necessary because ex-dates must occur on a business day that the listed exchange is open.[10]

Currently, when there is an unscheduled closing of a stock exchange and an ex-date is moved, DTC continues to apply the interim accounting process described above. However, because ex-date and record date now would be the same date (due to the exchange moving the ex-date to account for the unscheduled closure) and because the interim accounting process is based on a two-day settlement cycle, this results in due bills being applied to activity one day after record date. This, however, is not the intended result of the exchanges moving the ex-date. It is DTC's general understanding that when there is an unscheduled closure, the intent is for the last day of trading with a due bill to be the business day prior to the unscheduled closure because there should not be any executed trades in the security on the day of closure.[11]

As a result of DTC continuing to apply its standard interim accounting process under such circumstances, Participants must then perform adjustments to reverse the interim accounting on activity to which the interim accounting should not have applied, creating unnecessary work for the Participants. Therefore, to avoid the need for such adjustments, DTC proposes to no longer let the moving of an ex-date impact the interim accounting process when the change is the result of an unexpected closure of a stock exchange.

UTW Service

DTC's UTW service helps ensure that the appropriate non-resident alien withholding tax is applied to U.S.-sourced income paid to DTC's direct non-U.S. Participants. The applicable withholding tax is determined based on the type of income being paid along with the tax forms provided by the Participant.

The Distributions Guide currently states that the UTW service is available to non-U.S. Participants, ''*including subaccounts of U.S. participants*'' and that ''*Users [of the UTW service] must enter into a Withholding Agent Agreement*'' (emphasis added).[12] However, after performing a periodic review of the Distributions Guide, DTC determined that these two statements need to be removed.

Pursuant to U.S. tax regulations,[13] DTC, as a withholding agent, is obligated to withhold U.S. tax on payments it makes to its non-U.S. Participants. This obligation does not apply to U.S. Participants, only non-U.S. Participants. It is DTC's understanding that U.S. tax regulations do not contemplate a process under which DTC would withhold tax obligations of its U.S. Participants. However, DTC's obligation does apply regardless of whether there is or is not an agreement between DTC and its Participants to do so. Therefore, DTC proposes to remove (A) the ''including subaccounts of U.S. participants'' statement because DTC is not able to do so, and (B) the Withholding Agent Agreement statement because such an agreement is unnecessary.

Changes to the Rules

To effectuate the proposed changes to the Distributions Guide described above, (i) the following subsections of the ''Interim Accounting'' section would be updated to provide a clearer description of the interim accounting process, generally, including conforming and technical changes: ''Overview,'' ''Reasons for Interim Accounting,'' ''Without DTC's Interim Accounting,'' ''With DTC's Interim Accounting,'' and ''Interim Accounting Usage;'' (ii) a new ''Interim Accounting for an Ex-Date Change Due to Unscheduled Closing of a Stock Exchange'' subsection would be added; (iii) a new ''Interim Accounting on a Security being Delisted'' subsection would be added; and (iv) the ''U.S. Tax Withholding'' section would be updated to remove the statements that (A) the UTW service is available to subaccounts of U.S. Participants, and (B) users of the UTW service must enter into a Withholding Agent Agreement. Finally, the Important Legal Information section would be updated to change the copyright date from 2019 to 2020.

Implementation Timeframe

The proposed changes described above would take effect upon approval by the U.S. Securities and Exchange Commission.

2. Statutory Basis

DTC believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to DTC, as a registered clearing agency. Specifically, DTC believes the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act[14] and Rule 17Ad–22(e)(21) promulgated under the Act,[15] for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the rules of a clearing agency be designed, in general, to protect investors and the public interest.[16] As described above, the proposal would update the Distributions Guide to more clearly explain the interim accounting process and, more specifically, provide an explanation of the interim accounting process for a security being delisted, as well as update the copyright date. By providing greater clarity and information about how the interim accounting process works, both generally and for delisted securities specifically, as well as updating the copyright date, DTC is better informing Participants, investors, and the general public about how DTC manages due bill activity associated with Participants' securities transactions and its copyright information.

The proposal also would remove statements in the Distributions Guide that the UTW service is available to subaccounts of U.S. Participants and that users of the UTW service must enter into a Withholding Agent Agreement, as described above. Because DTC cannot offer the UTW service to such subaccounts and because requiring such an agreement is not necessary, removing the statements would clarify which Participants may use the UTW service and what is required to do so, all of which helps to better inform Participants, investors, and the general public.

Section 17A(b)(3)(F) of the Act also requires, in part, that the rules of a clearing agency be designed to remove impediments to and perfect the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions.[17] As described above, the proposal would change how DTC manages interim

[10] *See, e.g.,* FINRA Rule 11140—Transactions in Securities ''Ex-Dividend,'' ''Ex-Rights'' or ''Ex-Warrants'' *available at https://www.finra.org/rules-guidance/rulebooks/finra-rules/11140.*

[11] DTC has participated in various conversations with exchanges, industry representatives, and Participants to better understand and help address this issue.

[12] Distributions Guide, U.S. Tax Withholding, *supra* note 4.

[13] *See* 26 CFR 1.1441–7(a).

[14] 15 U.S.C. 78q–1(b)(3)(F).

[15] 17 CFR 240.17Ad–22(e)(21).

[16] 15 U.S.C. 78q–1(b)(3)(F).

[17] *Id.*

accounting when an ex-date is changed due to an unscheduled closure of a stock exchange, so that DTC would no longer capture interim activity that results from a stock exchange moving ex-dates due to an unexpected closure. With this change, Participants would no longer need to spend time and energy performing adjustments to reverse the interim accounting on activity to which the interim accounting should not have otherwise applied. By freeing Participants of this need, the proposal would help perfect DTC's interim accounting process for tracking due bills associated with Participants' securities transactions.

For these reasons, DTC believes that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act.[18]

Rule 17Ad–22(e)(21) under the Act requires that DTC establish, implement, maintain and enforce written policies and procedures reasonably designed to, in part, be efficient and effective in meeting the requirements of its Participants and the markets it serves.[19] As described above, the proposal would update the Distributions Guide to (i) more clearly explain the interim accounting process, generally; (ii) provide an explanation for the interim accounting process for a security being delisted; (iii) no longer apply interim accounting when an ex-date is changed due to an unscheduled closure of a stock exchange; and (iv) remove the statements that the UTW service is available to subaccounts of U.S. Participants, and (B) users of the UTW service must enter into a Withholding Agent Agreement.

Collectively these proposed changes are designed to more efficiently and effectively describe DTC's interim accounting practices, as well as the application and requirements of the UTW service, so that Participants are better informed about the practices, generally. With respect to the proposed change to no longer apply interim accounting when there is an unscheduled closure of an exchange, specifically, that proposed change is designed to more efficiently and effectively meet the needs of DTC's Participants, based on discussions with Participants.

Therefore, for the above reasons, DTC believes that the proposed rule change is designed to help DTC be more efficient and effective in meeting the requirements of its Participants and the markets it serves, consistent with Rule 17Ad–22(e)(21) under the Act.[20]

[18] *Id.*

[19] 17 CFR 240.17Ad–22(e)(21).

[20] *Id.*

(B) Clearing Agency's Statement on Burden on Competition

DTC does not believe that the proposed changes to the Distributions Guide to (i) clarify the interim accounting process, generally, (ii) add a description regarding DTC's interim accounting process for a security being delisted, or (iii) update the copyright date, as described above, will have any impact on competition because none of these changes will alter DTC's current practices. Rather, the changes are simply intended to provide more clarity and information for Participants.

Similarly, DTC does not believe the proposed changes to the Distributions Guide to remove the statements that (A) the UTW service is available to subaccounts of U.S. Participants, and (B) users of the UTW service must enter into a Withholding Agent Agreement, as described above, will impact competition because DTC is not able to provide the UTW service to subaccounts of U.S. Participants, anyway, and DTC will remain obligated to withhold U.S. tax on payments it makes to its non-U.S. Participants even without an agreement. As such, these changes should not have any practical implications on Participants or DTC's practices.

As for the proposed change to the Distributions Guide regarding how DTC manages interim accounting when an ex-date is changed due to an unscheduled closure of a stock exchange, as described above, DTC believes the change may impact competition. Specifically, the change could promote competition because Participants could redirect resources that would otherwise have been used to reverse the interim accounting to more competitive-focused activities.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

DTC has not received or solicited any written comments relating to this proposal. DTC will notify the Commission of any written comments received by DTC.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be 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–DTC–2020–019 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–DTC–2020–019. 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 DTC and on DTCC's website (*http://dtcc.com/legal/sec-rule-filings.aspx*). 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–DTC–

2020–019 and should be submitted on or before January 19, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28667 Filed 12–28–20; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90750; File No. SR–NYSE–2020–101]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Exchange Rules To Delete Rules That Are Not Applicable to Trading on the Pillar Trading Platform

December 21, 2020.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on December 9, 2020, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. 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 proposes to amend Exchange rules to delete rules that are not applicable to trading on the Pillar trading platform or are otherwise obsolete. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, 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 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 amend its rules to delete rules that are not applicable to trading on the Pillar trading platform or are otherwise obsolete.

To effect its transition of trading to the Pillar platform, the Exchange adopted Rules 1P through 13P. In addition, because certain Exchange rules pertaining to trading on a floor-based trading platform are not applicable to trading on the Pillar platform, the Exchange designated specified rules governing such trading with the following preamble: ''This rule is not applicable to trading on the Pillar trading platform.''[4]

On August 22, 2019, the Exchange completed its transition of all trading to the Pillar platform. Because the rules that are not applicable to trading on the Pillar trading platform are now obsolete, the Exchange proposes to delete rules that have been replaced by a Pillar rule. The following chart sets forth the proposed rules for deletion (left-hand column) and applicable Pillar rule (right-hand column):

Rule proposed for deletion	Applicable Pillar rule
Rule 4 (Stock)	Rule 1.1(r) (NMS Stock).
Rule 7 (Exchange BBO)	Rule 1.1(c) (BBO).
Rule 13 (Orders and Modifiers), provided that the Exchange proposes to retain the definition of ''retail'' modifier as set forth in Rule 13(f)(2) and proposes to rename Rule 13 as ''Retail Modifiers.''	Rule 7.31 (Orders and Modifiers).
Rule 14 (Bid or Offer Deemed Regular Way)	Rule 7.8 (Bid or Offer Deemed Regular Way).
Rule 15 (Pre-Opening Indications and Opening Order Imbalance Information).	Rule 7.35 (General) and Rule 7.35A (DMM-Facilitated Core Open and Trading Halt Auctions).
Rule 15A (Order Protection Rule)	Rule 7.37 (Order Execution and Routing).
Rule 19 (Locking or Crossing Protected Quotations in NMS Stocks)	Rule 7.37 (Order Execution and Routing).
Rule 51 (Hours for Business)	Rule 7.1 (Hours of Business) and Rule 7.2 (Holidays).
Rule 52 (Dealings on the Exchange—Hours)	Rule 7.34 (Trading Sessions).
Rule 55 (Unit of Trading—Stocks and Bonds)	Rule 7.5 (Trading Units).
Rule 56 (Unit of Trading—Rights)	Rule 7.5 (Trading Units).
Rule 60 (Dissemination of Quotations)	Rule 7.17 (Firm Orders and Quotes).
Rule 61 (Recognized Quotations)	Rule 7.5 (Trading Units).
Rule 62 (Variations)	Rule 7.6 (Trading Differentials).
Rule 70 (Execution of Floor Broker Interest), provided that the Exchange proposes to retain Supplementary Material .30 and .40 to this Rule and proposes to rename Rule 70 as ''Operation of an Exchange-Approved Booth Premise''.	Rule 7.31 (Orders and Modifiers).
Rule 72 (Priority of Bids and Offers and Allocation of Executions), provided that the Exchange proposes to retain paragraph (d) and Supplementary Material .10 of this Rule and proposes to rename Rule 72 as ''Priority of Cross Transactions''.	Rule 7.36 (Order Ranking and Display) and Rule 7.37 (Order Execution and Routing).
Rule 79A (Miscellaneous Requirements on Stock Market Procedures)	Rule 7.36 (Order Ranking and Display) and Rule 7.37 (Order Execution and Routing).
Rule 80C (Limit Up-Limit Down Plan and Trading Pauses in Individual Securities Due to Extraordinary Market Volatility).	Rule 7.11 (Limit Up-Limit Down Plan and Trading Pauses in Individual Securities Due to Extraordinary Market Volatility).
Rule 107C (Retail Liquidity Program)	Rule 7.44 (Retail Liquidity Program).

[21] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release Nos. 85962 (May 29, 2019), 84 FR 26188 (June 5, 2019) and 81225 (July 27, 2017), 82 FR 36033 (August 2, 2017) (SR–NYSE–2017–35).

Rule proposed for deletion	Applicable Pillar rule
Rule 115A (Orders at Opening)	Rule 7.35 (General) and Rule 7.35A (DMM-Facilitated Core Open and Trading Halt Auctions).
Rule 116 (''Stop'' Constitutes Guarantee)	Rule 7.35B (DMM-Facilitated Closing Auctions).
Rule 123C (The Closing Procedures)	Rule 1.1(s) (Definition of Official Closing Price), Rule 7.35 (General), Rule 7.35C (DMM-Facilitated Closing Auctions), and Rule 7.35C (Exchange-Facilitated Auctions).
Rule 123D (Openings and Halts in Trading), provided that the Exchange proposes to retain paragraphs (d) and (e) of this Rule and proposes to rename Rule 123D as ''Halts in Trading''.	Rule 7.35A (DMM-Facilitated Core Open and Trading Halt Auctions) and Rule 7.35C (Exchange-facilitated Auctions).
Rule 127 (Block Crosses Outside the Prevailing NYSE Quotation)	Not available.
Rule 128 (Clearly Erroneous Executions for NYSE Equities)	Rule 7.10 (Clearly Erroneous Executions).
Rule 1000 (Automatic Executions)	Rule 7.32 (Order Entry) and Rule 7.37 (Order Execution and Routing).
Rule 1001 (Execution of Automatically Executing Orders)	Rule 7.37 (Order Execution and Routing).
Rule 1002 (Availability of Automatic Execution Feature	Rule 7.37 (Order Execution and Routing).
Rule 1004 (Election of Buy Minus Zero Plus Orders)	Rule 7.31 (Orders and Modifiers).

In addition, the Exchange proposes to delete the following rules in their entirety as obsolete:

- Rule 133. Comparison—Non-cleared Transactions
- Rule 136. Comparison—Transactions Excluded from a Clearance
- Rule 137. Written Contracts
- Rule 137A. Samples of Written Contracts
- Rule 139. Recording
- Rule 140. Members Closing Contracts—Conditions
- Rule 141. ''Fail to Deliver'' Confirmations
- Rule 142. Effect on Contracts of Errors in Comparison, etc.
- Marking to the Market (Rules 165–168)
- Settlement of Contracts (Rules 175–227), with the exception of Supplementary Material .20 to Rule 200 (Assignments—By Member Organization)
- Dividends, Interest, Rights, etc. (Rules 235–251), with the exception of Rule 235 (Ex-Dividend, Ex-Rights) and Rule 236 (Ex-Warrants) [5]
- Due-Bills (Rules 255–259)
- Reclamations (Rules 265–275)
- Closing Contracts (Rules 280–295), with the exception of Rule 282 (Buy-in Procedures)
- Liquidation of Securities Loans and Borrowings (Rule 296)
- Miscellaneous Floor Procedure (Rules 297–299C)

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[6] in general, and furthers the objectives of Section 6(b)(5),[7] 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 its proposed rule change would remove impediments to and perfect the mechanism of a free and open market and a national market system because it would eliminate rules that are now obsolete. The elimination of obsolete rules would reduce potential confusion and improve the clarity of the Exchange's rules, thereby ensuring that members, regulators, and the public can more easily navigate and understand the Exchange's rulebook.

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 proposed change is not designed to address any competitive issue, but rather it is designed to eliminate obsolete rules and enhance the clarity of the Exchange's rules.

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. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [8] and Rule 19b–4(f)(6) [9] thereunder.

The Exchange has asked the Commission to waive the 30-day operative delay.[10] The Commission finds that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because waiver of the operative delay will eliminate the potential for confusion and improve clarity by eliminating rules that are no longer applicable or are otherwise obsolete. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[11]

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.

[5] The Exchange proposes to retain the section header ''Dividends, Interest, Rights, etc.'' and proposes to update the parenthetical to include only Rules 235 and 236.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[10] 17 CFR 240.19b–4(f)(6)(iii).

[11] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

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–NYSE–2020–101 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–2020–101. 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–NYSE–2020–101 and should be submitted on or before January 19, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28671 Filed 12–28–20; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90757; File No. SR–MRX–2020–23]

Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Harmonize Exchange Rule General 3, Section 2 With Recent Changes by the Financial Industry Regulatory Authority, Inc.

December 21, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 11, 2020, Nasdaq MRX, LLC (''MRX'' or ''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 substantially 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 proposes to harmonize Exchange Rule General 3, Section 2 with recent changes by the Financial Industry Regulatory Authority, Inc. (''FINRA''). This amendment would temporarily grant the Exchange Review Council (''ERC'') authority[3] to conduct hearings in connection with appeals of Membership Application Program decisions by video conference, if warranted by the current COVID–19-related public health risks posed by an in-person hearing. As proposed, the temporary amendment would be in effect through April 30, 2021.[4]

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/mrx/rules,* at the principal office of the Exchange, 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 proposes to harmonize Exchange Rule General 3, Section 2 with recent changes to FINRA Rule 1015 in order to temporarily grant the ERC authority to conduct hearings in connection with appeals of Membership Application Program decisions by video conference, if warranted by the current COVID–19-related public health risks posed by an in-person hearing.[5] As proposed, these temporary amendments would be in effect through April 30, 2021.

Background

The Exchange's rule regarding the hearing and evidentiary process for appeals of Membership Application Program decisions as set forth in Rule General 3, Section 2(g) is based on FINRA's Rule 1015. As adopted, the text of Exchange Rule General 3, Section 2(g)

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[12] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] For ERC hearings under Exchange Rule General 3, Section 2(g), this temporary authority is granted to the ERC or relevant Subcommittee.

[4] If the Exchange requires temporary relief from the rule requirements identified in this proposal beyond April 30, 2021, the Exchange may submit a separate rule filing to extend the expiration date of the temporary amendments under these rules. The amended Exchange rules will revert back to their original state at the conclusion of the temporary relief period and any extension thereof.

[5] *See* Exchange Act Release No. 89737 (September 2, 2020), 85 FR 55712 (September 9, 2020) (SR–FINRA–2020–027) (''FINRA Filing''). *See also* Exchange Act Release No. 90619 (December 9, 2020), 85 FR 81250 (December 15, 2020) (SR–FINRA–2020–042) (extending the relief in the FINRA Filing through April 30, 2021). The Exchange notes that the FINRA Filing also proposed to temporarily amend FINRA Rules 9261, 9524, and 9830, which govern hearings in connection with appeals of disciplinary actions, eligibility proceedings, and temporary and permanent cease and desist orders. The Exchange's Rules 9261, 9524, and 9830 incorporate by reference The Nasdaq Stock Market LLC rules, which are the subject of a separate filing. *See* SR–NASDAQ–2020–076 (November 5, 2020). Therefore, the Exchange is not proposing to adopt that aspect of the FINRA Filing.

is substantially the same as FINRA Rule 1015, with the exception of conforming and technical differences.

In view of the ongoing spread of COVID–19 and its effect on FINRA's adjudicatory functions nationwide, FINRA recently filed a temporary rule change to grant the National Adjudicatory Council (''NAC'') the authority to conduct certain hearings by video conference, if warranted by the current COVID–19-related public health risks posed by in-person hearings.[6] Accordingly, the Exchange proposes to file this temporary rule change to align with the temporary rule change filed by FINRA.

Mirroring FINRA's NAC, the ERC is the Exchange's appellate body, which reviews initial decisions issued by FINRA's Office of Hearing Officers (''OHO'') and—through Subcommittees—holds evidentiary hearings for Membership Application Program decision appeals and eligibility proceedings under Exchange Rule General 3, Section 2(g). This temporary proposed rule change will allow the ERC or relevant Subcommittee to make an assessment as to whether an in-person hearing would compromise the health and safety of the hearing participants such that the hearing should proceed by video conference.

Proposed Rule Change

Consistent with FINRA's temporary amendment to FINRA Rule 1015, the Exchange proposes to temporarily grant the ERC authority to conduct hearings in connection with appeals of Membership Application Program decisions by video conference, if warranted by the current COVID–19-related public health risks posed by an in-person hearing. The proposed change will permit the ERC to make an assessment, based on critical COVID–19 data and criteria, as to whether an in-person hearing would compromise the health and safety of the hearing participants such that the hearing should proceed by video conference. The Exchange believes that this is a reasonable procedure to follow in hearings under Rule General 3, Section 2(g).

To effectuate these changes, the Exchange proposes to add the following sentence to General 3, Section 2(g)(6):

> Upon consideration of the current public health risks presented by an in-person hearing, the Exchange Review Council or Subcommittee may, on a temporary basis, determine that the hearing shall be conducted, in whole or in part, by video conference.

[6] *See* FINRA Filing, 85 FR at 55712.

The proposed text is substantially the same as the language adopted by FINRA, excepting conforming and technical differences.[7]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Section 6(b)(5) of the Act,[9] in particular, 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, by providing greater harmonization between the Exchange rules and FINRA rules of similar purpose, resulting in less burdensome and more efficient regulatory compliance.

As previously noted, the text of Exchange Rule General 3, Section 2(g) is substantially the same as FINRA's rule. As such, the proposed rule change will foster cooperation and coordination with persons engaged in facilitating transactions in securities and will remove impediments to and perfect the mechanism of a free and open market and a national market system.

The Exchange believes that the proposed temporary rule change will permit the Exchange to effectively conduct hearings during the COVID–19 pandemic in situations where in-person hearings present likely public health risks. The ability to conduct hearings by video conference will thereby permit the Exchange's adjudicatory functions to continue unabated, thereby avoiding protracted delays. Conducting hearings via video conference will give the parties and adjudicators simultaneous visual and oral communication without the risks inherent in physical proximity during a pandemic.

The Exchange believes that the temporary proposed rule change strikes an appropriate balance between providing fair process and enabling the Exchange to fulfill its statutory obligations to protect investors and maintain fair and orderly markets while accounting for the significant health and safety risks of in-person hearings stemming from the outbreak of COVID–19.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the temporary proposed rule change will impose any burden on competition

[7] *See id.* at 55712.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but is rather intended solely to provide temporary relief given the impacts of the COVID–19 pandemic. In its filing, FINRA provides an abbreviated economic impact assessment maintaining that the changes are necessary to temporarily rebalance the attendant benefits and costs of the obligations under FINRA Rule 1015 in response to the impacts of the COVID–19 pandemic that is equally applicable to the changes the Exchange proposes.[10] The Exchange accordingly incorporates FINRA's abbreviated economic impact assessment by reference.

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

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[11] and subparagraph (f)(6) of Rule 19b–4 thereunder.[12]

The Exchange believes that this filing is non-controversial and eligible to become effective immediately because the proposal promotes uniformity in rules across self-regulatory organizations thereby enabling the Exchange to conduct hearings during the COVID–19 pandemic by video conference where the health risks of in-person hearings are significant. The proposed rule change is based on, and similar to, recent changes made to FINRA Rule 1015 that addressed the issue of balancing public health risks with conducting hearings during the COVID–19 pandemic. The Exchange proposes to adopt the rule change in

[10] *See* FINRA Filing, 85 FR at 55716.

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

substantially the same form as it was adopted by FINRA. The Exchange further believes that the proposed rule change would not significantly affect the protection of investors or the public interest or impose any significant burden on competition because the changes are based on the rules of FINRA. Moreover, the proposed rule change is not intended to address competitive issues but rather is concerned solely with providing temporary relief given the impacts of the COVID–19 pandemic.

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–MRX–2020–23 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–MRX–2020–23. 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, on business days between the hours of 10:00 a.m. and 3:00 p.m., located at 100 F Street NE, Washington, DC 20549. 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–MRX–2020–23 and should be submitted on or before January 19, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28656 Filed 12–28–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34145; 813–00395]

Signature PE Fund, LLC and McDermott Will & Emery LLP

December 21, 2020

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of application for an order under sections 6(b) and 6(e) of the Investment Company Act of 1940 (the ''Act'') granting an exemption from all provisions of the Act, except sections 9, 17, 30, and 36 through 53, and the rules and regulations under the Act (the ''Rules and Regulations''). With respect to sections 17(a), (d), (f), (g) and (j) of the Act, sections 30(a), (b), (e), and (h) of the Act and the Rules and Regulations and rule 38a–1 under the Act, applicants request a limited exemption as set forth in the application.

SUMMARY OF APPLICATION: Applicants request an order to exempt certain limited liability companies, partnerships, trusts, corporations or other entities (''Investment Funds'') formed for the benefit of eligible employees of McDermott Will & Emery LLC and its affiliates from certain provisions of the Act. Each Investment Fund will be an ''employees' securities company'' within the meaning of section 2(a)(13) of the Act.

APPLICANTS: Signature PE Fund, LLC (the ''Initial Fund'') and McDermott Will & Emery LLP.

FILING DATES: The application was filed on February 26, 2019 and amended on August 19, 2019, July 21, 2020 and December 1, 2020.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving applicants with a copy of the request by email. Hearing requests should be received by the Commission by 5:30 p.m. on January 15, 2021, 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: Secretary, U.S. Securities and Exchange Commission: *Secretarys-Office@sec.gov.* Applicants: McDermott Will & Emery LLP: *elaurenson@mwe.com.*

FOR FURTHER INFORMATION CONTACT: Barbara T. Heussler, Senior Counsel, at (202) 551–6990, or Trace W. Rakestraw, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. McDermott Will & Emery LLP is a law firm organized as an Illinois limited liability partnership (together with any ''affiliates'' as defined in rule 12b–2 under the Securities Exchange Act of 1934 (the ''Exchange Act'') of McDermott Will & Emery LLP that are organized to practice law, any successor entity of McDermott Will & Emery LLP or its affiliates or any entity that results from a reorganization of McDermott

[13] 17 CFR 200.30–3(a)(12).

Will & Emery LLP or its affiliates into a different type of entity or into an entity organized under the laws of another jurisdiction (the ''Company'')). McDermott Will & Emery LLP is an international law firm that is owned exclusively by its capital partners.

2. The Initial Fund is a Delaware limited liability company formed pursuant to a limited liability agreement. The applicants may in the future offer subsequent pooled investment vehicles substantially similar in all material respects (other than form of organization, investment objective and strategy, and other differences described in the application) to Eligible Investors (as defined below) (the ''Subsequent Funds'' and, together with the Initial Fund included in the term ''Investment Funds''). The applicants anticipate that each Subsequent Fund also will be structured as a limited liability company although a Subsequent Fund could be structured as a domestic or offshore general partnership, limited partnership, trust, corporation, or other form of business entity. The organizational documents for the Investment Funds are the ''Investment Fund Agreements.'' An Investment Fund may include a single vehicle designed to issue interests in series or having similar features to enable a single Investment Fund to function as if it were several successive Investment Funds for ease of administration. Each Investment Fund will be an employees' securities company within the meaning of section 2(a)(13) of the Act.

3. The Initial Fund has been established to enable certain Eligible Investors to participate in certain investment opportunities that come to the attention of the Company. These opportunities may include investments in operating businesses or real estate, separate accounts with registered or unregistered investment advisers, investments in pooled investment vehicles such as registered investment companies and investment companies exempt from registration under the Act, commodity pools, co-investments in operating entities and other investments (each particular investment being referred to herein as an ''Investment''). Applicants submit that a substantial community of interest exists among the Company and the members of the Investment Funds (''Members''). The Company will ''control'' each Investment Fund within the meaning of section 2(a)(9) of the Act.

4. Interests in an Investment Fund (''Interests'') will be offered and sold in reliance upon the exemption from registration under section 4(2) of the Securities Act of 1933 (the ''Securities Act'') or pursuant to Regulation D under the Securities Act, or outside the United States in a transaction exempt under Regulation S under the Securities Act. Interests in any Investment Fund (other than short-term paper) will offered solely to the Company or Eligible Investors. ''Eligible Investors'' means persons who at the time of investment are (a) partners of the Company and senior administrative employees of the Company (''Eligible Employees''), (b) the immediate family members of Eligible Employees, which are parents, children, grandchildren, spouses or spousal equivalents of children, spouses or spousal equivalents, and siblings, including step or adoptive relationships (''Eligible Family Members''), and (c) trusts or other entities or arrangements the sole beneficiaries of which consist of Eligible Employees or their Eligible Family Members, or the settlors and the trustees of which consist of Eligible Employees or Eligible Employees together with Eligible Family Members (''Eligible Trusts'').[1] To qualify as an Eligible Investor with respect to an Investment Fund, each such person must, if purchasing an Interest from an Investment Fund or from a Member, be an Accredited Investor as that term is defined in Rule 501(a) of Regulation D of the Securities Act, or, in the case of Eligible Trusts, a trust, entity or arrangement for which an Eligible Employee, who is an Accredited Investor, is a settlor and principal investment decision maker. The Company will be an Accredited Investor. Prior to offering Interests to an Eligible Employee or Eligible Family Member, the Investment Committee (as defined below) must reasonably believe that the Eligible Employee or Eligible Family Member is a sophisticated investor capable of understanding and evaluating the risks of participating in the Investment Fund without the benefit of regulatory safeguards. The Investment Committee may impose more restrictive standards for Eligible Investors in its discretion. The beneficial owners of an Eligible Trust will be persons eligible to hold interests in employees' securities companies as defined in section 2(a)(13) of the Act.

5. Each Investment Fund will be managed and administered by an investment committee (''Investment Committee''). The Investment Committee will be comprised of not less than three partners of the Company who are appointed to the Investment Committee by the Company's management committee. All investment decisions on behalf of an Investment Fund (including with respect to any series thereof) will be made by the Investment Committee.

6. An Investment Fund may have an administrator (''Administrator''). The Administrator may be an employee of the Company or the Investment Committee may determine to engage a third party to act as Administrator for an Investment Fund. The Administrator will in no event be a Member or otherwise hold any other security of an Investment Fund unless qualified as an Eligible Investor. The Administrator will not recommend Investments or exercise investment discretion. The only functions of the Administrator will be ministerial.

7. The specific investment objectives and strategies for an Investment Fund will be set forth in an informative memorandum relating to the Interests being offered and in the relevant Investment Fund Agreement, and each Eligible Investor will receive a copy of the informative memorandum and Investment Fund Agreement before making an investment in an Investment Fund. The terms of an Investment Fund will be disclosed to each Eligible Investor at the time the investor is invited to participate in that Investment Fund.

8. The value of the Members' capital accounts will be determined at such times as the Investment Committee deems appropriate or necessary; however, such valuation will be done at least annually at the Investment Fund's fiscal year-end. The Investment Committee will value the assets held by an Investment Fund at the current market price (closing price) in the case of marketable securities. All other securities and assets will be valued by the Investment Committee in good faith at fair value.

9. Each Investment Fund will generally bear its own expenses. The Company may be reimbursed by an Investment Fund for reasonable and necessary out of pocket costs directly associated with the organization and operation of the Investment Fund, including administrative expenses and overhead expenses. No Investment Fund will be charged legal fees by the Company. There will be no allocation of any of the Company's operating expenses to the Investment Funds other than those specifically related to the provision of administrative services by

[1] If an Eligible Trust is an entity or arrangement other than a trust, (a) the reference to ''settlor'' shall be construed to mean a person who created the vehicle or arrangement, alone or together with other Eligible Investors, and also contributed funds or other assets to the vehicle, and (b) the reference to ''trustee'' shall be construed to mean a person who performs functions similar to those of a trustee.

the Company to the Investment Funds and disclosed to Eligible Investors. Some of the investment opportunities available to an Investment Fund may involve parties for which the Company was, is or will be retained to act as legal counsel, and the Company may be paid by such parties or their affiliates for legal services and for related disbursements and charges. These amounts paid to the Company will not be paid by an Investment Fund itself but by the entities in which an Investment Fund invests or their affiliates. No management fee or other compensation will be paid by an Investment Fund or the Members to the Investment Committee or any member of the Investment Committee. Also, no fee of any kind will be charged in connection with the sale of Interests in an Investment Fund.

10. Within 120 days after the end of each fiscal year, or as soon as practicable thereafter, each Investment Fund will send its Members an annual report regarding its operations. The annual report of an Investment Fund will contain financial statements audited by an independent accounting firm. For purposes of this requirement, ''audit'' has the meaning defined in rule 1–02(d) of Regulation S–X. An Investment Fund will maintain a file containing any financial statements and other information received from the issuers of the Investments held by the Investment Fund and will make such file available for inspection by its Members in accordance with its Investment Fund Agreement. An Investment Fund, within 90 days after the end of the fiscal year of such Investment Fund, or as soon as practicable thereafter, will transmit a report to each Member setting out information with respect to that Member's distributive share of income gains, losses, credits and other items for federal income tax purposes resulting from the operation of the Investment Fund during that year.

11. Members will not be entitled to redeem their respective Interests in an Investment Fund. A Member will be permitted to transfer his or her Interest only with the express consent of the Investment Committee, which consent may be given or withheld in the Investment Committee's sole and absolute discretion, and then only to an Eligible Investor. A Member will not be subject to removal except for good cause as determined by the Investment Committee or if the Investment Committee, in its discretion, deems such withdrawal to be in the best interest of the Investment Fund. The Interests of a Member who is no longer eligible to own interests in an employees' securities company as defined in section 2(a)(13) of the Act will be repurchased, subject to the minimum payment provisions described below. The Investment Committee does not currently intend to require any Member to withdraw.[2] Upon withdrawal or sale of a Member's Interest, the Investment Fund or purchaser will at a minimum pay to the Member the lesser of (a) the amount of such Member's drawn Capital Commitment (defined below) plus interest (calculated at a rate determined by the Investment Committee to be reasonably comparable to interest earned by the Investment Fund on temporary investments) less prior distributions, or (b) the fair market value of the Interest as determined at the time of such withdrawal or sale in good faith by the Investment Committee. If a Member that is a Eligible Employee ceases to be a partner or senior administrative employee of the Company, such Member and related Eligible Investors will continue to be Members of an Investment Fund although with the consent of the Investment Committee, such Member and related Eligible Investors may be permitted to assign all or a portion of such Member's Interest to other Eligible Investors.

12. Each Member of an Investment Fund will make a separate capital commitment to the Investment Fund (''Capital Commitment'') relating to each Investment Fund in which such Member is participating. To provide flexibility in connection with an Investment Fund's obligation to contribute capital to fund an Investment of an Investment Fund and to meet the expenses with respect to that Investment Fund, the Investment Fund Agreements may provide that the Investment Fund may engage in borrowings in connection with such funding of Investments. Any borrowings by an Investment Fund with respect to the funding of Investments will be non-recourse to the Members[3] but may be secured by a pledge of the Members' respective capital accounts and unfunded Capital Commitments. An Investment Fund will not borrow from any person if the borrowing would cause any person not named in section 2(a)(13) of the Act to own any outstanding securities of an Investment Fund (other than short-term paper). If the Company makes a loan to an Investment Fund, the Company (as lender) will be entitled to receive interest, provided that the rate will be no less favorable to the borrower than the rate obtainable on an arm's length basis. An Investment Fund will not lend any funds to the Company. If the Company extends a loan to an Eligible Investor in respect of any Investment Fund, the loan will be made at an interest rate no less favorable than that which could be obtained on an arm's length basis. Loans will not be extended or arranged if otherwise prohibited by law, including the Sarbanes-Oxley Act of 2002.

13. The Investment Funds will not acquire any security issued by a registered investment company if immediately after the acquisition the Investment Fund would own more than 3% of the total outstanding voting stock of the registered investment company.

Applicants' Legal Analysis

1. Section 6(b) of the Act provides, in part, that the Commission will exempt employees' securities companies from the provisions of the Act to the extent that the exemption is consistent with the protection of investors. Section 6(b) provides that the Commission will consider, in determining the provisions of the Act from which the company should be exempt, the company's form of organization and capital structure, the persons owning and controlling the company's securities, the price of the company's securities and the amount of any sales load, the disposition of the proceeds of any sales of the company's securities, how the company's funds are invested, and the relationship between the company and the issuers of the securities in which it invests. Section 2(a)(13) defines an employees' securities company as any investment company all of whose securities (other than short-term paper) are beneficially owned (a) by current or former employees, or persons on retainer, of one or more affiliated employers, (b) by immediate family members of such persons, or (c) by such employer or employers together with any of the persons in (a) or (b).

[2] The following circumstances, among others, could warrant the withdrawal of a Member or sale of a Member's Interests to another Eligible Investor: If a Member who is an Eligible Employee ceases to be a partner or senior administrative employee of the Company; an Eligible Family Member's or Eligible Trust's related Eligible Employee ceases to be a partner or senior administrative employee of the Company; a Member defaults on his or her obligations to the Investment Fund; adverse tax consequences were to inure to the Investment Fund or a Member were that Member to remain a Member; or a situation in which the continued membership of the Member would violate applicable law or regulations.

[3] This excludes indebtedness incurred specifically on behalf of a Member where the Member has agreed to guarantee the loan or to act as co-obligor on the loan.

2. Section 7 of the Act generally prohibits investment companies that are not registered under section 8 of the Act from selling or redeeming their securities. Section 6(e) of the Act provides that, in connection with any order exempting an investment company from any provision of section 7, certain provisions of the Act, as specified by the Commission, will be applicable to the company and other persons dealing with the company as though the company were registered under the Act. Applicants request an order under sections 6(b) and 6(e) of the Act exempting applicants from all provisions of the Act, except sections 9, 17, 30, 36 through 53, and the Rules and Regulations. With respect to sections 17(a), (d), (f), (g) and (j) and 30(a), (b), (e) and (h) of the Act and the Rules and Regulations, and rule 38a–1 under the Act, applicants request a limited exemption as set forth in the application.

3. Section 17(a) of the Act generally prohibits any affiliated person of a registered investment company, or any affiliated person of an affiliated person, acting as principal, from knowingly selling or purchasing any security or other property to or from the company. Applicants request an exemption from section 17(a) to permit an Investment Fund to invest in or participate as a selling security-holder in a principal transaction with one or more affiliated persons (as defined in section 2(a)(3) of the Act) of an Investment Fund (''First-Tier Affiliates'') and affiliated persons of such First-Tier Affiliates (''Second-Tier Affiliates,'' and together with First-Tier Affiliates, ''Affiliates'').

4. Applicants submit that the exemptions sought from section 17(a) are consistent with the purposes of the Act and the protection of investors. Applicants state that the Members will be informed in an Investment Fund's offering materials of the possible extent of the dealings by such Investment Fund and any portfolio company with the Company. Applicants also state that, as professionals sophisticated and experienced in business and financial matters, the Members will be able to evaluate the risks associated with those dealings. Applicants assert that the community of interest among the Investment Committee, the Members and the Company will serve to reduce the risk of abuse in transactions involving an Investment Fund and the Company.

5. Section 17(d) of the Act and rule 17d–1 under the Act prohibit any affiliated person of a registered investment company, or any affiliated person of such person, acting as principal, from participating in any joint arrangement with the registered investment company unless authorized by the Commission. Applicants request an exemption from section 17(d) and rule 17d–1 to the extent necessary to permit an Investment Fund to engage in transactions in which an Affiliate participates as a joint or a joint and several participant with such Investment Fund.

6. Joint transactions in which an Investment Fund could participate might include the following: (a) A joint investment by one or more Investment Funds in a security in which the Company or another Investment Fund is a joint participant or plans to become a participant; (b) a joint investment by one or more Investment Funds in another Investment Fund; and (c) a joint investment by one or more Investment Funds in a security in which an Affiliate is an investor or plans to become an investor, including situations in which an Affiliate has a partnership or other interest in, or compensation arrangements with, such issuer, sponsor or offeror.

7. Applicants assert that compliance with section 17(d) and rule 17d–1 would cause an Investment Fund to forego investment opportunities simply because a Member, the Company or other Affiliates also had made, or is concurrently making, a similar investment. In addition, because attractive investment opportunities of the types considered by an Investment Fund often require that each participant make available funds in an amount that may be substantially greater than that available to the investor alone, there may be certain attractive opportunities of which an Investment Fund may be unable to take advantage except as a co-participant with other persons, including Affiliates. Applicants believe that the flexibility to structure co- and joint investments in the manner described above will not involve abuses of the type section 17(d) and rule 17d–1 were designed to prevent. Applicants acknowledge that any transactions subject to section 17(d) and rule 17d–1 for which exemptive relief has not been requested in the application would require specific approval by the Commission.

8. Section 17(f) of the Act designates the entities that may act as investment company custodians, and rule 17f–2 under the Act allows an investment company to act as self-custodian. Applicants request an exemption to permit the following exceptions from the requirements of rule 17f–2: (i) Compliance with paragraph (b) of the rule may be achieved through safekeeping in the locked files of the Company or a partner of the Company; (ii) for the purposes of the rule, (A) employees of the Company will be deemed employees of the Investment Funds, (B) officers and members of the Investment Committee will be deemed to be officers of such Investment Funds, and (C) the Investment Committee will be deemed to be the board of directors of such Investment Funds; and (iii) instead of the verification procedure under paragraph (f) of the rule, verification will be effected quarterly by two partners or employees, each of whom shall have sufficient knowledge, sophistication and experience in business matters to perform such examination. Applicants expect that most of the Investments will be evidenced by partnership agreements or similar documents. Such instruments are most suitably kept in the Company's files, where they can be referred to as necessary. Applicants will comply with all other provisions of rule 17f–2.

9. Section 17(g) and rule 17g–1 generally require the bonding of officers and employees of a registered investment company who have access to its securities or funds. Rule 17g–1 requires that a majority of directors who are not interested persons of a registered investment company (''disinterested directors'') take certain actions and give certain approvals relating to fidelity bonding. Applicants request an exemption from the requirement, contained in rule 17g–1, that a majority of the ''directors'' of the Investment Funds who are not ''interested persons'' of the respective Investment Funds (as defined in the Act) take certain actions and make certain approvals concerning bonding and request instead that such actions and approvals be taken by the Investment Committee, regardless of whether any of them is deemed to be an interested person of the Investment Funds. Each member of the Investment Committee will be an interested person of the Investment Funds.

10. The Investment Funds request an exemption from the requirements of rule 17g–1(g) and (h) relating to the filing of copies of fidelity bonds and related information with the Commission and relating to the provisions of notices to the board of directors. Applicants also request an exemption from the requirements of rule 17g–1(j)(3) that the Investment Funds have a majority of disinterested directors, that those disinterested directors select and nominate any other disinterested directors, and that any legal counsel for those disinterested directors be independent legal counsel. Applicants believe that the filing requirements of

rule 17g–1 are burdensome and unnecessary as applied to the Investment Funds. The Investment Committee will maintain the materials otherwise required to be filed with the Commission by rule 17g–1(g) and the applicants agree that all such material will be subject to examination by the Commission and its staff. The Investment Committee will designate a person to maintain the records otherwise required to be filed with the Commission under paragraph (g) of the rule. The Investment Funds will comply with all other requirements of rule 17g–1. The fidelity bond of the Investment Funds will cover the Investment Committee, and all employees of the Company who have access to the securities or funds of the Investment Funds.

11. Applicants request an exemption from the requirements, contained in section 17(j) of the Act and rule 17j–1 under the Act, that every registered investment company adopt a written code of ethics and every ''access person'' of such registered investment company report to the investment company with respect to transactions in any security in which such access person has, or by reason of the transaction acquires, any direct or indirect beneficial ownership. Applicants request an exemption from the requirements in rule 17j–1, with the exception of rule 17j–1(b), because they are burdensome and unnecessary as applied to an Investment Funds and because the exemption is consistent with the policy of the Act. Requiring the Investment Funds to adopt a written code of ethics and requiring access persons to report each of their securities transactions would be time-consuming and expensive and would serve little purpose in light of, among other things, the community of interest among the Members of the Investment Funds by virtue of their common association with the Company. Accordingly, the requested exemption is consistent with the purposes of the Act because the dangers against which section 17(j) and rule 17j–1 are intended to guard are not present in the case of the Investment Funds.

12. Applicants request an exemption from the requirements in sections 30(a), 30(b), and 30(e) of the Act, and the Rules and Regulations under those sections, that registered investment companies file with the Commission and mail to their shareholders certain periodic reports and financial statements. Applicants contend that the forms prescribed by the Commission for periodic reports have little relevance to an Investment Fund and would entail administrative and legal costs that outweigh any benefit to the Members. Applicants request exemptive relief to the extent necessary to permit an Investment Fund to report annually to their Members. Applicants also request an exemption from section 30(h) of the Act to the extent necessary to exempt the Investment Committee, any 10 percent shareholder, and any other person who may be deemed to be an officer, director, member of an advisory board, or otherwise subject to section 30(h), from filing Forms 3, 4 and 5 under section 16 of the Exchange Act with respect to their ownership of Interests in the Investment Funds. Applicants assert that, because there is no trading market for Interests and the transfer of Interests is severely restricted, these filings are unnecessary for the protection of investors and burdensome to those required to make them.

13. Rule 38a–1 requires investment companies to adopt, implement and periodically review written policies reasonably designed to prevent violation of the federal securities laws and to appoint a chief compliance officer. Each Investment Fund will comply with rule 38a–1(a), (c) and (d), except that (i) the members of the Investment Committee will fulfill the responsibilities assigned to the Investment Fund's board of directors under the rule, and (ii) because all members of the Investment Committee would be considered interested persons of the Investment Funds, approval by a majority of the disinterested board members required by rule 38a–1 will not be obtained. In addition, the Investment Funds will comply with the requirement in rule 38a–1(a)(4)(iv) that the chief compliance officer meet with the disinterested directors by having the chief compliance officer meet with the members of the Investment Committee.

Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. Each proposed transaction, to which an Investment Fund is a party, otherwise prohibited by section 17(a) or section 17(d) and rule 17d–1 (the ''Section 17 Transactions'') will be effected only if the Investment Committee determines that: (a) The terms of the Section 17 Transaction, including the consideration to be paid or received, are fair and reasonable to Members of the Investment Fund and do not involve overreaching of the Investment Fund or its Members on the part of any person concerned; and (b) the Section 17 Transaction is consistent with the interests of the Members of the Investment Fund, the Investment Fund's organizational documents and the Investment Fund's reports to its Members.

In addition, the Investment Committee will record and preserve a description of such Section 17 Transactions, the findings of the Investment Committee, the information or materials upon which their findings are based and the basis therefor. All such records will be maintained for the life of the Investment Fund and at least six years thereafter and will be subject to examination by the Commission and its staff. All such records will be maintained in an easily accessible place for at least the first two years.

2. If purchases or sales are made by an Investment Fund from or to an entity affiliated with the Investment Fund by reason of a member of the Investment Committee (a) serving as an officer, director, general partner or investment adviser of the entity, or (b) having a 5% or more investment in the entity, such individual will not participate in the Investment Fund's determination of whether or not to effect the purchase or sale.

3. The Investment Committee will adopt, and periodically review and update, procedures designed to ensure that reasonable inquiry is made, prior to the consummation of any Section 17 Transaction, with respect to the possible involvement in the transaction of any affiliated person or promoter of or principal underwriter for the Investment Fund, or any affiliated person of such a person, promoter, or principal underwriter.

4. The Investment Committee will not purchase for an Investment Fund any Investment in which a Co-Investor, as defined below, has or proposes to acquire the same class of securities of the same issuer, where the investment involves a joint enterprise or other joint arrangement within the meaning of rule 17d–1 in which the Investment Fund and the Co-Investor are participants, unless any such Co-Investor, prior to disposing of all or part of its investment: (a) Gives the Investment Fund holding such investment sufficient, but not less than one day's notice of its intent to dispose of its investment, and (b) refrains from disposing of its investment unless the Investment Fund holding such investment has the opportunity to dispose of its investment prior to or concurrently with, on the same terms as, and on a pro rata basis with the Co-Investor. The term ''Co-Investor'' with respect to an Investment Fund means any person who is: (a) An affiliated person of the Investment Fund; (b) the

Company; (c) a current partner, lawyer employed by or key administrative employee of the Company; (d) an entity in which the Company or a member of the Investment Committee acts as an officer, director, or general partner, or has a similar capacity to control the sale or disposition of the entity's securities; or (e) an investment vehicle offered, sponsored, or managed by the Company or an affiliated person of the Company.

The restrictions contained in this condition, however, shall not be deemed to limit or prevent the disposition of an investment by a Co-Investor: (a) To its direct or indirect wholly-owned subsidiary, to any company (a ''Parent'') of which the Co-Investor is a direct or indirect wholly-owned subsidiary, or to a direct or indirect wholly-owned subsidiary of its Parent; (b) to immediate family members of the Co-Investor or a trust established for the benefit of any such family member; (c) when the investment is comprised of securities that are listed on a national securities exchange registered under section 6 of the Exchange Act; (d) when the investment is comprised of securities that are national market system (''NMS'') stocks pursuant to section 11A(a)(2) of the Exchange Act and rule 600(a) of Regulation NMS thereunder; (e) when the investment is comprised of securities that are listed on or traded on any foreign securities exchange or board of trade that satisfies regulatory requirements under the law of the jurisdiction in which such foreign securities exchange or board of trade is organized similar to those that apply to a national securities exchange or a national market system of securities; or (f) when the investment is comprised of securities that are government securities as defined in section 2(a)(16) of the Act.

5. An Investment Fund will send, within 120 days after the end of its fiscal year, or as soon as practicable thereafter, to each Member who had an interest in the Investment Fund at any time during the fiscal year then ended, reports and information regarding the Investments, including financial statements for such Investment Fund audited by an independent accounting firm. The Investment Committee will make a valuation or have a valuation made of all of the assets of an Investment Fund as of each fiscal year end. In addition, within 90 days after the end of each fiscal year of the Investment Fund, or as soon as practicable thereafter, the Investment Fund shall send a report to each person who was a Member at any time during the fiscal year then ended setting forth such tax information as shall be necessary for the preparation by the Member of his or her federal and state income tax returns and a report of the investment activities of the Investment Fund during such year.

6. An Investment Fund will maintain and preserve, for the life of the Investment Fund and at least six years thereafter, such accounts, books, and other documents as constitute the record forming the basis for the audited financial statements and annual reports of the Investment Fund to be provided to its Members, and agrees that all such records will be subject to examination by the Commission and its staff. All such records will be maintained in an easily accessible place for at least the first two years.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28642 Filed 12–28–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90764; File No. 10–133]

Self-Regulatory Organizations; OneChicago, LLC; Notice of Filing and Request for Comment on OneChicago, LLC's Notice of Withdrawal of Registration as a National Securities Exchange Solely for the Purposes of Trading Security Futures Products

December 21, 2020.

I. Introduction

Notice is hereby given that on September 21, 2020, OneChicago, LLC (''OneChicago'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') notice of withdrawal of its registration as a national securities exchange solely for the purposes of trading security futures products, effective September 30, 2020, pursuant to Section 19(a)(3) of the Securities Exchange Act of 1934.[1] OneChicago ceased trading operations as of September 18, 2020. The Exchange has closed its trading facility and all positions have been closed out as of that date.[2]

II. Description

Prior to September 18, 2020, OneChicago operated as a national securities exchange solely for the purposes of trading security futures products, pursuant to 15 U.S.C. 78f(g).[3] On August 13, 2020, OneChicago released Notice to Members 2020–07, which announced that its controlling ownership, after a strategic review, determined to close the Exchange with the last day of trading to be September 18, 2020. OneChicago stated that it notified all impacted customers. The Exchange also stated that in order to maintain an orderly market through the closing process, pursuant to Exchange Rule 421 (Emergencies), on September 4, 2020, the Exchange announced that the December 18, 2020 expiration and the March 19, 2021 expirations would be accelerated to September 18, 2020. The Exchange represented that as of September 21, 2020, it has closed its trading facility and all positions have been closed out.[4]

Pursuant to 15 U.S.C. 78s(a)(3), OneChicago filed with the Commission a notice of withdrawal from registration as a national securities exchange solely for the purposes of trading security futures products, effective September 30, 2020. The Exchange stated that, pursuant to 7 U.S.C. 11, it also requested that, effective December 21, 2020, the Commodity Futures Trading Commission (''CFTC'') vacate OneChicago's registration as a designated contract market.[5] Pursuant to 15 U.S.C. 78f(g)(2)(C), the Exchange's registration as a national securities exchange solely for the purposes of trading security futures products would terminate when the CFTC's vacation order is effective, as OneChicago will no longer meet the condition of being designated by the CFTC as a contract market. Nonetheless, OneChicago filed a notice of withdrawal to take affirmative action to withdraw its registration, effective September 30, 2020.

Subsequent to the submission of the notice of withdrawal, the Exchange has represented to the Commission that it will maintain, for a period of 5 years from the effective date of the withdrawal of OneChicago's registration as a national securities exchange solely for the purposes of trading security futures products, all documents, books, and records, including correspondence, memoranda, papers, notices, accounts and other records (collectively ''records'') made or received by it in connection with proposed rule changes filed with the Commission or in connection with its operations as a national securities exchange as required

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[1] 15 U.S.C. 78s(a)(3).

[2] *See* letter from Thomas G. McCabe, Chief Regulatory Officer, OneChicago, to Vanessa Countryman, Secretary, Commission, dated September 21, 2020 (''McCabe Letter'').

[3] *See* McCabe Letter, supra note 2, at 1.

[4] *See id.*

[5] *See id.*

to be maintained under Rule 17a–1(a) and (b),[6] and produce such records and furnish such information at the request of any representative of the Commission.[7]

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the notice of withdrawal 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*).

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 10–133. 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 10–133, and should be submitted on or before January 19, 2021.

By the Commission.

Vanessa A. Countryman,

Secretary.

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BILLING CODE 8011–01–P

[6] *See* 17 CFR 240.17a–1(a) and (b).

[7] *See* email from David Downey, Chief Executive Officer, OneChicago, to David Dimitrious, Division of Trading and Markets, dated December 4, 2020.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90753; File No. SR–NYSE–2020–104]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Effective Date in Commentary .10 Under NYSE Rule 1210

December 21, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 15, 2020, the New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II 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 proposes a rule change to extend the effective date in Commentary .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE Rule 1210 (Registration Requirements) applicable to member organizations, from December 31, 2020 to April 30, 2021. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, 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 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 Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend the effective date in Commentary .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE Rule 1210 (Registration Requirements) applicable to member organizations,[3] from December 31, 2020 to April 30, 2021. The proposed rule change would extend the 120-day period that certain individuals can function as a principal without having successfully passed an appropriate qualification examination through April 30, 2021,[4] and would apply only to those individuals who were designated to function as a principal prior to January 1, 2021. This proposed rule change is based on a filing recently submitted by the Financial Regulatory Authority, Inc. (''FINRA'')[5] and is intended to harmonize the Exchange's registration rules with those of FINRA so as to promote uniform standards across the securities industry.

The COVID–19 pandemic is an unpredictable, exogenous event that has resulted in unavoidable disruptions to the securities industry and impacted member firms, regulators, investors and other stakeholders. In response to COVID–19, earlier this year FINRA

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The term ''member organization'' means a registered broker or dealer (unless exempt pursuant to the Securities Exchange Act of 1934) (the ''Act''), including sole proprietors, partnerships, limited liability partnerships, corporations, and limited liability corporations, approved by the Exchange pursuant to Rule 311. A registered broker or dealer must also be approved by the Exchange and authorized to designate an associated natural person to effect transactions on the floor of the Exchange or any facility thereof. *See* Rule 2(b)(i). The term ''member organization'' also includes any registered broker or dealer which does not own a trading license and agrees to be regulated by the Exchange as a member organization and which the Exchange has agreed to regulate. *See* Rule 2(b)(ii).

[4] If NYSE seeks to provide additional temporary relief from the rule requirements identified in this proposed rule change beyond April 30, 2021, NYSE will submit a separate rule filing to further extend the temporary extension of time.

[5] *See* Exchange Act Release No. 90617 (December 9, 2020), 85 FR 81258 (December 15, 2020) (SR–FINRA–2020–043) (the ''FINRA Filing''). The Exchange notes that the FINRA Filing also provides temporary relief to individuals registered with FINRA as Operations Professionals under FINRA Rule 1220. The Exchange does not have a registration category for Operations Professionals and therefore, the Exchange is not proposing to adopt that aspect of the FINRA Filing.

began providing temporary relief by way of frequently asked questions (''FAQs'')[6] to address disruptions to the administration of FINRA qualification examinations caused by the pandemic that have significantly limited the ability of individuals to sit for examinations due to Prometric test center capacity issues.[7]

FINRA published the first FAQ on March 20, 2020, providing that individuals who were designated to function as principals under FINRA Rule 1210.04[8] prior to February 2, 2020, would be given until May 31, 2020, to pass the appropriate principal qualification examination.[9] On May 19, 2020, FINRA extended the relief to pass the appropriate examination until June 30, 2020. On June 29, 2020, FINRA again extended the temporary relief providing that individuals who were designated to function as principals under FINRA Rule 1210.04 prior to May 4, 2020, would be given until August 31, 2020, to pass the appropriate principal qualification examination.

On September 25, 2020, NYSE filed with the Commission a proposed rule change for immediate effectiveness to extend the temporary relief provided via the FAQ by adopting temporary Commentary .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE Rule 1210 (Registration Requirements).[10] Pursuant to this rule filing, individuals who were designated prior to September 3, 2020, to function as a principal under NYSE Rule 1210.10 have until December 31, 2020, to pass the appropriate qualification examination.

The COVID–19 conditions necessitating the extension of relief provided in the FAQ and SR–NYSE–2020–80 persist and in fact appear to be worsening.[11] One of the impacts of COVID–19 continues to be serious interruptions in the administration of FINRA qualification examinations at Prometric test centers and the limited ability of individuals to sit for the examinations.[12] Although Prometric has been reopening its test centers, Prometric's safety practices mean that currently not all test centers are open, some of the open test centers are at limited capacity, and some open test centers are delivering only certain examinations that have been deemed essential by the local government.[13] Furthermore, Prometric has had to close some reopened test centers due to incidents of COVID–19 cases. The initial nationwide closure in March along with the inability to fully reopen all Prometric test centers due to COVID–19 have led to a significant backlog of individuals who are waiting to sit for FINRA examinations that are not available online, including the General Securities Principal Exam (Series 24).[14]

In addition, firms are continuing to experience operational challenges with much of their personnel working from home due to shelter-in-place orders, restrictions on businesses and social activity imposed in various states, and adherence to other social distancing guidelines consistent with the recommendations of public health officials.[15] As a result, firms continue to face potentially significant disruptions to their normal business operations that may include a limitation of in-person activities and staff absenteeism as a result of the health and welfare concerns stemming from COVID–19. Such potential disruptions may be further exacerbated and may even affect client services if firms cannot continue to keep principal positions filled as they may have difficulty finding other qualified individuals to transition into these roles or may need to reallocate employee time and resources away from other critical responsibilities at the firm.

These ongoing, extenuating circumstances make it impracticable for member organizations to ensure that the individuals whom they have designated to function in a principal capacity, as set forth in NYSE Rule 1210.03, are able to successfully sit for and pass an appropriate qualification examination within the 120-calendar day period required under the rule, or to find other qualified staff to fill this position. The ongoing circumstances also require individuals to be exposed to the health risks associated with taking an in-person examination, because the General Securities Principal examination is not available online. Therefore, NYSE is proposing to extend the effective date of the temporary relief provided through SR–NYSE–2020–80 until April 30, 2021. The proposed rule change would apply only to those individuals who were designated to function as a principal prior to January 1, 2021. Any individuals designated to function as a principal on or after January 1, 2021, would need to successfully pass an appropriate qualification examination within 120 days.

NYSE believes that this proposed continued extension of time is tailored to address the needs and constraints on a member organization's operations during the COVID–19 pandemic, without significantly compromising critical investor protection. The proposed extension of time will help to minimize the impact of COVID–19 on member organizations by providing continued flexibility so that member organizations can ensure that principal positions remain filled. The potential risks from the proposed extension of the 120-day period are mitigated by the member organization's continued requirement to supervise the activities of these designated individuals and ensure compliance with federal securities laws and regulations, as well as NYSE rules.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[16] in general, and furthers the objectives of Section 6(b)(5),[17] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and

[6] *See https://www.finra.org/rules-guidance/key-topics/covid-19/faq#qe.*

[7] At the outset of the COVID–19 pandemic, all FINRA qualification examinations were administered at test centers operated by Prometric. Based on the health and welfare concerns resulting from COVID–19, in March Prometric closed all of its test centers in the United States and Canada and began to slowly reopen some of them at limited capacity in May. Currently, Prometric has resumed testing in many of its United States and Canada test centers, at either full or limited occupancy, based on local and government mandates.

[8] NYSE Rule 1210.03 is the corresponding rule to FINRA Rule 1210.04.

[9] FINRA Rule 1210.04 (Requirements for Registered Persons Functioning as Principals for a Limited Period) allows a member firm to designate certain individuals to function in a principal capacity for 120 calendar days before having to pass an appropriate principal qualification examination. NYSE Rule 1210.03 provides the same allowance to member organizations.

[10] *See* Exchange Act Release No. 90111 (October 7, 2020), 85 FR 65090 (October 14, 2020) (Notice of Filing and Immediate Effectiveness of SR–NYSE–2020–80).

[11] *See, e.g.,* Meryl Kornfield, Jacqueline Dupree, Marisa Iati, Paulina Villegas, Siobhan O'Grady and Hamza Shaban, New daily coronavirus cases in U.S. rise to 145,000, latest all-time high, Wash. Post, November 11, 2020, *https://www.washingtonpost.com/nation/2020/11/11/coronavirus-covid-live-updates-us/.*

[12] Information about the continued impact of COVID–19 on FINRA-administered examinations is available at *https://www.finra.org/rules-guidance/key-topics/covid-19/exams.*

[13] Information from Prometric about its safety practices and the impact of COVID–19 on its operations is available at *https://www.prometric.com/corona-virus-update. See also supra* note 12.

[14] Earlier this year, an online test delivery service was launched for candidates seeking to take qualification examination remotely. Only certain qualification examinations are available online. *See supra* note 12. FINRA is considering making additional qualification examinations available remotely on a limited basis.

[15] *See, e.g.,* Centers for Disease Control and Prevention, How to Protect Yourself & Others, *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html.*

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

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 proposed rule change is intended to minimize the impact of COVID–19 on member organization operations by extending the 120-day period certain individuals may function as a principal without having successfully passed an appropriate qualification examination under NYSE Rule 1210.03 until April 30, 2021. The proposed rule change does not relieve member organizations from maintaining, under the circumstances, a reasonably designed system to supervise the activities of their associated persons to achieve compliance with applicable securities laws and regulations, and with applicable NYSE rules that directly serve investor protection. In a time when faced with unique challenges resulting from the COVID–19 pandemic, NYSE believes that the proposed rule change is a sensible accommodation that will continue to afford member organizations the ability to ensure that critical positions are filled and client services maintained, while continuing to serve and promote the protection of investors and the public interest in this unique environment.

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. As set forth in SR–NYSE–2020–80, the proposed rule change is intended solely to extend temporary relief necessitated by the continued impacts of the COVID–19 pandemic and the related health and safety risks of conducting in-person activities. In its filing, FINRA notes that the proposed rule change is necessary to temporarily rebalance the attendant benefits and costs of the obligations under FINRA Rule 1210 in response to the impacts of the COVID–19 pandemic that would otherwise result if the temporary amendments were to expire on December 31, 2020.[18] The Exchange accordingly incorporates FINRA's abbreviated economic impact assessment by reference.

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. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [19] and Rule 19b–4(f)(6) thereunder.[20]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii), the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately upon filing. As noted above, the Exchange stated that the proposed extension of time will help minimize the impact of the COVID–19 outbreak on member organizations' operations by allowing them to keep principal positions filled and minimizing disruptions to client services and other critical responsibilities. The Exchange further stated that the ongoing extenuating circumstances of the COVID–19 pandemic make it impractical to ensure that individuals designated to act in these capacities are able to take and pass the appropriate qualification examination during the 120-calendar day period required under the rules. The Exchange also explained that shelter-in-place orders, quarantining, restrictions on business and social activity and adherence to social distancing guidelines consistent with the recommendations of public officials remain in place in various states.[21] In addition, the Exchange observed that, following a nationwide closure of all test centers earlier in the year, some test centers have re-opened, but are operating at limited capacity or are only delivering certain examinations that have been deemed essential by the local government.[22] Although, as the Exchange noted, FINRA has launched an online test delivery service to help address this backlog, the General Securities Principal (Series 24) Examination is not available online.[23] Nevertheless, the Exchange explained that the proposed rule change will provide needed flexibility to ensure that these positions remain filled and is tailored to address the constraints on member organizations' operations during the COVID–19 pandemic without significantly compromising critical investor protection.[24]

The Commission observes that the Exchange's proposal, like the FINRA Filing, provides only an extension to temporary relief from the requirement to pass certain qualification examinations within the 120-day period in the rules. As proposed, this relief would extend the 120-day period that certain individuals can function as principals through April 30, 2021. If a further extension of temporary relief from the rule requirements identified in this proposal beyond April 30, 2021 is required, the Exchange noted that it may submit a separate rule filing to extend the effectiveness of the temporary relief under these rules.[25] For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest.[26] Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[27]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may

[18] *See* FINRA Filing, 85 FR at 81260.

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[21] *See supra* note 15.

[22] *See supra* notes 12 and 13. The Exchange states that Prometric has also had to close some reopened test centers due to incidents of COVID–19 cases.

[23] *See supra* note 14. FINRA is considering making additional qualification examinations available remotely on a limited basis.

[24] The Exchange states that member organizations remain subject to the continued requirement to supervise the activities of these designated individuals and ensure compliance with federal securities laws and regulations, as well as NYSE rules.

[25] *See supra* note 4.

[26] As noted above by NYSE, this proposal is an extension of temporary relief provided in a prior filing where NYSE also requested and the Commission granted a waiver of the 30-day operative delay. *See supra* note 10, 85 FR at 65092.

[27] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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–NYSE–2020–104 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–2020–104. 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 NYSE. 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–NYSE–2020–104 and should be submitted on or before January 19, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28665 Filed 12–28–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90758; File No. SR–Phlx–2020–53]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Harmonize Exchange Rule General 3, Section 16 With Recent Changes by the Financial Industry Regulatory Authority, Inc.

December 21, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 11, 2020, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared substantially 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 proposes to harmonize Exchange Rule General 3, Section 16 with recent changes by the Financial Industry Regulatory Authority, Inc. (''FINRA''). This amendment would temporarily grant the Exchange Review Council (''ERC'') authority[3] to conduct hearings in connection with appeals of Membership Application Program decisions by video conference, if warranted by the current COVID–19-related public health risks posed by an in-person hearing. As proposed, the temporary amendment would be in effect through April 30, 2021.[4]

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/phlx/rules,* at the principal office of the Exchange, 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 proposes to harmonize Exchange Rule General 3, Section 16 with recent changes to FINRA Rule 1015 in order to temporarily grant the ERC authority to conduct hearings in connection with appeals of Membership Application Program decisions by video conference, if warranted by the current COVID–19-related public health risks posed by an in-person hearing.[5] As proposed, these temporary amendments would be in effect through April 30, 2021.

Background

The Exchange's rule regarding the hearing and evidentiary process for appeals of Membership Application Program decisions as set forth in Rule

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[28] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] For ERC hearings under Exchange Rule General 3, Section 16, this temporary authority is granted to the ERC or relevant Subcommittee.

[4] If the Exchange requires temporary relief from the rule requirements identified in this proposal beyond April 30, 2021, the Exchange may submit a separate rule filing to extend the expiration date of the temporary amendments under these rules. The amended Exchange rules will revert back to their original state at the conclusion of the temporary relief period and any extension thereof.

[5] *See* Exchange Act Release No. 89737 (September 2, 2020), 85 FR 55712 (September 9, 2020) (SR–FINRA–2020–027) (''FINRA Filing''). *See also* Exchange Act Release No. 90619 (December 9, 2020), 85 FR 81250 (December 15, 2020) (SR–FINRA–2020–042) (extending the relief in the FINRA Filing through April 30, 2021). The Exchange notes that the FINRA Filing also proposed to temporarily amend FINRA Rules 9261, 9524, and 9830, which govern hearings in connection with appeals of disciplinary actions, eligibility proceedings, and temporary and permanent cease and desist orders. The Exchange's Rules 9261, 9524, and 9830 incorporate by reference The Nasdaq Stock Market LLC rules, which are the subject of a separate filing. *See* SR–NASDAQ–2020–076 (November 5, 2020). Therefore, the Exchange is not proposing to adopt that aspect of the FINRA Filing.

General 3, Section 16 is based on FINRA's Rule 1015. As adopted, the text of Exchange Rule General 3, Section 16 is substantially the same as FINRA Rule 1015, with the exception of conforming and technical differences.

In view of the ongoing spread of COVID–19 and its effect on FINRA's adjudicatory functions nationwide, FINRA recently filed a temporary rule change to grant the National Adjudicatory Council (''NAC'') the authority to conduct certain hearings by video conference, if warranted by the current COVID–19-related public health risks posed by in-person hearings.[6] Accordingly, the Exchange proposes to file this temporary rule change to align with the temporary rule change filed by FINRA.

Mirroring FINRA's NAC, the ERC is the Exchange's appellate body, which reviews initial decisions issued by FINRA's Office of Hearing Officers (''OHO'') and—through Subcommittees—holds evidentiary hearings for Membership Application Program decision appeals and eligibility proceedings under Exchange Rule General 3, Section 16. This temporary proposed rule change will allow the ERC or relevant Subcommittee to make an assessment as to whether an in-person hearing would compromise the health and safety of the hearing participants such that the hearing should proceed by video conference.

Proposed Rule Change

Consistent with FINRA's temporary amendment to FINRA Rule 1015, the Exchange proposes to temporarily grant the ERC authority to conduct hearings in connection with appeals of Membership Application Program decisions by video conference, if warranted by the current COVID–19-related public health risks posed by an in-person hearing. The proposed change will permit the ERC to make an assessment, based on critical COVID–19 data and criteria, as to whether an in-person hearing would compromise the health and safety of the hearing participants such that the hearing should proceed by video conference. The Exchange believes that this is a reasonable procedure to follow in hearings under Rule General 3, Section 16.

To effectuate these changes, the Exchange proposes to add the following sentence to General 3, Section 16(a)(vi):

Upon consideration of the current public health risks presented by an in-person hearing, the Exchange Review Council or Subcommittee may, on a temporary basis, determine that the hearing shall be conducted, in whole or in part, by video conference.

The proposed text is substantially the same as the language adopted by FINRA, excepting conforming and technical differences.[7]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Section 6(b)(5) of the Act,[9] in particular, 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, by providing greater harmonization between the Exchange rules and FINRA rules of similar purpose, resulting in less burdensome and more efficient regulatory compliance.

As previously noted, the text of Exchange Rule General 3, Section 16 is substantially the same as FINRA's rule. As such, the proposed rule change will foster cooperation and coordination with persons engaged in facilitating transactions in securities and will remove impediments to and perfect the mechanism of a free and open market and a national market system.

The Exchange believes that the proposed temporary rule change will permit the Exchange to effectively conduct hearings during the COVID–19 pandemic in situations where in-person hearings present likely public health risks. The ability to conduct hearings by video conference will thereby permit the Exchange's adjudicatory functions to continue unabated, thereby avoiding protracted delays. Conducting hearings via video conference will give the parties and adjudicators simultaneous visual and oral communication without the risks inherent in physical proximity during a pandemic.

The Exchange believes that the temporary proposed rule change strikes an appropriate balance between providing fair process and enabling the Exchange to fulfill its statutory obligations to protect investors and maintain fair and orderly markets while accounting for the significant health and safety risks of in-person hearings stemming from the outbreak of COVID–19.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the temporary proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but is rather intended solely to provide temporary relief given the impacts of the COVID–19 pandemic. In its filing, FINRA provides an abbreviated economic impact assessment maintaining that the changes are necessary to temporarily rebalance the attendant benefits and costs of the obligations under FINRA Rule 1015 in response to the impacts of the COVID–19 pandemic that is equally applicable to the changes the Exchange proposes.[10] The Exchange accordingly incorporates FINRA's abbreviated economic impact assessment by reference.

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

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[11] and subparagraph (f)(6) of Rule 19b–4 thereunder.[12]

The Exchange believes that this filing is non-controversial and eligible to become effective immediately because the proposal promotes uniformity in rules across self-regulatory organizations thereby enabling the Exchange to conduct hearings during the COVID–19 pandemic by video conference where the health risks of in-person hearings are significant. The proposed rule change is based on, and

[6] *See* FINRA Filing, 85 FR at 55712.

[7] *See id.* at 55712.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] *See* FINRA Filing, 85 FR at 55716.

[11] 15 U.S.C. 78s(b)(3)(A)(iii).

[12] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

similar to, recent changes made to FINRA Rule 1015 that addressed the issue of balancing public health risks with conducting hearings during the COVID–19 pandemic. The Exchange proposes to adopt the rule change in substantially the same form as it was adopted by FINRA. The Exchange further believes that the proposed rule change would not significantly affect the protection of investors or the public interest or impose any significant burden on competition because the changes are based on the rules of FINRA. Moreover, the proposed rule change is not intended to address competitive issues but rather is concerned solely with providing temporary relief given the impacts of the COVID–19 pandemic.

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–Phlx–2020–53 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–Phlx–2020–53. 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–Phlx–2020–53 and should be submitted on or before January 19, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28672 Filed 12–28–20; 8:45 am]

BILLING CODE 8011–01–P

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34147; 812–15096–01]

KKR Registered Advisor LLC and KKR Real Estate Select Trust Inc.

December 22, 2020.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from section 23(a)(1) of the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain registered closed-end management investment companies (''closed-end funds'') and business development companies (''BDCs'',[1] and together with the closed-end funds, ''Funds'') to pay Advisory Fees (defined below) in shares of their common stock (''Shares'').

APPLICANTS: KKR Registered Advisor LLC (the ''Existing Adviser'') and KKR Real Estate Select Trust Inc. (the ''KREST Fund'' and together with the Existing Adviser, the ''Applicants'').

FILING DATES: The application was filed on February 19, 2020, and amended on May 28, 2020, September 14, 2020, November 5, 2020, and December 18, 2020.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving Applicants with a copy of the request by email. Hearing requests should be received by the Commission by 5:30 p.m. on January 18, 2021, and should be accompanied by proof of service on the 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: Secretary, U.S. Securities and Exchange Commission: *Secretarys-Office@sec.gov.* Applicants: Lori Hoffman, Esq., *General.Counsel@kkr.com.*

FOR FURTHER INFORMATION CONTACT: Hae-Sung Lee, Senior Counsel, at (202) 551–7345, or Trace W. Rakestraw, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number or an Applicant using the ''Company'' name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. Applicants seek an order of the Commission under section 6(c) of the Act, granting an exemption from section 23(a)(1) of the Act to the extent necessary to allow a Fund[2] to pay its

[1] The term ''BDC'' means business development company as defined under Section 2(a)(48) of the Act.

[2] The term ''Fund'' means (i) the KREST Fund and (ii) any existing or future closed-end management investment company (A) that is registered under the Act or has elected to be

Adviser[3] all or part of the Advisory Fees[4] earned by the Adviser in Shares in lieu of paying an equivalent amount in cash.

2. The Existing Adviser, a Delaware limited liability company registered as an investment adviser under the Advisers Act, currently serves as the investment adviser to the KREST Fund pursuant to its Advisory Agreement. The Existing Adviser, or another Adviser registered under the Advisers Act, would serve as investment adviser to each Fund.

3. The KREST Fund, a Maryland corporation that would register under the Act as a closed-end management investment company, would continuously offer its Shares and expects to offer periodic liquidity with respect to its Shares through tender offers conducted in compliance with rule 13e–4 under the Securities Exchange Act of 1934 (as amended, the ''Exchange Act'').[5] The KREST Fund would be non-listed, and the Shares would not trade on an exchange.[6] The KREST Fund expects to invest primarily in illiquid assets.

4. As required by section 15 of the Act, the Adviser would manage the Fund pursuant to an Advisory Agreement that precisely describes the nature and method of calculation of the Advisory Fees. The Advisory Agreement would specify that the Adviser may elect to receive payment of the Advisory Fees it has earned, in whole or in part, in an amount of Shares equal in value to the dollar figure of the Advisory Fees owed. Each fund would disclose this mechanism in its registration statements and proxy statements.

5. Applicants represent that each fund's advisory agreement would specify the fee calculation period for Advisory Fees (*e.g.,* annually, quarterly, monthly, etc.) (such period, the ''Fee Calculation Period''). At the beginning of each Fee Calculation Period, each Fund's Adviser would elect to receive its Advisory Fees for such period in cash, Shares or some combination of both.[7] In making such an election, the Adviser must consider the best interests of the Fund and its shareholders.

6. The number of Shares the Adviser would receive would be calculated by dividing the earned Advisory Fees elected by the Adviser for payment in Shares by the greater of (i) the current net asset value (''NAV'') per share of the class of Shares the Adviser would receive, as determined by or under the supervision of the Fund's board of directors in accordance with the Act and (ii) the current offering price of the class of Shares the Adviser would receive. For example, if an Adviser earned Advisory Fees amounting to $200,000 for a given Fee Calculation Period and the Fund's NAV per share and offering price per share was $25 at the time of issuance to the Adviser, the Fund would issue 8,000 Shares to the Adviser if the Adviser had elected to receive its entire Advisory Fee in Shares for that Fee Calculation Period.

7. A Fund would only rely on the requested relief to issue Shares of a class that is otherwise available for purchase, and reasonably expected to be purchased, by other similarly eligible investors. Furthermore, the Adviser would receive Shares at the same price as such other investors acquiring the same class of Shares. Such class of Shares would not exist solely for investment by the Adviser and/or its affiliates. The Fund's Advisory Agreement would detail the specific class of Shares that the Fund may issue to the Adviser as compensation in lieu of a cash payment.

8. For any Fee Calculation Period during which the Adviser has elected to receive all or a portion of its Advisory Fees in Shares, the Fund would post a notice to that effect on the Fund's website. The Fund would also maintain and make publicly available on its website a historical record of how the Adviser was compensated for each Fee Calculation Period during the Fund's last three fiscal years. The Fund would include, in response to any item on the applicable form for registration of securities requiring a description of the Adviser's compensation (currently Item 9 of Form N–2), a cross-reference noting the availability of such historical information on the Fund's website.

9. Any Shares received by the Adviser in lieu of cash would be subject to the same fees and expenses applicable to the Fund's other shareholders in the relevant class, would not receive preferential voting, dividend or liquidity rights with respect to its Shares, and would otherwise have the same rights and obligations as Shares of the same class issued to other investors in the Fund, except that an Adviser would ''mirror vote'' any Shares received in lieu of a cash payment for Advisory Fees.

10. Each Adviser would have the same opportunity and rights to liquidate Shares of a fund it received in lieu of cash payment of Advisory Fees as other shareholders of that fund. As required by section 30(h) of the Act, each Adviser and its affiliated persons would make public filings with the Commission disclosing any transactions in a Fund's Shares as required by Section 16 of the Exchange Act.

11. An Adviser that elects to receive payment in Shares, however, would commit to not selling those Shares for at least 12 months from the date of issuance, except in exceptional circumstances such as if it no longer serves as the investment adviser of the Fund. In such a case, the Adviser would keep a record of the reason for selling the Shares within 12 months and the records would be maintained and preserved in accordance with rule 204–2(e)(1) under the Advisers Act. Applicants state that this commitment would provide further assurances that an Adviser bears the long-term benefits and risks of an investment in a Fund's Shares and decreases the likelihood of any potential over-reaching by the Adviser. Each fund would publicly disclose the Adviser's commitment in the Fund's registration statement.

12. Consistent with fiduciary obligations under the Act, on an annual basis, the Independent Directors (defined below) of each Fund will review such Fund's Advisory Agreement in accordance with section 15(c) and subject to section 36 of the Act, including those provisions allowing for payment of Advisory Fees

regulated as a BDC, (B) whose investment adviser is an Adviser (as defined below) and (C) that intends to rely the requested order. Each person that currently intends to rely on the requested order is named as an Applicant. Any person that relies on the requested order in the future would do so only in accordance with the terms and conditions contained in the Application.

[3] The term ''Adviser'' means (i) the Existing Adviser, (ii) any investment adviser that controls, is controlled by or is under common control with the Existing Adviser and is registered as an investment adviser under the Investment Advisers Act of 1940, as amended (the ''Advisers Act'') or (iii) any successor in interest to any entity described under (i) and (ii) of this definition. For purposes of the requested order, the term ''successor'' is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization.

[4] The term ''Advisory Fees'' means the compensation a Fund agrees to pay its Adviser pursuant to an investment advisory agreement with its Adviser subject to section 15 of the Act (each, an ''Advisory Agreement''). Such compensation may include base management fees, income-based incentive fees, and/or capital gains-based incentive fees, as applicable and permissible under the Advisers Act. With respect to the requested relief, the Applicants do not differentiate among these types of Advisory Fees because, in each case, an Adviser would receive shares in lieu of a dollar amount of Advisory Fees.

[5] Other Funds that rely on the requested order in the future may offer periodic liquidity in compliance with rule 23c–3 under the Act (''Interval Funds'').

[6] If the KREST Fund, or any other Fund, lists its Shares, it would no longer rely on the requested order.

[7] If an Adviser elects to receive its Advisory Fees in a combination of cash and shares of common stock, it would also choose at the beginning of the Fee Calculation Period what portion of Advisory Fees it would receive in Shares.

in Shares. To the extent an Adviser receives any fallout benefits from receiving compensation in Shares rather than in cash, the Adviser would disclose such benefits to the Independent Directors.

13. The Adviser would have the ability to assign its right to receive payment of any Advisory Fees to an entity it controls, is controlled by or with which it is under common control (a ''control affiliate''); provided that such an assignment may not disadvantage the fund. Any Shares issued to a control affiliate of an Adviser would be subject to the same conditions of the requested relief as if the Shares were issued to and held by the Adviser directly and an Adviser's obligations to a Fund under the Advisory Agreement would remain unchanged. To the extent an Adviser receives any fallout benefits from an assignment to a control affiliate, the Adviser would disclose such benefits to the Independent Directors [8] of the applicable Fund in connection with their annual review of such Fund's Advisory Agreement in accordance with section 15(c) of the Act.

Applicants' Legal Analysis

14. Section 23(a)(1) of the Act prohibits a registered closed-end investment company from issuing any of its securities in exchange for services. Section 63 of the Act makes the prohibition in section 23(a)(1) applicable to BDCs.

15. Section 6(c) of the Act provides that an exemptive order may be granted if and to the extent that such an exemption is ''necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions'' of the Act.

16. Applicants assert that the concerns underlying section 23(a)(1) of the Act do not exist under the requested relief. These concerns include: (i) Preferential treatment of investment company insiders and the use of options and other rights by insiders to obtain control of the investment company; (ii) complication of the investment company's structure that made it difficult to determine the value of the company's shares; and (iii) dilution of stockholders' equity in the investment company.[9]

17. In particular, section 23(a)(1) of the Act was enacted in response to a then-common practice of funds paying insiders a definite number of shares of the fund at a future date for their services (rather than assigning a fixed dollar value to the services).[10] If the value of the fund's shares appreciated by the time the shares were payable by the fund, the compensation paid to the insiders exceeded the original cash value of the services provided. As a result, the fund treated insiders on a basis more favorable than other shareholders by allowing them to acquire fund shares at less than the net asset value of the shares. The insiders received a ''windfall'' that diluted the value of the shares held by other shareholders. Applicants maintain that the proposed arrangement addresses this concern because the value of the Shares an investment adviser would receive would be equal to a fixed-dollar amount as calculated under the fund's investment advisory agreement.

18. Applicants assert that the requested relief does not raise otherwise concerns about preferential treatment of Applicant's insiders because an Adviser would receive a class of Shares that is available for purchase by similarly qualified investors and that would be issued at the same price per share available to other investors in the Fund at the time of issuance to the Adviser. No Adviser would receive any preferential voting, dividend or liquidity rights with respect to Shares. The Shares would be subject to the same fees and expenses applicable to other shareholders in the relevant class. Furthermore, the Adviser and any control affiliate would mirror vote any Shares received in lieu of cash for Advisory Fees. Thus, Applicants state that the requested relief would not become a means for insiders to obtain control of any Fund.

19. The Funds would not modify their capital structure as a result of the requested relief. The Fund's registration statements and proxy statements would include ''plain English'' disclosure on the existence of the relief, a statement that the Adviser may be compensated in Shares in lieu of cash and any potential risks associated with relying on the relief. Such risk disclosure may explain that third party shareholders would not have priority over the Adviser or its affiliates with respect to receiving liquidity during any periodic tender or repurchase offers and that may have the effect of diluting third party shareholders with respect to any such offers.

20. Applicants believe the proposed arrangement does not raise dilution concerns associated with other forms of equity-based compensation, such as stock options. The Fund would issue Shares to the Adviser at the greater of their current NAV per share and their current offering price, and the Fund would increase its assets in direct proportion to the Shares issued to the Adviser, forestalling any dilutive effect.

21. Applicants believe the requested relief is appropriate and in the interest of the Funds' shareholders because when an Adviser elects to receive its Advisory Fees in Shares, it would increase fund assets available for investment purposes and create better alignment of interests between the Fund and the Adviser. Absent the requested relief, a fund would be required to hold a greater amount of investable assets in cash for payment of Advisory Fees or could be forced to liquidate assets at unfavorable times or prices to pay Advisory Fees in cash, which could be problematic for a fund that invests primarily in illiquid assets. For any Fee Calculation Period where the Adviser elects payment in Shares, the advance notice provided by the Adviser's election would allow the Fund to deploy the cash that would otherwise need to be held for payment of Advisory Fees, reducing cash ''drag'' and opportunity costs for the Fund.

22. Applicants assert that the requested relief further aligns the interests of an Adviser with those of Fund shareholders because the Adviser has more so-called ''skin in the game.'' As opposed to payment in cash, an Adviser would invest in the Fund alongside, and at the same price as, other investors. This would further align the interests of Fund shareholders and the Fund's Adviser because the Adviser's realizable compensation for any past payment is tied to maintaining or increasing the NAV per share price until the Adviser liquidates such Shares.

23. Applicants state that the Commission has previously provided exemptive relief to allow internally managed closed-end funds and BDCs to issue restricted stock, and in some cases, stock options, as part of a compensation package for employees, officers, and directors. Applicants believe the rationale for such relief is similar to the requested relief because both would provide for investment strategy alignment while allowing the funds to maximize cash available to investments.

[8] The term ''Independent Directors'' means members of the Fund's board of directors who are not ''interested persons'' of the Fund within the meaning of section 2(a)(19) of the Act.

[9] *See* H.R. Rep. No. 76–2639, at 8 (1940) and S. Rep. No. 76–1775, at 7 (1940).

[10] *Investment Trusts and Investment Companies: Hearings on H.R. 10065 Before the House Subcomm, on Interstate and Foreign Commerce,* 76th Cong., 3d Sess. 109 (1940) (statement of David Schenker, Chief Counsel, Investment Trust Study, SEC).

Applicants' Conditions

Applicants agree that any order granting the requested relief would be subject to the following conditions:

1. Each Fund will adopt an Advisory Agreement that specifies that its Adviser may opt to receive Shares in lieu of cash payment of Advisory Fees. Such Advisory Agreement will contain:

a. A precise formula for determining the number of Shares to be issued as compensation to the Adviser for each applicable Fee Calculation Period, including the date upon which the calculation shall be performed, stating that the number of Shares that an Adviser will receive will be equal to the quotient of (x) the sum of Advisory Fees elected by the Adviser for payment in Shares and (y) the greater of (i) the current NAV per share of the class of Shares the Adviser will receive, as determined by or under the supervision of the Fund's board of directors in accordance with section 23(b) of the Act and (ii) the current offering price of the class of Shares the Adviser will receive.

b. A provision ensuring that such Adviser must elect in advance of each Fee Calculation Period whether the Advisory Fees for that Fee Calculation Period will be payable in cash, Shares of the Fund, or some combination of cash and Shares of the Fund, and if a combination of cash and Shares, what the breakdown will be.

2. Any Shares received by an Adviser in lieu of cash payment of Advisory Fees will have the same rights and obligations as Shares of the same class issued to other investors in the Fund, except that an Adviser will mirror vote any Shares received in lieu of cash payment of Advisory Fees in the same proportion as the vote of all other shareholders that are not (i) an Adviser or its control affiliates, and (ii) to the Adviser's knowledge, affiliates of the Adviser (excluding control affiliates), for so long as the Adviser serves as the investment adviser to the Fund. The Adviser will not receive preferential voting, dividend or liquidity rights with respect to its Shares and will be subject to the same fees and expenses applicable to the Fund's other shareholders in the relevant class.

3. Each Fund will disclose in its registration statements and proxy statements (i) that its Adviser may be compensated in Shares in lieu of cash payments in reliance on the relief, (ii) that its Adviser will commit not to sell any Shares received in lieu of a cash payment of Advisory Fees for at least 12 months from the date of issuance, except in exceptional circumstances (in such a case, the Adviser will keep a record of the reason for selling the Shares within 12 months and the records will be maintained and preserved in accordance with rule 204–2(e)(1) under the Advisers Act), and (iii) any potential risks related to relying on the relief. For any Fee Calculation Period during which the Adviser has elected to receive all or a portion of its Advisory Fees in Shares, the Fund will post a notice to that effect on the Fund's website. The Fund will maintain and make publicly available on the Fund's website a historical record of how the Adviser was compensated for each Fee Calculation Period during the Fund's last three fiscal years. The Fund will include, in response to any item on the applicable form for registration of securities requiring a description of the Adviser's compensation (currently Item 9 of Form N–2), a cross-reference noting the availability of such historical information on the Fund's website.

4. The requested relief will expire on the effective date of any Commission rule under the Act that provides relief addressing the ability of closed-end investment companies to pay their investment advisers their advisory fees in shares in lieu of paying an equivalent amount in cash.

By the Commission.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2020–28749 Filed 12–28–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34149; File No. 812–15169]

ALPS ETF Trust, et al.

December 22, 2020.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from sections 2(a)(32), 5(a)(1), 22(d) and 22(e) of the Act and rule 22c–1 under the Act, and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act.

APPLICANTS: ALPS ETF Trust (the ''Trust''), ALPS Advisors, Inc. (the ''Initial Adviser''), and ALPS Portfolio Solutions Distributor, Inc. (the ''Distributor'').

SUMMARY OF APPLICATION: Applicants request an order (''Order'') that permits: (a) Shielded Alpha ETFs (as described in the Reference Order (defined below)) to issue shares (''Shares'') redeemable in large aggregations only (''creation units''); (b) secondary market transactions in Shares to occur at negotiated market prices rather than at net asset value; (c) certain Shielded Alpha ETFs to pay redemption proceeds, under certain circumstances, more than seven days after the tender of Shares for redemption; and (d) certain affiliated persons of a Shielded Alpha ETF to deposit securities into, and receive securities from, the Shielded Alpha ETF in connection with the purchase and redemption of creation units. The relief in the Order would incorporate by reference terms and conditions of the same relief of a previous order granting the same relief sought by applicants, as that order may be amended from time to time (''Reference Order'').[1]

FILING DATE: The application was filed on October 8, 2020 and amended on December 21, 2020.

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 by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving applicants with a copy of the request by email. Hearing requests should be received by the Commission by 5:30 p.m. on January 19, 2021, 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: Secretary, U.S. Securities and Exchange Commission, *Secretarys-Office@sec.gov. Applicants:* Cara B. Owen, Esq., *cara.owen@alpsinc.com.*

FOR FURTHER INFORMATION CONTACT: Laura J. Riegel, Senior Counsel, at (202) 551–3038 or Trace W. Rakestraw,

[1] Blue Tractor ETF Trust and Blue Tractor Group, LLC, Investment Company Act Rel. Nos. 33682 (Nov. 14, 2019) (notice) and 33710 (Dec. 10, 2019) (order). Applicants are not seeking relief under section 12(d)(1)(J) of the Act for an exemption from sections 12(d)(1)(A) and 12(d)(1)(B) of the Act (the ''Section 12(d)(1) Relief''), and relief under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act relating to the Section 12(d)(1) Relief, as granted in the Reference Order. Accordingly, to the extent the terms and conditions of the Reference Order relate to such relief, they are not incorporated by reference into the Order.

Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants

1. The Trust is a statutory trust organized under the laws of Delaware and will consist of one or more series operating as a Shielded Alpha ETFs. The Trust is registered as an open-end management investment company under the Act. Applicants seek relief with respect to Funds (as defined below), including an initial Fund (the ''Initial Fund''). The Funds will operate as Shielded Alpha ETFs as described in the Reference Order.[2]

2. The Initial Adviser is a corporation organized under the laws of Colorado and will be the investment adviser to the Initial Fund. Subject to approval by the Trust's board of trustees, an Adviser (as defined below) will serve as investment adviser to each Fund. The Initial Adviser is, and any other Adviser will be, registered as an investment adviser under the Investment Advisers Act of 1940 (''Advisers Act''). The Adviser may enter into sub-advisory agreements with other investment advisers to act as sub-advisers with respect to the Funds (each a ''Sub-Adviser''). Any Sub-Adviser to a Fund will be registered under the Advisers Act.

3. The Distributor is a corporation organized under the laws of Colorado and a broker-dealer registered under the Securities Exchange Act of 1934, as amended, and will act as the principal underwriter of Shares of the Funds. Applicants request that the requested relief apply to any distributor of Shares, whether affiliated or unaffiliated with the Adviser and/or Sub-Adviser (included in the term ''Distributor''). Any Distributor will comply with the terms and conditions of the Order.

Applicants' Requested Exemptive Relief

4. Applicants seek the requested Order under section 6(c) of the Act for an exemption from sections 2(a)(32), 5(a)(1), 22(d) and 22(e) of the Act and rule 22c–1 under the Act, and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act. The requested Order would permit applicants to offer Funds that operate as Shielded Alpha ETFs. Because the relief requested is the same as certain of the relief granted by the Commission under the Reference Order and because the Initial Adviser has entered into a licensing agreement with Blue Tractor Group LLC, or an affiliate thereof, in order to offer Funds that operate as Shielded Alpha ETFs, the Order would incorporate by reference the terms and conditions of the same relief of the Reference Order.

5. Applicants request that the Order apply to the Initial Fund and to any other existing or future registered open-end management investment company or series thereof that: (a) Is advised by the Initial Adviser or any entity controlling, controlled by, or under common control with the Initial Adviser (any such entity, along with the Initial Adviser, included in the term ''Adviser''); (b) operates as a Shielded Alpha ETF as described by the Reference Order; and (c) complies with the terms and conditions of the Order and the terms and conditions of the Reference Order that are incorporated by reference into the Order (each such company or series and the Initial Fund, a ''Fund'').[3]

6. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction, or any class of persons, securities or transactions, from any provisions of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 17(b) of the Act authorizes the Commission to exempt a proposed transaction from section 17(a) of the Act if evidence establishes that the terms of the transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, and the transaction is consistent with the policies of the registered investment company and the general purposes of the Act. Applicants submit that for the reasons stated in the Reference Order the requested relief meets the exemptive standards under sections 6(c) and 17(b) of the Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2020–28763 Filed 12–28–20; 8:45 am]

BILLING CODE 8011–01–P

[2] To facilitate arbitrage, among other things, each day a Fund would publish a basket of securities and cash that, while different from the Fund's portfolio, is designed to closely track its daily performance.

[3] All entities that currently intend to rely on the Order are named as applicants. Any other entity that relies on the Order in the future will comply with the terms and conditions of the Order and the terms and conditions of the Reference Order that are incorporated by reference into the Order.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90763; File No. SR–OCC–2020–016]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of Filing of Proposed Rule Change Concerning The Options Clearing Corporation's System for Theoretical Analysis and Numerical Simulation (''STANS'') Methodology Documentation

December 21, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act''),[1] and Rule 19b-4 thereunder,[2] notice is hereby given that on December 9, 2020, the Options Clearing Corporation (''OCC'') 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 OCC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

This proposed rule change by OCC would adopt a new document describing OCC's System for Theoretical Analysis and Numerical Simulation (''STANS''), which OCC uses to calculate daily and intra-day margin requirements for its Clearing Members (such document being the ''STANS Methodology Description''). OCC also proposes to make conforming and other non-substantive changes to its Margin Policy.

The proposed STANS Methodology Description is submitted without marking in confidential Exhibit 5A to SR–OCC–2020–016 because this document is being submitted in its entirety as new rule text. The proposed changes to OCC's current rule text related to the STANS methodology, known as the Margins Methodology, are contained in confidential Exhibit 5B to SR–OCC–2020–016. Material proposed to be added to the current rule text is

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

marked by underlining and material proposed to be deleted is marked by strikethrough text. The proposed changes to the Margin Policy are contained in confidential Exhibit 5C to SR–OCC–2020–016.[3] Material proposed to be added to the Margin Policy is marked by underlining and material proposed to be deleted is marked by strikethrough text. The proposed rule change does not require any changes to the text of OCC's By-Laws or Rules. All terms with initial capitalization that are not otherwise defined herein have the same meaning as set forth in OCC's By-Laws and Rules.[4]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, OCC 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. OCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(1) Purpose

Background

The STANS methodology is OCC's proprietary risk management system for calculating Clearing Member margin requirements.[5] In general, STANS utilizes large-scale Monte Carlo simulations to forecast price and volatility movements in determining a Clearing Member's margin requirement.[6] The STANS margin requirement is calculated at the portfolio level of Clearing Member accounts with positions in marginable securities. The STANS margin requirement consists of an estimate of a 99% expected shortfall (''ES'')[7] over a two-day time horizon with additional charges for model risk, stress tests, liquidation costs, and various add-ons. The STANS methodology is used to measure the exposure of portfolios of options, futures, and cash instruments cleared by OCC.[8]

OCC maintains technical documentation that describes in detail how the various quantitative components of STANS were developed and operate, including the various parameters and assumptions contained within those components[9] and the mathematical theories underlying the selection of those quantitative methods (''Model Whitepapers''). The Model Whitepapers are currently synthesized in a single document, the Margins Methodology, describing how STANS operates from end to end. The Margins Methodology includes material aspects of OCC's risk-based margin system, which OCC must establish as a covered clearing agency under the Exchange Act and the rules promulgated thereunder, and which must be reasonably designed to, in part ''(i) [produce] margin levels commensurate with [the] risks and particular attributes of each relevant product, portfolio, and market; (ii) [mark] participant positions to market and [collect] margin, including variation margin or equivalent charges if relevant, at least daily . . . ; (iii) [calculate] margin sufficient to cover its potential future exposure to participants in the interval between the last margin collection and the close out of positions following a participant default; (iv) [use] reliable sources of timely price data and [use] procedures and sound valuation models for addressing circumstances in which pricing data are not readily available or reliable; [and] (v) [use] an appropriate method for measuring credit exposure that accounts for relevant product risk factors and portfolio effects across products . . .''[10] The Margins Methodology also includes information that would not be considered material aspects of OCC's methodology, such as internal procedural and administrative details, or details that could be reasonably and fairly implied by OCC's existing rules or other information contained in the document.

Over time, OCC has filed sections of the Margins Methodology with the Commission as proposed rule changes under Section 19(b)(1) of the Exchange Act and Rule 19b–4 thereunder to effect changes to individual components of STANS.[11] Thus, those chapters of the Margins Methodology have become codified as OCC rule text under Section 19(b)(1) of the Exchange Act and Rule 19b–4. However, OCC now proposes to adopt a new STANS Methodology Description, which would replace the Margins Methodology document and codify the STANS methodology in its entirety under Section 19(b)(1) of the Exchange Act and Rule 19b–4. After adoption of the STANS Methodology Description, OCC would no longer maintain the Margins Methodology, neither as an OCC rule nor as an internal document.

In connection with this proposed rule change, OCC would also retire as rule text any chapters of the Margins Methodology previously filed with the Commission, as the proposed STANS Methodology Description is intended to cover the material aspects of the STANS methodology. Those chapters of the Margins Methodology that OCC has previously filed under Section 19(b)(1) of the Exchange Act and Rule 19b–4[12] would be superseded in their entireties by new corresponding sections in the

[3] OCC has filed a proposed rule change with the Commission to adopt a new Third-Party Risk Management Framework (''TPRMF''), which would replace the Counterparty Credit Risk Management Policy and provide an overview of OCC's approach to third-party risk management. That proposed rule change also includes conforming changes to OCC's Margin Policy. *See* Securities Exchange Act Release No. 90406 (November 12, 2020), 85 FR 73582 (November 18, 2020) (SR–OCC–2020–014). The proposed changes to the Margin Policy currently pending Commission review in SR–OCC–2020–014 are marked in double underlining and double strikethrough text.

[4] OCC's By-Laws and Rules can be found on OCC's public website: *https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules.*

[5] *See* Securities Exchange Act Release No. 53322 (February 15, 2006), 71 FR 9403 (February 23, 2006) (SR–OCC–2004–20).

[6] *See* OCC Rule 601.

[7] The ES component is established as the estimated average of potential losses higher than the value-at-risk (''VaR'') threshold. VaR refers to a statistical technique that is used in risk management to measure the potential risk of loss for a given set of assets over a particular time horizon.

[8] Pursuant to OCC Rule 601(e)(1), OCC also calculates initial margin requirements for segregated futures accounts on a gross basis using the Standard Portfolio Analysis of Risk Margin Calculation System (''SPAN''). SPAN is separate from STANS and is therefore not described in the STANS Methodology Description.

[9] *See* Securities Exchange Act Release No. 82473 (January 9, 2018), 83 FR 2271 (January 16, 2018) (SR–OCC–2017–011), which describes how OCC periodically reviews the parameters and assumptions used by STANS pursuant to its Model Risk Management Policy and in accordance with 17 CFR 240.17Ad–22(e)(6).

[10] 17 CFR 240.17Ad–22(e)(6).

[11] *See* Securities Exchange Act Release No. 74966 (May 14, 2015), 80 FR 29784 (May 22, 2015) (SR–OCC–2015–010); Securities Exchange Act Release No. 76128 (December 28, 2015), 81 FR 135 (January 4, 2016) (SR–OCC–2015–016); Securities Exchange Act Release No. 79818 (January 18, 2017), 82 FR 8455 (January 25, 2017) (SR–OCC–2017–001); Securities Exchange Act Release No. 82161 (November 28, 2017), 82 FR 57306 (December 4, 2017) (SR–OCC–2017–022); Securities Exchange Act Release No. 84524 (November 2, 2018), 83 FR 55918 (November 8, 2018) (SR–OCC–2018–014); Securities Exchange Act Release No. 85440 (March 28, 2019), 84 FR 13082 (April 3, 2019) (SR–OCC–2019–002); Securities Exchange Act Release No. 85755 (April 30, 2019), 87 FR 19815 (May 6, 2019) (SR–OCC–2019–004); Securities Exchange Act Release No. 86296 (July 3, 2019), 84 FR 32816 (July 9, 2019) (SR–OCC–2019–005); Securities Exchange Act Release No. 87387 (October 23, 2019), 84 FR 57890 (October 29, 2019) (SR–OCC–2019–010); Securities Exchange Act Release No. 89392 (July 24, 2020), 85 FR 45938 (July 30,2020) (SR–OCC–2020–007); Securities Exchange Act Release No. 90139 (October 8, 2020), 85 FR 65886 (October 16, 2020) (SR–OCC–2020–012).

[12] *Id.*

STANS Methodology Description, as described in further detail herein.

The current text of the Margins Methodology includes various details that would no longer be OCC rule text following the adoption of the proposed STANS Methodology Description. While the details that OCC proposes to remove are described in further detail herein, thematically, they consist of the following:

- Details on OCC's historical modeling practices and potential future enhancements, which do not describe how a model currently functions;
- Details on the exact set of current products applied to each STANS component, which will change from time to time as OCC-cleared products are listed and delisted;
- Various configuration choices made by OCC, such as data sources, model parameters, and model performance monitoring, that are not inherent to model selection or design and that do not materially impact a model's results, which OCC may from time to time determine it should modify based on current market conditions and business practices;
- Extensive, detailed testing results and explanatory rationale supporting a model;
- Recitations of standard mathematical and economic theories/techniques that are well-known in quantitative finance, readily found in public sources, and do not include OCC-specific modifications or applications;
- Redundant descriptions of a model component appearing in multiple chapters;
- Details on OCC's implementation of a model in its internal technology systems and application of model results in operational procedures that are not inherent to a model and that OCC could change from time to time without affecting a model's results; and
- Manual margin adjustments and add-ons OCC employs pursuant to OCC rules, policies, and/or procedures outside the STANS methodology.

The proposed STANS Methodology Description is intended to be a comprehensive description of STANS that is made available to Clearing Members and enable an informed reader to understand OCC's modeling choices and the interconnectedness of STANS model components in producing OCC margin requirements. Therefore, OCC believes the details summarized above and described herein are extraneous to this purpose. Rather, OCC believes these types of details are more appropriately covered—to the extent these details are specific to an OCC model—in other OCC rules and policies, Model Whitepapers, or other internal OCC documentation.

OCC also believes, as described in Item II.A.2 below, these details do not need to maintained as OCC ''rules'' as defined by Section 19(b)(1) of the Exchange Act and Rule 19b–4.[13] These internal procedural and administrative details used by OCC's model developers and model validators would: (1) Be reasonably and fairly implied by the proposed STANS Methodology Description, OCC's Margin Policy,[14] OCC's Model Risk Management Policy,[15] and other OCC rules; and/or (2) otherwise not be deemed to be material aspects of OCC's margin setting-related operations. While OCC would not maintain these details in the STANS Methodology Description, OCC would continue to maintain and update these details when necessary in the Model Whitepapers and other internal OCC documentation, where these details are also currently found.[16]

STANS Methodology Description

The proposed STANS Methodology Description would describe the material aspects of OCC's margin methodology. Specifically, the STANS Methodology Description would include (i) an executive summary; (ii) descriptions of the quantitative model components of STANS; and (iii) ''model utilities'' intended to enhance the quality of model results. Each of these sections is described in further detail below.[17]

Executive Summary

The STANS Methodology Description would provide an executive summary of STANS. This executive summary would describe how the purpose of STANS is to determine margin requirements for OCC's Clearing Members (as described below), and in doing so meet various risk management goals and regulatory requirements for OCC. The executive summary would then describe the types of positions and collateral modeled through STANS, which include (i) valued securities and stock loans; (ii) equity, index, and futures options; (iii) Flexible Exchange (''FLEX'') options; (iv) equity and index futures; (v) volatility futures; and (vi) commodity futures. The executive summary would then provide an overview of the STANS methodology, which includes (i) econometric calibration; (ii) copula estimation and Monte Carlo simulation; (iii) volatility forecasting; (iv) theoretical underlying price generation; (v) theoretical derivatives price generation; and (vi) aggregation and margin calculation. These components are described in further detail below. The executive summary would then describe OCC's model monitoring activities, which include (i) daily backtesting and (ii) ongoing parameter monitoring pursuant to monitoring plans established by OCC's Model Risk Working Group (''MRWG'').[18] The executive summary would then describe that STANS relies on price feeds of real-time market data to generate theoretical values in calculating margin requirements, and how OCC staff may use price editing techniques to improve the quality of pricing data for input into STANS.[19] Lastly, the executive summary would briefly outline the organization of the sections of the STANS Methodology Description that substantively describe the core components of the STANS methodology

[13] Section 19(b)(1) of the Exchange Act requires a self-regulatory organization (''SRO'') such as OCC to file with the Commission any proposed rule or any proposed change in, addition to, or deletion from the rules of such SRO. *See* 15 U.S.C. 78s(b)(1). Section 3(a)(27) of the Exchange Act defines ''rules of a clearing agency'' to mean its (1) constitution, (2) articles of incorporation, (3) bylaws, (4) rules, (5) instruments corresponding to the foregoing and (6) such ''stated policies, practices and interpretations'' (''SPPI'') as the Commission may determine by rule. *See* 15 U.S.C. 78c(a)(27). Exchange Act Rule 19b–4(a)(6) defines the term ''SPPI'' to include (i) any material aspect of the operation of the facilities of an SRO and (ii) statements made generally available to membership of, to all participants in, or to persons having or seeking access to facilities of an SRO that establishes or changes certain standards, limits, or guidelines. *See* 17 CFR 240.19b–4(a)(6). Rule 19b–4(c) provides, however, that an SPPI may not be deemed to be a proposed rule change if it is: (i) Reasonably and fairly implied by an existing rule of the SRO or (ii) concerned solely with the administration of the SRO and is not an SPPI with respect to the meaning, administration, or enforcement of an existing rule the SRO. *See* 17 CFR 240.19b–4(c).

[14] *See* Securities Exchange Act Release No. 82355 (December 19, 2017), 82 FR 61058 (December 26, 2017) (SR–OCC–2017–007).

[15] *See* Securities Exchange Act Release No. 82473 (January 9, 2018), 83 FR 2271 (January 16, 2018) (SR–OCC–2017–011).

[16] OCC's Model Risk Management Policy establishes detailed standards for Model Whitepapers and governance to adopt or make changes to a Model Whitepaper. *See id.*

[17] The proposed STANS Methodology Description would also include the following non-substantive sections: (i) A table of contents; (ii) a list of references to academic and technical documents, both public and internal to OCC; and (iii) a table of defined terms used in the STANS Methodology Description.

[18] OCC's Margin Policy and Model Risk Management Policy provide more detail on OCC's model monitoring activities. *See supra* notes 14 and 15.

[19] OCC's Collateral Risk Management Policy and Margin Policy provide more detail on the function of OCC's Pricing & Margins department. *See* Securities Exchange Act Release No. 82009 (November 3, 2017), 82 FR 52079 (November 9, 2017) (SR–OCC–2017–008) and *supra* note 14.

and the related data processing utilities used by STANS.

The proposed text of this executive summary would replace current OCC rule text from the Margins Methodology's introductory section. The current text, in addition to summarizing the STANS methodology as would the proposed text described above, includes descriptions of the following:

- OCC's historical modeling practices: OCC does not believe this historical information is needed to understand how the model functions.
- Redundant details of the STANS methodology also found in the main body of both the Margins Methodology and the proposed STANS Methodology Description: This information, would already be detailed in the main body of the STANS Methodology Description, and OCC does not believe repeating it here is needed to understand how STANS functions.
- A ''documentation guide'' describing what information can be found within various sections of the Margins Methodology: OCC does not believe this documentation guide is needed to understand how STANS functions, or to understand the organization of the proposed STANS Methodology Description.

For the reasons stated above, OCC proposes to delete this rule text in its entirety without adding new, corresponding rule text in the STANS Methodology Description.

STANS Methodology Components

The STANS Methodology Description would next describe the components of OCC's risk-based margin methodology, which OCC uses to cover the credit exposures presented by Clearing Members in accordance with Rule 17Ad–22(e)(6). In particular, the STANS Methodology Description would describe the (i) calibration of various parameters and price data inputs used by OCC's econometric and pricing models to create risk factors; (ii) construction of a copula from the risk factors that identifies correlations among simulated changes in the various risk factors; (iii) application of the simulated risk factor changes and correlations to actual data through Monte Carlo simulations that estimate 10,000 possible scenarios for each risk factor, then estimation of theoretical prices for securities, derivatives, and futures using these theoretical scenarios; and (iv) application of the theoretical prices to actual Clearing Member positions to calculate margin requirements.

i. Model and Econometric Calibration

The STANS Methodology Description would describe how the quantitative models used by STANS incorporate various historical price data and econometric parameter inputs, which are used to estimate and simulate the risk for an associated product. These inputs consist of (i) returns on equity securities; (ii) implied volatilities; (iii) energy and commodity futures; (iv) treasury securities; (v) variance futures; and (vi) volatility futures. In total, there are currently approximately 40,000 of these inputs. The exact number of inputs is subject to change based on the types of products that OCC clears and OCC's research on what risk factors correlate with prices changes in these products. Historical price data comes from OCC's Pricing & Margins department, which obtains the data from external vendors and then validates it for use within STANS.[20] STANS uses several models, described below, to calibrate this historical data and then transform the historical data into theoretical values that, along with specialized volatility forecast and marginal distribution parameters constructed by other OCC models described below, are used to construct a copula, described in the next step.

Equity Returns

STANS uses returns on equity securities that are based on current market prices. STANS first calibrates this data by simply creating a time series of logarithmic returns based on the closing, and in some cases opening, prices. This transformation does not require a separate model. The data is used to create econometric parameters and for pricing as described further below.

Implied Volatility

STANS uses implied volatility risk factors to measure the expected future volatility of an option's underlying security at expiration, which is reflected in the current option premium in the market. To address variations in implied volatility, OCC models a volatility surface for options by incorporating into the econometric models underlying STANS certain risk factors called ''pivot points.'' These pivot points are chosen such that their combination allows STANS to identify changes in the level, skew, convexity, and term structure of the implied volatility surface. STANS generates a value for each of the nine pivot points for each eligible underlying asset and for each business day in the historical data period. To calibrate this data, for each of the nine pivot points STANS performs a kernel smoothing technique[21] on the historical data. Application of these pivot points enables STANS to simulate implied volatility scenarios, which are then used to create the specialized volatility forecast and marginal distribution parameters described below, and in the pricing of options through OCC's option pricing models described further below.[22]

The proposed text would replace current OCC rule text from the Margins Methodology's section on implied volatility. The current rule text also includes other information related to the implied volatility model. Specifically, the current rule text includes descriptions of the following:

- Products eligible for implied volatility scenarios modeling in STANS: OCC does not believe the exact list of products to which this model is applied is needed to understand how the model functions, and this list may change from time to time as OCC-cleared products are listed and delisted.
- Data sources used by STANS to perform the kernel smoothing technique: These data sources are configuration choices made by OCC that are not inherent to the model's selection or design and that OCC could change from time to time without affecting the model's results.
- Rationale for the assumptions underlying implied volatility modeling of longer-tenor options: OCC does not believe that the justification for these model assumptions is needed to understand how the model currently functions.
- Historical background on OCC's decision to incorporate implied volatility modeling into STANS: OCC does not believe that this historical information is needed to understand how the model currently functions.
- Model testing and validation results for the implied volatility model: OCC does not believe that the internal testing and validation performed to verify the model is fit for use is needed to understand how the model currently functions.

OCC believes that this information is more appropriately covered in the Implied Volatility Scenarios Model Whitepaper and other internal OCC documentation rather than in OCC's

[20] *See supra* note 14.

[21] ''Kernel smoothing'' is a statistical process by which data points are better fitted to an expected function using weighted averages and a ''smoothing parameter.''

[22] *See* Securities Exchange Act Release No. 76128 and Securities Exchange Act Release No. 84524 for more information on the function and application of the implied volatility model.

rules for the reasons listed above. Therefore, OCC proposes to delete this rule text in its entirety without adding new, corresponding rule text in the STANS Methodology Description.

Treasury Securities

STANS prices treasury securities [23] using a Nelson-Siegel framework,[24] a commonly used polynomial model for constructing the term structure of an interest rate and modeling changes in a yield curve.[25] STANS constructs a theoretical yield curve using current and historical settlement prices for treasury securities.

STANS calibrates this data by transforming the market prices into a time series of unobservable factors that represents the yield curve. STANS fits these Nelson-Siegel parameters using observed bond prices. In simulation, STANS creates ''shocks'' on theoretical Nelson-Siegel parameters [26] to create theoretical interest rate curves, which are in turn used to price treasury securities.

The proposed text would replace current OCC rule text from the Margins Methodology's section on U.S. Treasury bills and fixed rate notes, bonds, and strips. The current rule text also includes other information related to the treasury securities and interest rate model. Specifically, the current rule text includes the following:

- Summary and introduction sections that describe OCC's need to model treasury securities and interest rates and provide an overview of the U.S. Treasury securities market: OCC does not believe these background descriptions of the macroeconomic environment, found in public sources, are needed to understand how the model currently functions.
- Restatements of mathematical definitions and equations describing the relationship between the forward and yield curves, and the payoff function for bonds used to describe all interest rate curves: This information, while relevant to understanding how the model functions, is foundational information commonly understood in quantitative finance and readily found in public academic sources. To the extent the text does not describe OCC's application of these theories, OCC does not believe this information needs to be maintained in OCC's rules.
- Details on how OCC implemented the model in its technology systems: These implementation details relate to OCC's internal administration of its technology systems and are not needed to understand how the model currently functions. Because these details are not inherent to the model's selection or design, OCC could also change them from time to time without affecting the model's results.
- Redundant description of the copula constructed by STANS: This information, described further below, would already be detailed in the STANS Methodology Description section related to the construction of a copula, and OCC does not believe repeating it here is needed to understand how the model currently functions.

OCC believes that this information is more appropriately covered in the Nominal Treasury Securities Model Whitepaper and other internal OCC documentation rather than in OCC's rules for the reasons listed above. Therefore, OCC proposes to delete this rule text in its entirety without adding new, corresponding rule text in the STANS Methodology Description.

Generic Futures

Relying on current futures prices and time series of spot prices as inputs, STANS uses a generic futures model to price linear derivatives with limited term structures. Using basic economic assumptions that the relationship of spot prices to forward prices does not allow for arbitrage and that futures prices equal forward prices, or that any deviations from this are adequately addressed through costs implicit in carrying such positions,[27] the model estimates and applies theoretical discount factors to the futures prices. These discount factors are based on a ratio of estimated spot prices on the underlying securities to the futures prices.

Variance Futures

STANS uses a specialized factor model to price variance futures, which uses historical data for both variance futures products and the Standard and Poor's 500 Index (''SPX''). This model relies on basic assumptions that the short-term volatility of variance futures prices tends to revert towards a mean (*i.e.,* volatility remains relatively close to an average value), but the long-term volatility is itself stochastic. Using these assumptions, STANS fits current values of the volatility and volatility mean reversion level, in addition to parameters describing the dynamics, to the current term structure of variance futures prices. Modeling variance futures prices based on these assumptions allows the theoretical prices to move in a realistic fashion.

The model is first calibrated with historical data on variance futures prices and their recent dynamics. It then simulates prices for variance futures using two sets of random variables: (i) SPX returns; and (ii) changes in the long-term volatility level, represented by normal random numbers that STANS generates daily for use only with variance futures and that have no correlation with other theoretical numbers generated by STANS. Both random variables are used to simulate scenarios for prices of the variance futures tenors.

Synthetic Futures

Using logarithmic daily returns of active futures and various other securities, STANS uses a ''synthetic futures'' model to estimate prices of certain products such as volatility index-based futures (*e.g.,* VIX futures). In general, the synthetic futures model creates an artificial (or ''synthetic'') time series of price innovations for actual futures contracts with approximately the same tenor as the actively-traded futures.[28] This synthetic time series then serves as a uniform substitute for a time series of daily settlement prices for the actual futures contracts, which persists over many expiration cycles and thus can be used as a basis for econometric analysis. STANS performs this analysis by fitting the synthetic time series with associated volatility forecast and marginal distribution parameters, which are described below.

The traded futures contracts are then mapped to the simulated return scenarios of the corresponding synthetic contracts to produce theoretical prices. The first synthetic contract in the series contains returns of the front contract on any given day. STANS switches the

[23] While OCC does not clear treasury securities or derivatives on such products, OCC permits Clearing Members to deposit treasury securities as margin collateral.

[24] *See* Nelson, C.R. and Siegel, A.F., ''Parsimonious Modeling of Yield Curves,'' 60 *The J. of Bus.* 4, 473–489 (1987) (describing the Nelson-Siegel model).

[25] In addition to pricing treasury securities, STANS uses a Nelson-Siegel framework to simulate potential changes in interest rates. Refer to the below description of the interest rate curve model utility.

[26] STANS also introduces extra ''noise'' into the bond prices to account for the bonds' idiosyncratic behaviors and prevent the resulting treasury securities price movements from being perfectly correlated.

[27] As described previously, pursuant to OCC's Model Risk Management Policy OCC periodically reviews all parameters and assumptions used in STANS and they are subject to change.

[28] *See* Securities Exchange Act Release No. 85440 for further information on OCC's synthetic futures model as applied to volatility index-based products. OCC notes that the synthetic futures model can also be used for other futures products, such as interest rate futures. *See e.g.,* Securities Exchange Act Release No. 89392 and Securities Exchange Act Release No. 90139.

front contract of the series to the next one out on the day following the expiration date of the front contract. While the synthetic time series contain returns from different contracts, a return on any given date is constructed from prices of the same contract. Using a synthetic time series allows STANS to better approximate correlations between futures contracts of different tenors by creating more price data points and their margin offsets. These synthetic time series are mapped to the underlying futures product they are intended to represent.

The proposed text would replace current OCC rule text from the Margins Methodology's section on synthetic futures. The current rule text also includes other information related to the synthetic futures model. Specifically, the current rule text includes descriptions of the following:

• Rationale for making changes to the model in 2019 [29] and other historical information: OCC does not believe that this rationale and historical information is needed to understand how the model currently functions.

• Equations for standard GARCH provided for introductory purposes: A description of OCC's GARCH model, described further below, would already be detailed in the STANS Methodology Description section related to GARCH parameters, and OCC does not believe repeating it here is needed to understand how the model functions. Furthermore, the GARCH equations as implemented in STANS are modified from the standard GARCH equations provided here, and OCC believes this text could create confusion around the exact GARCH equations used in STANS.[30]

OCC believes that this information is more appropriately covered in the Synthetic Futures Model Whitepaper and other internal OCC documentation rather than in OCC's rules for the reasons listed above. Therefore, OCC proposes to delete this rule text in its entirety without adding new, corresponding rule text in the STANS Methodology Description.

GARCH and NRIG Parameters

STANS utilizes econometric parameters related to volatility forecasts and marginal distributions, and calibrates these parameters using ten-year histories of the data inputs described above. For both volatility forecasts and marginal distributions, STANS utilizes a generalized autoregressive conditional heteroskedasticity (''GARCH'') model. GARCH is a common statistical model for, in a time series of data, comparing the variance of one point in the time series to the previous point in the series rather than an arithmetic average of all the points in the series. This is particularly useful when the value of volatility at one point in a time series is known to be correlated with the volatility at previous points in the series. STANS estimates these GARCH parameters through a maximum likelihood estimation method. By fitting these GARCH parameters to a time series of risk factor innovations, STANS is able to remove the effects of volatility from—or ''devolatilize''—the risk factor time series so that the copula described below can estimate the correlations among the risk factors irrespective of their individual volatilities.

To model volatility forecast parameters, STANS fits the time series of implied volatility pivot points (described above) into a Student's t-distribution, a continuous probability distribution that is commonly used to estimate the mean of a population with a relatively small sample size and unknown standard deviation. To determine the appropriate degrees of freedom for a particular distribution, STANS applies an Anderson-Darling test.

To model marginal distribution parameters, STANS utilizes a normal reciprocal inverse Gaussian (''NRIG'') distribution, a special case of the generalized hyperbolic distribution.[31] The returns [32] of each risk factor used in STANS are assumed to exhibit returns in the shape of a symmetric NRIG distribution.[33] Consequently, STANS calibrates NRIG parameters that are designed to describe the shape of every risk factor individually.

As described previously, STANS constructs these GARCH and NRIG parameters from the historical price data and econometric parameter inputs that are first calibrated by the models described above. These historical price data and econometric parameters, and the resulting GARCH and NRIG parameters, are the foundational data elements used by the copula and pricing models described in the proceeding steps.

The STANS Methodology Description would also describe the controls that may be placed on the GJR–GARCH parameters after their initial calibration. GARCH volatility forecasting models can be very reactive in certain market environments. As a result, OCC may implement parameter controls for risk factors and classes of risk factors, which are subject to periodic review and approval by the MRWG.

The proposed text would replace current OCC rule text from the Margins Methodology's section on GARCH forecasts. OCC notes that the current rule text describes the standard NRIG cumulative distribution function that is widely available in public academic texts. The proposed rule text would describe the same function in a re-parameterized form that is proprietary to OCC. While the two forms are mathematically equivalent, the re-parameterized form is used in the Econometric Model for Risk Factors in STANS Model Whitepaper and the proposed text would therefore be made consistent with the Model Whitepaper. The proposed rule text would also include a citation to an academic paper describing the rationale for the re-parameterization.

The current rule text also includes other information related to OCC's GARCH model. Specifically, the current rule text includes descriptions of the following:

• Introductory language describing the standard Glosten-Jagannathan-Runkle GARCH model and the use of a Student's t-distribution: This information, while relevant to understanding how the model functions, is foundational information commonly understood in quantitative finance and readily found in public academic sources. To the extent this text does not describe OCC's application of GARCH and the Student's t-distribution, OCC does not believe this information needs to be maintained in OCC's rules.

• Details on variance forecasting (*i.e.,* considering how securities volatility tends to clusters during certain periods) as rationale for model selection: OCC believes this information is extraneous to understanding how the GARCH model currently functions in STANS.

• Variance forecasting as applied to the One-Day and Two-Day Scenarios model utility: This information, described further below, would already be detailed in the STANS Methodology Description section related to the One-Day and Two-Day Scenarios model

[29] *See id.*

[30] *See infra* note 36.

[31] The generalized hyperbolic distribution is a special type of continuous probability distribution. *See* Barndorff-Nielsen, O., ''Exponentially decreasing distributions for the logarithm of particle size,'' 353 *Proc. of the Royal Soc'y of London. Series A, Mathematical and Physical Sci.* 1674, 401–419 (1977) (explaining the generalized hyperbolic distribution).

[32] ''Return'' refers generally to changes in a risk factor's value over a time interval. Returns could take the form of simple differences, log returns, or other forms.

[33] Except for (i) Chicago Volatility Index (''VIX'') futures, which are assumed to follow an asymmetric NRIG distribution, and (ii) implied volatility, which is assumed to follow a Student's t-distribution.

utility, and OCC does not believe repeating it here is needed to understand how the model utility currently functions.

• Mathematical rationale for the cumulative distribution function,[34] inverse cumulative distribution function, and degrees of freedom for the Student's t-distribution used by the GARCH model for implied volatility risk factors: OCC believes this information is extraneous to understanding how the GARCH model currently functions in STANS. This information is also foundational information commonly understood in quantitative finance and readily found in public academic literature. To the extent this text does not describe OCC's application of these functions and the Student's t-distribution, OCC does not believe this information needs to be maintained in OCC's rules.

• Explanatory mathematical formulas for variance forecasting of implied volatility risk factors and a likelihood function [35] and equations related to the Anderson-Darling test,[36] including the Student's t cumulative distribution function for integer values of **ν**: These details relate to implementation of the GARCH model in OCC's internal technology systems, are not inherent to the model's selection or design, and are not needed to understand how the model currently functions.

• Expressions for the Gamma and Beta functions: [37] This information, while relevant to understanding how the model functions, is foundational information commonly understood in quantitative finance and readily found in public academic literature. To the extent the text does not describe OCC's application of Gamma and Beta functions in the model, OCC does not believe this information needs to be maintained in OCC's rules.

OCC believes that this information is more appropriately covered in the underlying GARCH Model Whitepaper and other internal OCC documentation rather than in OCC's rules for the reasons listed above. Therefore, OCC proposes to delete this rule text in its entirety without adding new, corresponding rule text in the STANS Methodology Description.

ii. Copula Construction

The STANS Methodology Description would describe how a copula is used to quantify the joint behavior and dependence structure of the risk factors used by STANS. A copula is a mathematical construct used in probability theory to calculate the cumulative distribution of a set of random variables. The fitted copula can then be used by STANS to perform Monte Carlo simulations of theoretical prices for underlying securities and associated derivatives, which will be used in the aggregation step during which margin requirements are calculated.

To estimate the copula, STANS first transforms two years of historical data for the risk factors produced by the models described above into a data set described by the Student's t-distribution with four degrees for freedom.[38] STANS then performs a singular value decomposition of this data set to obtain the eigenvector decomposition [39] of the correlation matrix. This means the resulting fitted copula is a Student's t copula with four degrees of freedom.

Before the copula is estimated, STANS performs an ''alignment'' step on the time series to identify and separately process risk factors with incomplete data sets that lack sufficient data to estimate the copula. Specifically, for pricing data/models for underlyings OCC extracts data on the previous two years (*i.e.,* 500 business days) and ensures (i) the data has no more than 100 missing returns as compared to baseline dates and (ii) the five latest returns are not missing as compared to baseline dates. If a risk factor's data set does not meet each of these three criteria, it is subject to a conditional or default simulation, described below.

To simulate price movements, STANS draws random samples from the multivariate Student's t-distribution described by the copula. These random draws are abstract values that correspond to correlated, uniform, normalized shocks in the risk factors. STANS then reincorporates the individual volatility and marginal distribution of the risk factors to create appropriate return scenarios. STANS next applies these theoretical returns to current market prices to generate potential price scenarios for underlying securities. STANS essentially performs the reverse of the function that was performed to fit the econometrics of the risk factors.

The proposed text would replace current OCC rule text from the Margins Methodology's section on the Student-t Copula model. The current rule text also includes other information related to the construction and simulation of a copula in STANS. Specifically, the current rule text includes a mathematical justification for using a copula generally, and introductory text describing the general properties of a Student's t copula. OCC believes this information is extraneous to understanding how the Student-t Copula model currently functions in STANS. This information is also foundational information commonly understood in quantitative finance and readily found in public academic literature. To the extent this text does not describe OCC's application of a mathematical copula, OCC does not believe this information needs to be maintained in OCC's rules. Instead, OCC believes that this information is more appropriately covered in the underlying Student-t Copula Model Whitepaper and other internal OCC documentation rather than in OCC's rules for the reasons listed above. Therefore, OCC proposes to delete this rule text in its entirety without adding new, corresponding rule text in the STANS Methodology Description.

Conditional and Default Simulations

For risk factors with data sets that have only recently become available, or that have experienced drastic changes in their return characteristics, and do not meet one or more of the criteria in the alignment step, there may be too small of a sample size to reliably estimate correlations among the data. In such cases, these risk factors are excluded from the copula simulation in STANS and OCC applies conditional or default simulation.

OCC applies a conditional simulation when it believes that a risk factor that has been identified during the alignment step does not meet the data quality criteria but has an appreciable correlation with another risk factor that has a more robust dataset. OCC uses that more robust risk factor's data as a proxy for the identified risk factor. The identified risk factor is assumed to

[34] In probability theory, the cumulative distribution function of a random variable is the probability that the variable will be less than or equal to a set value.

[35] A likelihood function is a tool used to measure the goodness of fit of a statistical model to sample data.

[36] The Anderson-Darling test is a statistical test of whether a given sample of data is drawn from a population of data with a specific probability distribution.

[37] Gamma and Beta functions, respectively, are related one and two-variable functions that serve as foundations for various mathematical applications.

[38] Based on OCC's research, four degrees of freedom is in the conservative end of a range of degrees of freedom that are generally suitable fits for univariate distributions and is therefore appropriate for use in constructing the copula.

[39] In the context of linear transformations, an Eigenvector is a value that does not change direction when the transformation is applied to it, but rather changes in scale based on the application of a scalar factor, called an Eigenvalue. Eigenvectors and Eigenvalues are used to analyze the characteristics of linear transformations, including correlation/covariance matrices, and generate random variables with the equivalent correlation.

exhibit simulated results that follow an NRIG distribution of specified mean, variance, and shape parameters, and any variation from the proxy data is assumed to be purely idiosyncratic. Pursuant to OCC's Margin Policy, OCC periodically reviews whether applying a conditional simulation to a particular risk factor continues to be appropriate.

OCC applies a default simulation when it does not believe an identified risk factor has any obvious proxy and has no view on its prospective volatility, or when a risk factor is identified by STANS during nightly margin processing and OCC has not already selected it to undergo a conditional simulation. In a default simulation, movements in the risk factor are assumed to be entirely idiosyncratic and have a volatility that is typical of highly volatile stocks.

The proposed text would replace current OCC rule text from the Margins Methodology's section on default, derived, and conditional factors. The current rule text also includes other information related to conditional and default simulations. Specifically, the current rule text includes the following:

- Introductory text restating the use of time series in STANS: This information would already be described elsewhere in the STANS Methodology Description where applicable, and OCC does not believe repeating it here is needed to understand how the model functions.
- A description of ''derived scenarios,'' a special case of conditional simulations related to exchange rate risk factors: This special case is applied pursuant to internal OCC procedures, and occurs outside of the STANS methodology. Therefore, OCC does not believe this information is needed to understand how the model currently functions.
- A description of the how OCC operationally applies conditional simulations: These operational details relate to OCC's application of the model's results in operational procedures and are not inherent to the model's selection or design, and that OCC could change from time to time without affecting the model's results.
- Details on how OCC implemented default scenarios in its internal technology systems: These implementation details relate to OCC's internal administration of its technology systems and are not inherent to the model's selection or design, and that OCC could change from time-to-time without affecting the model's results.

OCC believes that this information is more appropriately covered in the Student-t Copula Model Whitepaper or other internal OCC documentation rather than in OCC's rules for the reasons listed above. Therefore, OCC proposes to delete this rule text in its entirety without adding new, corresponding rule text in the STANS Methodology Description.

iii. Implied Volatility Smoothing and Options Pricing

The STANS Methodology Description would next describe how STANS utilizes the inputs and outputs described above to (i) perform implied volatility smoothing, (ii) price European and American options, (iii) price Asian FLEX options, and (iv) price Cliquet options.

Implied Volatility Smoothing

STANS employs an Implied Volatility Smoothing model to estimate fair prices of listed option contracts based on their bid and ask price quotes. This model supports pricing of the following types of options: (i) European and American options on equity products with a dividend yield or with discrete cash dividends; (ii) European and American options on futures on equity indices, currencies, and commodities; (iii) options on volatility indices for which volatility futures trade (*e.g.,* VIX options [40]); (iv) forward start options; and (v) Asian FLEX options.

The model is essentially an advanced data filtering and pre-processing technique to improve data quality to support option pricing during the calibration and simulation phases of the STANS methodology. It makes use of the same theory that underpins OCC's Vanilla Options model, described below. The most important stages of the Implied Volatility Smoothing model are: (i) A preprocessing procedure, to filter out ''bad'' price quotes; (ii) an implied forward price calculation using prices from near-the-money options on the same securities at all tenors or expiration dates; (iii) the smoothing, in which prices are generated for all plain vanilla listed options at all strikes by using corresponding bid and ask price quotes and forward prices (from step two); and (iv) construction of a volatility surface based on linear interpolation of total variance among the smoothed prices and performing any necessary post-processing. When applied to prices estimated by the option pricing models described below, the model functions to (i) makes data points comprising the volatility surface more consistent with the actual bid-ask spreads found in current market prices and (ii) correct data that would create arbitrage opportunities by not having monotonicity and convexity with respect to the strike and/or not satisfying put-call parity.[41]

The proposed text would replace current OCC rule text from the Margins Methodology's section on the Implied Volatility Smoothing model. The current rule text also includes other information related to the model. Specifically, the current rule text includes the following:

- A description of the use of target prices based on model parameters: This represents configuration choices made by OCC that are not inherent to the model's selection or design and that do not materially impact the model's results, which OCC may from time to time determine it should modify based on current market conditions and business practices.
- Economic rationale for various features of the model: OCC does not believe that this economic rationale is needed to understand how the model currently functions.
- A discussion of the model's performance in deriving theoretical spot prices from underlying futures and indices, and specific ''if/then'' conditions the model applies to bid and ask prices to filter out poor quality data based on certain control parameters: These data filtering parameters are configuration choices made by OCC that are not inherent to the model's selection or design and that do not materially impact the model's results, which OCC may from time to time determine it should modify based on current market conditions and business practices.
- Mathematical rationale for the method by which the smoothing algorithm calculates implied forward prices: OCC does not believe that the rationale for the model's configuration is needed to understand how the model currently functions.
- A detailed description of the Vega-weighted least squares calculation performed during the first round of optimization to produce arbitrage-free options prices for European options: This information, while relevant to understanding how the model functions, is foundational information commonly understood in quantitative finance and readily found in public academic sources. To the extent the text does not describe OCC's application of a Vega-weighted least squares calculation, OCC does not believe this

[40] VIX options are treated as options on VIX futures and thus represent a type of option on futures that is also supported by the implied volatility smoothing.

[41] *See* Securities Exchange Act Release No. 86296 for further information on the smoothing algorithm used in STANS.

information needs to be maintained in OCC's rules.

• Operational details on (1) how the model's results are applied to other models for pricing European and American options, options on futures, and long-dated[42] volatilities; (2) price smoothing for contracts that are otherwise missing smoothed prices for various reasons, FLEX options, and over-the-counter options; and (3) detailed steps for a linear interpolation/extrapolation used to construct a volatility surface from smoothed volatilities: These details relate to configuration choices made by OCC to applying a model overlay in certain cases where there is insufficient data, that are not inherent to the model's selection or design, and that do not materially impact the model's results, which OCC may from time to time determine it should modify based on current market conditions and business practices.

OCC believes that this information is more appropriately covered in the Implied Volatility Smoothing Model Whitepaper and other internal OCC documentation rather than in OCC's rules for the reasons listed above. Therefore, OCC proposes to delete this rule text in its entirety without adding new, corresponding rule text in the STANS Methodology Description.

European and American Options

The Vanilla Options model is used by STANS to price European and American options. This model is comprised of several modules that (i) calculate theoretical option prices, (ii) calculate risk sensitivities of the option prices with respect to the market variables (the ''Greeks''), and (iii) calculate implied volatilities from option prices. The model prices European options using a modified Black-Scholes formula and American options using a Leisen-Reimer binomial tree.[43]

The proposed text would replace current OCC rule text from the Margins Methodology's section on the Vanilla Options model. The current rule text includes other information related to the model. Specifically, the current rule text includes the following:

• Rationale and testing to support the number of steps used in the Leisen-Reimer binomial tree: OCC does not believe the rationale to support this model choice is needed to understand how the model currently functions.

• Equations describing the calculation of various ''Greeks'' (*i.e.,* Gamma, Vega, Theta, and Rho), restatements of standard Black's formulas, and a restatement of the standard Leisen-Reimer binomial tree: This information, while relevant to understanding how the model functions, is foundational information commonly understood in quantitative finance and readily found in public academic literature. To the extent the text does not describe OCC's application of the ''Greeks,'' Black's formulas, and the Leisen-Reimer binomial tree, OCC does not believe this information needs to be maintained in OCC's rules.

• A list of control parameters of the Newton-Raphson method used to calculate implied volatilities for vanilla options: These control parameters are configuration choices made by OCC that are not inherent to the model's selection or design and that do not materially impact the model's results, which OCC may from time to time determine it should modify based on current market conditions and business practices.

OCC believes that this information is more appropriately covered in the Vanilla Options Model Whitepaper and other internal OCC documentation rather than in OCC's rules for the reasons listed above. Therefore, OCC proposes to delete this rule text in its entirety without adding new, corresponding rule text in the STANS Methodology Description.

Asian FLEX Options

Like European options, Asian FLEX options are priced based on a Black-Scholes formula.[44] Asian FLEX options are modeled with assumptions that volatility, interest rates and cost of carry remain constant across an option's tenor. Furthermore, implied volatility is determined from ''terminal'' option (*i.e.,* the last option in a series) volatilities, which are obtained from prices of available regular options expiring at the same tenor or, in their absence, by interpolating terminal volatilities of existing tenor regular options using an internal calculator developed by OCC.

Cliquet Options

STANS also prices Cliquet options using a Black-Scholes model. Like Asian FLEX options, Cliquet options are modeled with assumptions that volatility, interest rates, and cost of carry remain constant across an option's tenor. STANS calculates options premiums based on the premiums of the individual forward starting options that comprise the Cliquet option. This valuation is then repeated for each ''reset period'' of the Cliquet option.

Forward Start Options

STANS can also be used to price forward start options. Forward start options are options for which the strike price in dollars is unknown prior to the determination date of the strike shortly before expiration.[45] Forward start option values depend on the same input model parameters as vanilla options and on the determination date of the strike. Using the Black-Scholes framework, the pricing problem of a forward-start option prior to strike determination can be transformed into the valuation of a plain vanilla option at determination time, after which the option can be priced using a standard application of Black's formula.

iv. Aggregation

The STANS Methodology Description would next describe how STANS applies the theoretical derivatives prices to actual positions in Clearing Members' accounts to calculate margin requirements. This is accomplished by aggregating (i) a base margin charge, which consists of an ES calculation with the addition of Extreme Value Theory (''EVT'') loss modeling and a stress test component; (ii) an error compensation charge; (iii) a liquidation cost charge; (iv) a positive risk reversal charge; and (v) various add-on charges that are applied based on accounting principles.

Base Margin Charge

STANS first calculates the base margin charge. This is accomplished by identifying the positions present in a Clearing Member's account,[46] multiplying the values of those positions to each of the 10,000 theoretical values calculated in the above step, then adding the products' values together to obtain possible 10,000 net asset values (''NAVs'') for the account. The account's actual NAV is then subtracted from each of these 10,000 possible NAVs to obtain 10,000 possible Profit and Loss (''P&L'') statements. STANS then constructs a VaR line separating the 100 most extreme negative projected P&L

[42] In the context of volatility smoothing, ''long-dated'' refers to expirations beyond the listed expiration date of standard exchange-traded options.

[43] *See* Securities Exchange Act Release No. 86296 for further information on OCC's Vanilla Options model, which prices American and European options and generic futures.

[44] *See* Securities Exchange Act Release No. 74966 for further information on how STANS models Asian-style options.

[45] Instead, forward start options trade with strikes defined as a fraction α, known prior to expiration, of the underlying closing price on the determination date.

[46] The netting/offsetting of a Clearing Member's positions within an account pursuant to OCC's rules occurs outside STANS before the position data is brought into STANS for this step.

statements over a two-day horizon from the remaining 9,900 simulated outcomes, representing the worst 1% of the projected scenarios, and calculates the average of these 100 values to obtain a single ES value for the account. This is called the empirical ES because STANS uses actual historical prices in calibrating the simulation, which represents the historical dependence among the various risk factors.

In addition to calculating the empirical ES, STANS applies EVT to parametrically fit the largest losses and parametrically calculate ES. EVT is based on a tenet of probability theory that the distribution of extremes of a univariate random variable converge to a Generalized Pareto distribution.[47] The parametric EVT estimator can use a larger tail sample than the empirical estimator, which, for ES at the 99th percentile, is limited to 100 (*i.e.,* 1% of 10,000) points. Empirical ES is used when there is indication that the tail is not well fit by EVT.

STANS next applies a stress test component to its base charge. This component includes additional calculations related to (i) concentration, which is intended to consider extreme idiosyncratic moves in concentrated positions and to counteract ''survivor bias'' in historical equity returns data (*i.e.,* that historical data typically does not incorporate certain extreme movements in a firm's stock prices, such as when a firm declares bankruptcy or is subject to a rich takeover); and (ii) dependence, in which the ES calculations described above are performed twice again, once assuming perfect correlation among the various risk factors and once assuming no correlation among the various risk factors. After performing these concentration and dependence calculations, STANS takes the higher of the two factors and combines it with the empirical ES to create a more conservative margin requirement for the account.

The proposed text would replace current OCC rule text from the Margins Methodology's chapter on the base charge, stress-test add-on charge, and total margin charge. The current rule text also includes a summary section summarizing historical changes OCC has made to the manner in which STANS calculates a total margin charge. OCC does not believe this information is needed to understand how STANS currently functions. OCC further believes that this information is more appropriately covered in the Portfolio Risk Measures Model Whitepaper or other internal OCC documentation rather than in OCC's rules for this reason. Therefore, OCC proposes to delete this rule text in its entirety without adding new, corresponding rule text in the STANS Methodology Description.

Error Compensation

An inherent property of ES calculations is the existence of estimation error. To compensate for the potential risk that a STANS ES calculation includes such an error on the positive (lower loss) side, the ES value based on the simulated results is shifted through a compensation term to a more conservative level. Mathematically, the error compensator shifts ES to the left by 1.2 standard deviations of the loss tail, covering the 70% quantile of estimation error. The extent to which this alters the calculated ES in absolute varies based on the distribution's kurtosis (*i.e.,* the shift is more significant for distributions with fatter tails).

Liquidation Cost Charge

The default of a Clearing Member requires OCC to close-out that Clearing Member's positions, which results in OCC incurring costs. Closing out positions in a defaulted portfolio may also entail selling long positions at the current bid price and covering short positions at the current ask price, which could create additional costs based on the bid-ask spread. To account for these costs, STANS calculates a daily liquidation cost charge based on a liquidation cost grid, calibrated with data from historical stressed periods, and applies this calculated cost as an add-on charge. In general, the Liquidation Charge model calculates two risk-based liquidation costs for a portfolio, Vega[48] liquidation cost (''Vega LC'') and Delta liquidation cost (''Delta LC''), using ''Liquidation Grids.'' More specifically, the model consists of: (1) The decomposition of the defaulter's portfolio into sub-portfolios by underlying security; (2) the creation and calibration of Liquidation Grids used to determine liquidation costs; (3) the calculation of the Vega LC (including a minimum Vega LC charge) for options products; (4) the calculation of Delta LCs for both options and Delta-one products; (5) the calculation of Vega and Delta concentration factors; and (6) the calculation of volatility correlations for Vega LCs.[49] STANS applies both Vega and Delta LCs to options products, but only applies a Delta charge to Delta-one[50] products such as futures contracts, Treasury securities, and equity securities.

The proposed text would replace current OCC rule text from the Margins Methodology's section on the Liquidation Charge model. The current rule text also includes other information related to the model. Specifically, the current rule text includes the following:

- Background historical information on adoption of the model: OCC does not believe this historical information is needed to understand how the model currently functions.
- Classifications OCC applies to an underlying equity security based on the security's liquidity level to determine which liquidation grid is most appropriate: These details represent configuration choices made by OCC that are not inherent to the model's selection or design and that do not materially impact the model's results, which OCC may from time to time determine it should modify based on current market conditions and business practices.
- Intermediate equations used to define variables for calculating Vega LC: OCC does not believe these intermediate, explanatory equations are needed to understand how the model currently functions.
- Descriptions of the parameters used to calibrate liquidation grids: These calibration parameters represent configuration choices made by OCC that are not inherent to the model's selection or design and that do not materially impact the model's results, which OCC may from time to time determine it should modify based on current market conditions and business practices.

OCC believes that this information is more appropriately covered in the underlying Liquidation Charge Model Whitepaper and other internal OCC documentation rather than in OCC's rules for the reasons listed above. Therefore, OCC proposes to delete this rule text in its entirety without adding new, corresponding rule text in the STANS Methodology Description.

Positive Risk Reversal

As an additional conservative measure, STANS applies a ''positive

[47] A Generalized Pareto distribution is a type of continuous probability distribution that can be used to model the distribution of the tail of another underlying distribution.

[48] The Delta and Vega of an option represent the sensitivity of the option price with respect to the price and volatility of the underlying security, respectively.

[49] *See* Securities Exchange Act Release No. 85755 for more detail on the liquidation cost model used by STANS.

[50] ''Delta one products'' refer to products for which a change in the value of the underlying asset results in a change of the same, or nearly the same, proportion in the value of the product.

risk reversal'' charge to ensure that the total calculated margin requirement is at least equal to the estimated liquidation cost, even in the event a position is liquidated at the current market price (or a more favorable price). STANS incorporates the positive risk reversal charge by simply applying a minimum margin requirement to a position that is equal to the estimated liquidation cost charge.

Various Add-On Charges

In addition to the charges described above, OCC may, pursuant to its rules, elect to apply additional charges to a Clearing Member's margin requirements for various reasons; *e.g.,* based on the Clearing Member's Watch Level status or to account for rebates, adjustments and add-ons related to stock loan positions.[51] These additional charges occur outside of STANS and are outside the scope of the STANS Methodology Description.

The proposed text would replace current OCC rule text from a section in the Margins Methodology's base charge, stress-test add-on charge, and total margin charge chapter covering add-on charges. The current rule text notes that OCC may apply various add-on charges to its margin requirements outside the STANS methodology, which could include additional margin charges related to (i) cross-margin accounts, established by OCC Rule 704; (ii) placement on a heightened Watch Level based on OCC's credit risk surveillance, established by OCC's Counterparty Credit Risk Management Policy; [52] (iii) interest payments and adjustments to stock loan positions, established by OCC Rule 601, Interpretation & Policy .05; (iv) customer positions subject to certain margin requirements promulgated by the U.S. Commodity Futures Trading Commission, established by OCC Rule 601, Interpretation & Policy .07; (v) concentration risk for equity securities exceeding an average daily trading volume threshold, established by OCC's Collateral Risk Management Policy; [53] and (vi) OCC's extended trading hours program, established generally by OCC's Margin Policy and specified in OCC's Extended Trading Hours Set-Up and Monitoring Procedure.[54]

As outlined above, these add-on charges are applied pursuant to other OCC rules, policies, and/or procedures, and are established outside of the STANS methodology. Therefore, OCC believes that they are more appropriately covered in the underlying OCC rules, policies, and procedures that establish them, and, accordingly, proposes to delete this text in its entirety without adding new, corresponding rule text in the STANS Methodology Description.

Model Utilities

The STANS Methodology Description would next describe several ''model utilities'' that are applied at various points in the STANS methodology, to incorporate various market and operational factors that affect options pricing and thereby produce model results which more accurately reflect current and potential market conditions.

i. Dividends

The STANS Methodology Description would describe how STANS incorporates expected cash dividends on a stock into options pricing.[55] STANS obtains daily information on general dividend yields and discrete dividends from pricing vendors, then applies a dividend growth rate to this information to forecast dividends (typically) 16 quarters into the future.

STANS accounts for the possibility that cash dividends may be paid on stocks, which would affect their pricing, through a dividend utility that interacts with the pricing models in STANS. Daily, STANS retrieves from an external vendor data on forecasted cash dividends and yield curves associated with the issuance of those dividends. STANS uses this data to forecast when a security may go ex-dividend, and accordingly incorporates this into pricing the associated equity security. STANS also accounts for the possibility that an option may be exercised early to obtain a cash dividend on the underlying security. Using the same external dividend data, STANS calculates when an option would likely be exercised early to receive the dividend and prices it accordingly.

ii. Interest Rate Curve

This model utility calculates the yield curve using (i) overnight, one-week, one-month, two-month, and three-month cash deposit interest rates; (ii) Eurodollar interest rate futures with three-month to two-year tenors; and (iii) interest rate swaps with three-year to 30-year tenors. The model utility calculates a discount factor from a given date to any future date along the curve. This discount factor is used as an input to pricing models to generate theoretical prices for instruments based on these rates.

iii. Overnight and Daily Returns

STANS calculates margin requirements on a daily basis, using prices from that day's market close. However, some positions may expire or be exercised during a business day and before the following day's margin settlement. Since OCC clears derivatives that are settled on both opening and closing prices, both types of events affect derivatives prices and their corresponding margin requirements. Therefore, the STANS Methodology Description would describe how STANS obtains relevant risk factors for both the most recent opening price and the most recent closing price. STANS includes within the copula it constructs, described previously, a joint distribution of both overnight and daily returns on relevant risk factors.

The proposed text would replace current OCC rule text from the Margins Methodology's section on overnight and daily innovations. The current rule text also includes other information on the overnight and daily returns model utility. Specifically, the current rule text includes the following:

- Details on how OCC implemented the model utility in its technology systems: These implementation details relate to OCC's internal administration of its technology systems and are not needed to understand how the model currently functions. Because these details are not inherent to the model's selection or design, OCC could also change them from time to time without affecting the model's results.
- Redundant detail related to the copula constructed by STANS: These details, described above, would be described in the STANS Methodology Description's section on the Student-t Copula model, and OCC does not believe repeating it here is needed to understand how the model utility currently functions.

OCC believes that this information is more appropriately covered in the Daily and Overnight Theoretical Price

[51] *See* Securities Exchange Act Release No. 82355, which states that OCC's Margin Policy establishes the application of add-on charges.

[52] *See* Securities Exchange Act Release No. 81949 (October 26, 2017), 82 FR 50719 (November 1, 2017) (SR–OCC–2017–009) for more information on OCC's Watch Level framework. OCC has filed a proposed rule change with the Commission to adopt a new TPRMF, which would replace the Counterparty Credit Risk Management Policy and provide an overview of OCC's overall approach to third-party risk management. *See supra* note 3.

[53] *See* Securities Exchange Act Release No. 82009, which describes OCC's Collateral Risk Management Policy.

[54] The specific margin add-on charges OCC may apply are subject to change in accordance with internal governance established by OCC's Margin Policy and supporting procedures.

[55] OCC considers the potential effects of stock dividends outside of STANS.

Scenario Simulation Model Whitepaper or other internal OCC documentation rather than in OCC's rules for the reasons listed above. Therefore, OCC proposes to delete this rule text in its entirety without adding new, corresponding rule text in the STANS Methodology Description.

iv. One-Day and Two-Day Scenarios

As noted previously, OCC has established margin levels to cover the costs of liquidating positions over a two-day margin period of risk. Furthermore, and as described above, during this interval expiring OCC-cleared or cross-margined positions may experience final settlement based on either the opening or closing price of the underlying security. Therefore, the STANS Methodology Description would describe how STANS calculates for each underlying price scenario simulated prices at four different points in time: (i) Opening price on day one; (ii) closing price on day one; (iii) opening price on day two; and (iv) closing price on day two. STANS must account for these additional prices to avoid under-margining portfolios with both expiring and non-expiring positions in a risk group, and to reflect the prices of underlying securities and associated derivatives that are forecasted to go ex-dividend or ex-coupon on T+1 or T+2 (where T represents the activity date). To calculate the two additional prices that may be observed over the two-day margin period of risk, STANS applies a randomly generated permutation to the return scenarios. The second-day return scenarios and securities that go ex-dividend on T+2 are then applied scenario-by-scenario to the first-day results in the same fashion.

v. Portfolio Specific Haircuts

Some Clearing Members have deposited securities as margin collateral that are also used in STANS as risk factors, and therefore potential price movements in these securities are factored into margin requirement calculations. However, a Clearing Member may want—or be required—to withdraw or deposit such margin collateral intraday. This would change the concentration of the Clearing Member's collateral types and would also change the sensitivity of how the Clearing Member's portfolio responds to such changes. To account for these changes in concentration and sensitivity, the STANS Methodology description would describe how STANS utilizes a Portfolio Specific Haircuts model. This model provides haircut values for withdrawals or deposits of collateral, which are then applied to the previous day's collateral values to arrive at the impact of the collateral movements on the margin requirement. These haircuts represent the sensitivity of that Clearing Member account's risk profile to its position in the collateral security being withdrawn or deposited. These haircuts are designed to provide an estimate of the resulting change in margin requirements if the entire margin calculation were re-run following the withdrawal or deposit. A different haircut is associated with each combination of Clearing Member account and security posted as margin collateral.

Margins Methodology Chapters Not Found in STANS Methodology Description

The current rule text from the Margins Methodology describes that STANS uses historical and current prices for listed tenors of energy and other commodity futures to simulate prices of energy and other commodity futures using two variants of a two-factor Schwartz and Smith's model: [56] One variant to incorporate the effects of seasonality [57] for pricing futures related to nonseasonal commodities such as crude oil and the other variant to incorporate the effects of seasonality and is used to price futures related to seasonal commodities such as natural gas, heating oil, gasoline, electricity, and petrochemicals. The products for which OCC previously used this model to calculate margin requirements are no longer listed, and therefore OCC has decommissioned this associated pricing model. Therefore, OCC proposes to delete this rule text in its entirety without adding new, corresponding rule text in the STANS Methodology Description.

The current text from the Margins Methodology also includes information on a model used to price European-style binary options. The products for which OCC used this model to calculate margin requirements are no longer listed, and OCC decommissioned the model. The current text also includes information on OCC's use of the Vanilla Options model to calculate margin requirements for Currency Options and Foreign Index Futures, both of which are products OCC no longer clears. Therefore, OCC proposes to delete this rule text in its entirety without adding new, corresponding rule text in the STANS Methodology Description.

The current rule text from the Margins Methodology also includes information on certain processes OCC uses to operationalize the STANS methodology in its systems. Specifically, these processes are (i) daily calibration and transfer, which describes implementation of the processes to daily obtain pricing data and calibrate pricing models; (ii) Monte Carlo marginals, which describes implementation of the processes that create price scenarios for underlying risk factors from either copula draws or (in the absence of a copula) conditional or default simulations; (iii) Monte Carlo theoreticals, which describes implementation of the processes that calculate theoretical values for futures and options; and (iv) monthly copula estimation and simulation, which describes implementation of the processes that generate copula scenarios for underlying risk factors based on calibrated parameters.

These chapters describe implementation details related to OCC's internal administration of its technology systems and are not needed to understand how the STANS models currently function. Because these details are not inherent to model selection or design, OCC could also change them from time to time without affecting model results. OCC believes that this information is more appropriately covered in the underlying Model Whitepapers and other internal OCC documentation rather than in OCC's rules for this reason. Therefore, OCC proposes to delete this rule text in its entirety without adding new, corresponding rule text in the STANS Methodology Description.

Margin Policy

Lastly, OCC would make conforming changes to its Margin Policy to reflect the adoption of the STANS Methodology Description and the retirement of the Margins Methodology. OCC would also make other non-substantive changes to the Margin Policy to correct typographical errors, update references to other related internal OCC policies and procedures, and conform the policy to OCC's current internal policy template. The proposed changes are intended to promote the accuracy and clarity of OCC's Margin Policy and would not impact OCC's margin setting practices or processes.

[56] The Schwartz and Smith's model is a two-factor model of commodity prices that allows for mean reversion in short-term prices and uncertainty in the long-term equilibrium level to which prices revert. *See* Schwartz, E. and Smith, E., ''Short-Term Variations and Long-Term Dynamics in Commodity Prices,'' 46 Mgmt. Sci. 7, 893–911 (2000) (describing the Schwartz and Smith's model).

[57] Seasonality is a characteristic of futures products that exhibit regular and predictable price changes that recur every calendar year.

(2) Statutory Basis

OCC believes that the proposed rule change is consistent with Section 17A of the Act [58] and the rules thereunder applicable to OCC. Section 17A(b)(3)(F) of Act [59] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts, and transactions. The purpose of the proposed rule change is to adopt a STANS Methodology Description document to clearly and concisely describe the material aspects of OCC's quantitative methodology for calculating Clearing Member margin requirements. OCC uses the margin it collects to limit its credit exposures to participants and to protect other Clearing Members from losses that may arise as a result of a default and ensure that OCC is able to continue the prompt and accurate clearance and settlement of its cleared products. As a result, OCC believes the proposed STANS Methodology Description is designed to promote the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts, and transactions in accordance with Section 17A(b)(3)(F) of the Act.[60]

Rule 17Ad–22(b)(1) [61] requires that a registered clearing agency that performs central counterparty services establish, implement, maintain and enforce written policies and procedures reasonably designed to measure its credit exposures to its participants at least once a day and limit its exposures to potential losses from defaults by its participants under normal market conditions so that the operations of the clearing agency would not be disrupted and non-defaulting participants would not be exposed to losses that they cannot anticipate or control. As described above, the proposed STANS Methodology Description described herein details the risk-based margin methodology by which OCC measures its credit exposures to its participants on a daily basis and determines margin requirements based on such calculations. OCC believes that the proposed STANS Methodology Description would result in a more transparent and clearly understandable description of the methodology used to measure and mitigate credit exposures to OCC's Clearing Members, and that the proposed rule change is therefore designed to ensure that OCC sets margin requirements that would serve to limit OCC's exposures to potential losses from defaults by its participants under normal market conditions so that the operations of OCC would not be disrupted, and non-defaulting participants would not be exposed to losses that they cannot anticipate or control. Accordingly, OCC believes the proposed rule change is consistent with Rule 17Ad–22(b)(1).[62]

Rule 17Ad–22(b)(2) [63] further requires, in part, that a registered clearing agency that performs central counterparty services establish, implement, maintain and enforce written policies and procedures reasonably designed to use margin requirements to limit its credit exposures to participants under normal market conditions and use risk-based models and parameters to set margin requirements. The STANS Methodology Description is intended to better describe how the STANS methodology is designed to limit OCC's credit exposures to participants under normal market conditions in a manner consistent with Rule 17Ad–22(b)(2).[64]

Rules 17Ad–22(e)(6)(i), (iii), and (v) [65] further require that a covered clearing agency establish, implement, maintain and enforce written policies and procedures reasonably designed to cover its credit exposures to its participants by establishing a risk-based margin system that, among other things: (1) Considers, and produces margin levels commensurate with, the risks and particular attributes of each relevant product, portfolio, and market; (2) calculates margin sufficient to cover its potential future exposure to participants in the interval between the last margin collection and the close out of positions following a participant default; and (3) uses an appropriate method for measuring credit exposure that accounts for relevant product risk factors and portfolio effects across products. As described in detail above, OCC believes that the proposed STANS Methodology Description would result in a clearer, more transparent document describing OCC's risk-based margin system that, among other things: (1) Considers, and produces margin levels commensurate with, the risks and particular attributes of each relevant product, portfolio, and market; (2) calculates margin sufficient to cover its potential future exposure to participants in the interval between the last margin collection and the close out of positions following a participant default; and (3) uses an appropriate method for measuring credit exposure that accounts for relevant product risk factors and portfolio effects across products. OCC therefore believes the proposed STANS Methodology Description is reasonably designed to consider and produce margin levels commensurate with the risks and particular attributes of products cleared by OCC, calculate margin sufficient to cover its potential future exposure to participants in the interval between the last margin collection and the close out of positions following a participant default, and apply an appropriate method for measuring credit exposure that accounts for risk factors and portfolio effects of products cleared by OCC in a manner consistent with Rules 17Ad–22(e)(6)(i), (iii), and (v).[66]

Rule 17Ad–22(e)(23) [67] further requires, in part, that a covered clearing agency establish, implement, maintain, and enforce written policies and procedures reasonably designed to provide sufficient information to enable participants to identify and evaluate the risks, fees, and other material costs they incur by participating in the covered clearing agency. The STANS Methodology Description is designed to provide Clearing Members with greater transparency into the STANS Methodology than the current rule text of the Margins Methodology, which OCC does not make generally available to participants and includes various details that, as described herein, OCC does not believe constitute material aspects of the STANS methodology. In addition, OCC has organized and written the STANS Methodology Description in a way that would more clearly identify for Clearing Members the material aspects of the STANS methodology. Specifically, OCC has organized the STANS Methodology Description in a way that enables a reader to better understand how the various quantitative model components of STANS function in concert to produce OCC margin requirements, rather than organizing the document in a way that would serve OCC's internal purposes but not facilitate comprehension of the STANS methodology by a third party. Furthermore, by including in the STANS Methodology Description only the OCC rule text covering the material, quantitative aspects of the STANS methodology, and either not describing extraneous or immaterial aspects of the STANS methodology in the STANS Methodology Description or referring

[58] 15 U.S.C. 78q–1.

[59] 15 U.S.C. 78q–1(b)(3)(F).

[60] *Id.*

[61] 17 CFR 240.17Ad–22(b)(1).

[62] *Id.*

[63] 17 CFR 240.17Ad–22(b)(2).

[64] *Id.*

[65] 17 CFR 240.17Ad–22(e)(6)(i), (iii), and (v).

[66] *Id.*

[67] 17 CFR 240.17Ad–22(e)(23).

the reader to other OCC or external sources where appropriate,[68] the proposed STANS Methodology Description would more clearly identify for an informed reader how the STANS methodology's quantitative model components form OCC's basis for calculating margin requirements, and what aspects of the STANS methodology OCC may adjust in the course of its business pursuant to its other rules and internal policies and procedures. OCC believes that this additional clarity, transparency, and enhanced readability regarding the material quantitative model components of the STANS methodology promote the requirements of Rule 17Ad–22(e)(23).

Finally, Section 19(b)(1) of the Act and Rule 19b–4 thereunder set forth the requirements for SRO proposed rule changes, including the regulatory filing requirements for ''stated policies, practices and interpretations.'' [69] OCC proposes to retire its existing Margins Methodology, which was, in part, previously filed as an OCC ''rule'' with the Commission, as the STANS Methodology Description would supersede the Margins Methodology in its entirety. Under the proposal, the material aspects of the STANS methodology would be contained in the proposed STANS Methodology Description described herein.

As described in detail herein, various details in the current Margins Methodology would no longer be OCC rule text following adoption of the STANS Methodology Description. These internal procedural and administrative details used by OCC's model developers and model validators would: (1) Be reasonably and fairly implied by the proposed STANS Methodology Description, OCC's Margin Policy,[70] OCC's Model Risk Management Policy,[71] and other OCC rules; and/or (2) otherwise not be deemed to be material aspects of OCC's risk-based margin system. Specifically, OCC believes the details it proposes to remove from OCC's rule text are consistent with Section 19(b)(1) of the Act and Rule 19b–4 thereunder for the following reasons:

- To the extent the current rule text includes details on OCC's historical modeling practices and potential future enhancements, OCC does not believe such text constitutes an SPPI of OCC because it does not describe OCC's current practices;
- To the extent the current rule text includes details on the exact set of current products applied to each STANS component, which will change from time to time as OCC-cleared products are listed and delisted, OCC believes such text is reasonably and fairly implied by the proposed rule text establishing the scope of instruments for which the STANS methodology calculates margin requirements;
- To the extent the current rule text includes details on various configuration choices made by OCC, such as data sources, model parameters, and model performance monitoring, that are not inherent to model selection or design and that do not materially impact a model's results, which OCC may from time to time determine it should modify based on current market conditions and business practices, OCC does not believe such text constitutes an SPPI because it does not describe a *material* aspect of the operation of the facilities of OCC;
- To the extent the current rule text includes details on testing results and explanatory rationale supporting a model, OCC does not believe such text constitutes an SPPI because it does not describe an OCC policy, practice, or interpretation;
- To the extent the current rule text includes recitations of standard mathematical and economic theories/techniques that are well-known in quantitative finance, readily found in public sources, and do not include OCC-specific modifications or applications, OCC believes such text is reasonably and fairly implied by the rule text establishing the theories/techniques selected by OCC if OCC has not applied such theories/techniques in a modified or idiosyncratic manner;
- To the extent the current rule text includes redundant descriptions of a model component appearing in multiple chapters, the rule text has been consolidated to describe the model component in the single location;
- To the extent the current rule text includes details on OCC's implementation of a model in its internal technology systems and application of model results in operational procedures that are not inherent to a model and that OCC could change them from time to time without affecting a model's results, OCC does not believe such text constitutes an SPPI because (1) it does not describe a *material* aspect of the operation of the facilities of OCC and (2) it is reasonably and fairly implied that the calculations described in the STANS Methodology Description must be implemented in some manner through internal OCC's systems and processes. For example, current chapters of the Margins Methodology describe the processes run by internal OCC systems to execute the calculations described in the proposed STANS Methodology Description. These chapters do not describe material aspects of OCC's models or methodology. Rather, these chapters describe, for example, the timing and sequencing of various processes and the code libraries maintained by OCC to support the STANS methodology. Changes in such processes would not be considered changes to OCC's models/methodology and would not materially impact OCC's margin requirements. Moreover, Clearing Members and market participants can reasonably and fairly infer that OCC maintains such systems and processes to effectuate the daily calculation of margin requirements using the models and methodology described herein; and
- To the extent the current rule text includes manual margin adjustments and add-ons OCC employs pursuant to OCC rules, policies, and/or procedures outside the STANS methodology, OCC does not believe such text constitutes an SPPI because it is reasonably and fairly implied by other existing rules of OCC.

Accordingly, OCC believes the proposed changes would be consistent with the requirements of Section 19(b)(1) of the Act and Rule 19b–4 thereunder.[72]

(B) Clearing Agency's Statement on Burden on Competition

Section 17A(b)(3)(I) of the Act requires that the rules of a clearing agency do not impose any burden on competition not necessary or appropriate in furtherance of the purposes of Act.[73] OCC does not believe that the proposed rule change would impact or impose any burden on competition. The proposed STANS Methodology Description describes OCC's STANS margin setting methodology that currently applies to all Clearing Members. Therefore, the proposal has no impact on Clearing Members, and OCC does not believe that the proposed rule change would

[68] For example, the STANS Methodology Description would refer to other OCC rules to establish manual, non-modeled margin components or adjustments made by OCC, and would refer to public academic sources for descriptions of common mathematical theories and methods that do not represent OCC-specific applications or modifications of those theories and methods.

[69] *See supra* note 13.

[70] *See* Securities Exchange Act Release No. 82355 (December 19, 2017), 82 FR 61058 (December 26, 2017) (SR–OCC–2017–007).

[71] *See* Securities Exchange Act Release No. 82473 (January 9, 2018), 83 FR 2271 (January 16, 2018) (SR–OCC–2017–011).

[72] *See* 15 U.S.C. 78s(b)(1) and 17 CFR 240.19b–4.

[73] 15 U.S.C. 78q–1(b)(3)(I).

unfairly inhibit access to OCC's services or disadvantage or favor any particular user in relationship to another user. In addition, the proposal currently applies uniformly to all Clearing Members in establishing their margin requirements.

For the foregoing reasons, OCC believes that the proposed rule change is in the public interest, would be consistent with the requirements of the Act applicable to clearing agencies, and would not impact or impose a burden on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were not and are not intended to be solicited with respect to the proposed rule change and none have been received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self- regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be 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 Exchange 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–OCC–2020–016 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–OCC–2020–016. 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 OCC and on OCC's website at *https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules#rule-filings.*

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–OCC–2020–016 and should be submitted on or before January 19, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[74]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28662 Filed 12–28–20; 8:45 am]

BILLING CODE 8011–01–P

[74] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34150; 812–15158]

J.P. Morgan Investment Management Inc., et al.; Notice of Application

December 22, 2020.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

SUMMARY: J.P. Morgan Investment Management Inc., et al. have applied for exemption from rules within the Investment Company Act of 1940 to use an Amended Liquidity Program for the Covered Funds.

DATES: The application was filed on September 14, 2020, and amended on November 20, 2020.

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: Margery K. Neale and Anne Choe, Willkie Farr & Gallagher LLP, at *MNeale@willkie.com* or *AChoe@willkie.com,* respectively.

FOR FURTHER INFORMATION CONTACT: Jessica Shin, Attorney-Adviser, at (202) 551–3685, or Daniele Marchesani, Assistant Chief Counsel, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office), or Thoreau Bartmann, Senior Special Counsel, at (202) 551–6745.

SUPPLEMENTARY INFORMATION: Notice of an application by J.P. Morgan Investment Management Inc., et al. under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from rules 22e–4(a)(6), 22e–4(a)(8), 22e–4(a)(10), 22e–4(a)(12), 22e–4(b)(1)(ii), 22e–4(b)(1)(iii), and 22e–4(b)(1)(iv) under the Act, and for an exemption from Items B.7, B.8 and C.7 of Form N–PORT and from Parts B through D of Form N–LIQUID, to the extent necessary to use an Amended Liquidity Program for the Covered Funds.

Applicants:

Each registered open-end management investment company listed in Exhibit A of the Application (the ''Companies''), on its own behalf and on behalf of its respective underlying series listed in Exhibit A of the Application (each such series, a ''JPM Fund''), and J.P. Morgan Investment Management Inc. (''JPMIM'' and collectively with the Companies, the ''Applicants'').

Summary of Application:

The requested exemptions would permit Applicants to use the Amended Liquidity Program for the Covered Funds. The Amended Liquidity Program would replace rule 22e–4's liquidity classification system with core elements of an alternative liquidity classification methodology generated under a Liquidity Risk Framework (as defined below) established by JPMIM and its affiliates (collectively, ''JPM''). The Applicants would also modify related reporting requirements on Form N–PORT and Form N–LIQUID solely to the extent necessary to implement the Amended Liquidity Program.

Hearing or Notification of Hearing:

An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving Applicants with a copy of the request by email.

Hearing requests should be received by the Commission by 5:30 p.m. on January 19, 2021, and should be accompanied by proof of service on the 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.*

The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number or an Applicant using the ''Company'' name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

I. Applicants

1. Each JPM Fund that is advised by JPMIM and that has adopted the Existing 22e–4 Program (as defined below) is listed in Exhibit A of the Application. Applicants request that the order apply to any additional or new series of a Company and any other registered open-end management investment company or series thereof that currently exists or may be created in the future that is subject to rule 22e–4 and for which JPMIM or any successor thereto or an investment adviser controlling, controlled by, or under common control (within the meaning of section 2(a)(9) of the Act) with JPMIM or any successor thereto serves as investment adviser (each such investment company or a series thereof, a ''Future Fund'' and collectively with the JPM Funds, the ''Covered Funds,'' and each such investment adviser collectively with JPMIM, an ''Adviser'').[1]

2. JPMIM serves as the investment adviser to the JPM Funds. JPMIM is a Delaware corporation with its principal place of business in New York, New York. JPMIM is, and any other Adviser will be, registered with the SEC as an investment adviser under section 203 of the Investment Advisers Act of 1940.

II. Background

3. Applicants request an exemptive order to use a proposed liquidity risk management program for the Covered Funds that reflects certain differences from the requirements of rule 22e–4 as described in this Notice and also specified in the Application (''Amended Liquidity Program'').

4. Since 2016, and independent of the adoption of rule 22e–4, JPM developed and implemented an alternative liquidity classification methodology generated under its liquidity risk framework (the ''Liquidity Risk Framework''). JPMIM applies the Liquidity Risk Framework to investment funds it advises globally, including investment funds that are not registered under the Act and, therefore, not subject to rule 22e–4. The Liquidity Risk Framework includes a quantitative assessment of liquidity risk and is an essential component of the Existing 22e–4 Program. The Amended Liquidity Program will replace the liquidity classification system used in the JPM Funds' existing liquidity risk management program, which complies with the requirements of rule 22e–4 (''Existing 22e–4 Program''). However, because the framework does not use the classification methodology of rule 22e–4, JPM maintains a second classification methodology under the Existing 22e–4 Program solely to satisfy the specific requirements of rule 22e–4, including for purposes of complying with rule 22e–4's classification, illiquid investment limitation, highly liquid investment minimum, and related reporting requirements. The requested relief would allow the Applicants to solely maintain the classification methodology generated under JPM's Liquidity Risk Framework and discontinue the operation of JPM Funds' second liquidity classification program under the Existing 22e–4 Program for the JPM Funds. This would enable JPM to avoid maintaining dual classification methodologies.

Rule 22e–4 and Related Reporting Requirements

5. Rule 22e–4 requires each open-end registered investment company, excluding money market funds (each, a ''fund''),[2] to establish a written liquidity risk management program to assess, manage, and periodically review its liquidity risk. Rule 22e–4 requires a fund to classify each of its portfolio investments, including its derivatives transactions, into one of four liquidity categories: ''highly liquid investments,''[3] ''moderately liquid investments,''[4] ''less liquid investments,''[5] and ''illiquid investments''[6] (together, the ''four buckets''). The classification process of rule 22e–4 requires funds to classify portfolio investments into one of the four buckets generally based on the time the fund reasonably expects to be able to convert the investment to cash in current market conditions without significantly changing the market value of the investment. In determining the appropriate bucket, the fund must also take into account the fund's ability to trade varying portions of a position in a particular portfolio investment or asset class, in sizes that it reasonably anticipates trading, without reasonably expecting to significantly affect the investment's liquidity (referred to as ''RATS'').[7] It also must take into account relevant market, trading, and investment-specific considerations.[8]

6. Additional requirements in rule 22e–4 are triggered from the definitions of the four buckets. In particular, a fund that does not primarily hold assets that are highly liquid investments is required to determine a minimum level of highly liquid investments (the ''HLIM''), and take certain related actions.[9] Further, a fund may not acquire additional illiquid investments if, after the acquisition, it would hold more than 15% of its net assets in illiquid investments.[10] Additionally, in classifying its investments, a fund must identify the percentage of the fund's highly liquid investments that it has segregated or pledged in connection with derivatives transactions that are ''moderately liquid'', ''less liquid'', and ''illiquid investments''.[11] Furthermore, for purposes of determining whether a fund primarily holds assets that are ''highly liquid investments'', a fund must exclude from its calculations the percentage of the fund's assets that are ''highly liquid investments'' that it has segregated to cover all derivatives transactions that the fund has classified as ''moderately liquid'', ''less liquid'', and ''illiquid investments'', or pledged to satisfy margin requirements in connection with those derivatives transactions, as determined pursuant to paragraph (b)(1)(ii)(C) of rule 22e–4.[12]

7. Rule 22e–4 also requires funds to use the classification under the four buckets for purposes of Form N–PORT reporting. In particular, Item B.7 of

[1] All existing entities that intend to rely on the requested order have been included in Exhibit A to the Application. Any other existing or future entity that subsequently relies on the order will comply with the terms and conditions of the order.

[2] Money-market funds are subject to separate liquidity requirements pursuant to rule 2a–7 under the Act.

[3] Rule 22e–4(a)(6).

[4] Rule 22e–4(a)(12).

[5] Rule 22e–4(a)(10).

[6] Rule 22e–4(a)(8).

[7] Rule 22e–4(b)(1)(ii)(B).

[8] Rule 22e–4(b)(1)(ii).

[9] Rule 22e–4(b)(1)(iii).

[10] Rule 22e–4(b)(1)(iv).

[11] Rule 22e–4(b)(1)(ii)(C).

[12] Rule 22e–4(b)(1)(iii)(B).

Form N–PORT requires a fund to report, as applicable, its HLIM, the number of days the fund was below such HLIM, and any changes to the HLIM during the reporting period. Item B.8 requires disclosure of the percentage of a fund's highly liquid investment minimum assets that have been segregated or pledged in connection with certain derivatives transactions. Item C.7 requires funds to report the liquidity classification for each investment across the four buckets. For any investments with multiple liquidity classifications, item C.7 asks that a fund report the percentage attributable to each bucket.

8. Rule 30b1–10 and Form N–LIQUID require a fund to notify the Commission when the fund's level of ''illiquid investments'' that are assets exceeds 15% of its net assets or when its ''highly liquid investments'' fall below its HLIM.[13]

Applicants' Liquidity Risk Framework

9. Applicants' Liquidity Risk Framework classifies portfolio investments held by a Covered Fund, including any assets pledged to derivatives transactions, among the following five liquidity categories rather than the four buckets specified in rule 22e–4:[14]

Category 1—Able to be sold in one trading day;

Category 2—able to be sold between two and three trading days;

Category 3—able to be sold between four and ten trading days;

Category 4—able to be sold between eleven and twenty trading days; and

Category 5—able to be sold in more than twenty trading days.

This classification generally would be based on the ability to *sell the full position size* of each investment or transaction in current market conditions with no significant change to the market value of the investment (''Full Position Size Approach'').[15] The Liquidity Risk Framework uses days-to-sale (rather than rule 22e–4's ''days-to-cash'' approach) and applies an expected settlement cycle.[16] The Liquidity Risk Framework also uses a quantitative modeling approach that seeks to identify any potential estimated liquidity mismatches between a Covered Fund's assets and the potential size of a Covered Fund's anticipated redemptions.[17] Each portfolio investment is then distributed among the five liquidity categories, as applicable.

10. The positions in the five categories would be converted into the four buckets to (i) comply with the HLIM requirements and illiquid investment limitations in rule 22e–4, (ii) comply with classification reporting on Form N–PORT, and (iii) determine whether a Form N–LIQUID filing will be required. To effect this conversion, JPMIM would apply an ''overlay'' across the five liquidity categories based on the RATS of the fund's portfolio investments or asset classes (a ''RATS Overlay'') implemented in compliance with rule 22e–4(b)(1)(ii)(B).[18] JPMIM would then apply a settlement period modifier to take into account the expected settlement period of the portfolio position. Finally, JPMIM would make certain adjustments to its framework, as described below, for investments segregated to cover, or pledged to satisfy margin requirements in connection with, certain derivatives transactions of the Covered Fund in compliance with rule 22e–4(b)(1)(ii)(C).

11. After applying the RATS Overlay and settlement period modifier, portfolio positions that are in Category 1 of JPMIM's Liquidity Risk Framework, and that have an expected settlement period of T+3 or less, would be converted into rule 22e–4's ''highly liquid'' bucket. Investments in Category 2 that have an expected settlement period of T+3 or less would be converted into the ''moderately liquid'' bucket of rule 22e–4. Any investments in either of JPMIM's Categories 1 or 2 that have an expected settlement period of *more* than T+3 would be converted into the ''less liquid'' bucket. Finally, after applying the RATS Overlay and settlement period modifier, investments that are in JPMIM's Categories 3, 4, and 5 would be converted into the ''illiquid investments'' bucket of rule 22e–4 because, in part, they make take more time to sell than the seven days established in rule 22e–4.

[13] On October 28, 2020, the Commission adopted rule 18f–4 under the Act with respect to the use of derivatives by registered investment companies. *See Use of Derivatives by Registered Investment Companies and Business Development Companies,* Investment Company Act Release No. 34078 (Oct. 28, 2020), which, in part, amends and re-titles Form N–LIQUID as Form N–RN, amends rule 22e–4 to remove references to assets ''segregated to cover'' derivatives transactions, and adopts conforming amendments to Form N–PORT. Accordingly, the Applicants seek relief from rules 22e–4(b)(1)(ii)(C) and (b)(1)(iii)(B) and item B.8 of Form N–PORT as currently in effect and as amended, upon the date of the Covered Funds' compliance with rule 18f–4. In addition, all references herein to Form N–LIQUID shall be deemed to be to Form N–RN once the re-titling of the Form is effective.

[14] As required by rule 22e–4(b)(1)(ii), the Amended Liquidity Program would use information obtained after reasonable inquiry and taking into account relevant market, trading, and investment-specific considerations when classifying investments. Applicants are not seeking an exemption from this requirement.

[15] JPM believes that use of the Full Position Size Approach creates a more useful view of fund liquidity and potentially lends itself to more conservative portfolio risk management overall because it does not result in a single holding, which may need to be sold over time, being classified in a single liquidity category. This approach reflects the fact that a fund may not be able to sell an entire position at once. The approach of allocating a single holding across multiple liquidity categories is generally consistent with SEC guidance for permissible methods of reporting on Form N–PORT. *See Investment Company Liquidity Disclosure,* Investment Company Act Release No. 33142 (June 28, 2018) at 25.

[16] *See Investment Company Liquidity Risk Management Programs,* Investment Company Act Release No.32315 (Oct. 13, 2016) at 89–96. Rule 22e–4 generally requires classification based on the number of days a fund reasonably anticipates it would convert an investment to cash, without the conversion significantly changing the market value of the investment, which generally refers to the ability to sell the investment, with the sale settled. The Amended Liquidity Program uses days-to-sale and assumes a standard settlement cycle.

[17] The Amended Liquidity Program applies three Asset Side Liquidity constraints to each Covered Fund portfolio: A security specific assessment by position (''Bottoms Up Constraint''), a broader asset class market depth assessment (''Top Down Constraint''), and a pro-rata risk constraint, applicable to the most liquid 85% of a Covered Fund's holdings (''Pro Rata Constraint''), that reflects the goal of meeting shareholder redemptions while seeking to maintain risk profile consistency in a Covered Fund's portfolio. Application of the constraints seeks to provide a conservative estimate of daily portfolio liquidity.

The Amended Liquidity Program then applies Liability Side modeling which considers both historical redemption time periods as well as the potential for the largest two investors to redeem their investments.

[18] Rule 22e–4(b)(1)(ii)(B) requires that ''[i]n classifying and reviewing its portfolio investments or asset classes (as applicable), the fund must determine whether trading varying portions of a position in a particular portfolio investment or asset class, in sizes that the fund would reasonably anticipate trading, is reasonably expected to significantly affect its liquidity, and if so, the fund must take this determination into account when classifying the liquidity of that investment or asset class.''

Bucket	Rule 22e–4 four buckets [19]	Amended liquidity program converted buckets
Highly Liquid Investment; Rule 22e–4(a)(6).	Any cash held by a fund and any portfolio investment that the fund reasonably expects to be convertible into cash in current market conditions in three business days or less without the conversion to cash significantly changing the market value of the investment.	Any cash and any fund portfolio investment (1) that a fund's investment adviser reasonably expects could be sold in one trading day in current market conditions without causing a significant change in the market value of the investment and (2) that has an expected settlement period of T+3 or less.
Moderately Liquid Investment; Rule 22e–4(a)(12).	Any portfolio investment that the fund reasonably expects to be convertible into cash in current market conditions in more than three calendar days but in seven calendar days or less without the conversion to cash significantly changing the market value of the investment.	Any portfolio investment (1) that a fund's investment adviser reasonably expects could be sold in two to three trading days in current market conditions without significantly changing the market value of the investment and (2) that has an expected settlement period of T+3 or less.
Less Liquid Investment; Rule 22e–4(a)(10).	Any portfolio investment that the fund reasonably expects to be able to sell or dispose of in current market conditions in seven calendar days or less without the sale or disposition significantly changing the market value of the investment but where the sale or disposition is reasonably expected to settle in more than seven calendar days.	Any portfolio investment that could be sold within three trading days without significantly changing the market value of the investment, but is determined to have an expected settlement period of longer than T+3.[20]
Illiquid Investment; Rule 22e–4(a)(8).	Any portfolio investment that the fund reasonably expects cannot be sold or disposed of in current market conditions in seven calendar days or less, without the sale or disposition significantly changing the market value of the investment.	Any portfolio investment that a fund's investment adviser reasonably expects could not be sold within three trading days without the sale or disposition significantly changing the market value of the investment.

III. Request for Exemptive Relief

12. Applicants request an order under section 6(c) of the Act for an exemption from the provisions of rule 22e–4 discussed below and the related reporting requirements on Forms N–PORT and N–LIQUID solely to the extent necessary to implement the Amended Liquidity Program.

Rule 22e–4 Exemptions

13. Applicants seek an exemption from rule 22e–4(b)(1)(ii) to permit Covered Fund holdings to be classified under the Amended Liquidity Program across the five liquidity categories, as described above, for purposes of assessing and monitoring each Covered Fund's liquidity risk. Applicants are not seeking an exemption from that section's requirement to use information obtained after reasonable inquiry and taking into account relevant market, trading, and investment specific considerations when classifying investments.

14. Applicants also seek an exemption to use the Amended Liquidity Program's modified definitions of the rule 22e–4 four buckets in order to comply with the HLIM requirements and illiquid investment limitations in rule 22e–4. Using the modified definitions would permit the Applicants to convert the five liquidity categories into the four buckets.

15. Rule 22e–4 requires funds that do not primarily hold assets that are highly liquid investments to determine a minimum HLIM level. Applicants seek an exemption to use the modified definitions to assess if a Covered Fund is required to maintain an HLIM, to determine the amount of any such HLIM, and to assess ongoing compliance with the requirement.

16. Rule 22e–4 currently requires a fund to exclude from its calculations of HLIM the percentage of fund assets that are highly liquid investments that it has segregated to cover, or pledged to satisfy margin requirements in connection with, derivatives transactions that the fund has classified as moderately liquid, less liquid, and illiquid investments.[21] For purposes of complying with this requirement, Applicants seek an exemption to permit a Covered Fund to exclude Category 1 assets that are segregated to cover, or pledged to satisfy margin requirements in connection with, derivatives transactions that are not classified within Category 1; for purposes of complying with rule 22e–4(b)(1)(iii)(B), as amended, Category 1 assets that are pledged as margin or collateral in connection with derivatives transactions that are not classified within Category 1 will be excluded from the Covered Fund's calculation of whether the Covered Fund primarily holds assets that are highly liquid investments.

17. Rule 22e–4 currently also requires a fund to identify the percentage of the fund's highly liquid investments that it has segregated to cover, or pledged to satisfy margin requirements in connection with, derivatives transactions classified as moderately liquid, less liquid, and illiquid.[22] For purposes of determining this percentage, Applicants seek an exemption to permit the Covered Funds to identify Category 1 assets that are segregated to cover, or pledged to satisfy margin requirements in connection with, derivatives transactions that are classified as moderately liquid, less liquid, and illiquid under the modified definitions; for purposes of compliance with rule 22e–4(b)(1)(ii)(C), as amended, the Applicants seek an exemption to permit the Covered Funds to identify Category 1 assets under the Liquidity Risk Framework that are pledged as margin or collateral in connection with, derivatives transactions that are assigned to other categories under the Liquidity Risk Framework.

18. Rule 22e–4 prohibits a fund from acquiring any illiquid investment if, immediately after such acquisition, the fund would have invested more than 15% of its net assets in illiquid investments that are assets.[23] Further, the rule imposes certain requirements in the event a fund holds more than 15% of its net assets in illiquid investments. For purposes of complying with these requirements, Applicants seek an exemption to permit the Covered Funds to use the modified definition of illiquid investments.

[19] *See supra* note 9. As required by rule 22e–4(b)(1)(ii), the Amended Liquidity Program would use information obtained after reasonable inquiry and taking into account relevant market, trading, and investment-specific considerations when classifying investments. The Applicants are not seeking an exemption from this requirement of Rule 22e–4(b)(1)(ii).

[20] This category will include holdings that fall within Category 1 or Category 2 and that are determined to have a standard settlement period of longer than T+3. This currently includes loan assignments and participations and certain emerging markets instruments and securities. *See* Application at note 14 and accompanying text.

[21] Rule 22e–4(b)(1)(iii)(B).

[22] Rule 22e–4(b)(1)(ii)(C).

[23] Rule 22e–4(b)(1)(iv).

Reporting Exemptions

19. Applicants request an exemption from items B.7, B.8 and C.7 of Form N–PORT [24] in order for the Covered Funds to adopt and implement the Amended Liquidity Program. Specifically, they seek relief in order for each Covered Fund to use the modified definitions under the Amended Liquidity Program for purposes of reporting. Each Covered Fund that implements the Amended Liquidity Program would include an explanatory note with respect to the information reported in response to these items.[25] The Covered Funds would otherwise file Form N–PORT as required under rule 30b1–9 under the Act.

20. Applicants request an exemption from Parts B through D of Form N–LIQUID in order for the Covered Funds to use the modified definitions for purposes of determining whether a filing on Form N–LIQUID is required. A Covered Fund would use the modified definitions of ''highly liquid investment'' and ''illiquid investment'' described in the chart above. Each Covered Fund that implements the Amended Liquidity Program would include appropriate explanatory notes in any Form N–LIQUID filing describing the classification methodology used to determine ''highly liquid investments'' or ''illiquid investments,'' as applicable, and any related assumptions. The Covered Funds would otherwise file Form N–LIQUID as required under rule 30b1–10 under the Act.

IV. Arguments in Support of the Requested Relief

21. Applicants maintain that the Amended Liquidity Program is designed to effectively accomplish the SEC's primary goals for rule 22e–4, which are to reduce the risk that funds would be unable to meet redemption and other legal obligations, minimize dilution, and elevate the overall quality of liquidity risk management across the fund industry.

22. Applicants assert that investors would continue to benefit from the protections of rule 22e–4 to the extent that the Amended Liquidity Program incorporates elements of the Existing 22e–4 Program. Applicants note that the use of the five liquidity categories results in a quantitative breakdown of Covered Fund liquidity that JPM believes meets the general public policy requirements of rule 22e–4, while providing JPM with detailed information specific to its analytical purpose. Applicants assert that the Amended Liquidity Program, which would permit an assessment of a Covered Fund's liquidity profile that is no less robust than the assessment produced under the Existing 22e–4 Program, creates a more useful view of fund liquidity and potentially lends itself to more conservative portfolio risk management overall.[26] Absent the requested relief, JPM would continue to maintain a separate classification methodology for the Covered Funds solely to the meet the requirements in rule 22e–4 discussed above and related reporting requirements. The Applicants would thereby continue to incur significant costs and administrative burdens through the maintenance of dual liquidity classification programs, as well as those associated with satisfying the HLIM and margin requirements specified in rule 22e–4 and the related reporting requirements.

23. Applicants maintain that the use of modified definitions of ''highly liquid investment'' and ''illiquid investment'' for purposes of the Amended Liquidity Program should result in a Covered Fund holding a substantially similar percentage of ''illiquid investments'' and ''highly liquid investments'' as would be the case using the current definitions under rule 22e–4. Any differences would be limited and would primarily relate to the use of different vendors and data, as well as the Amended Liquidity Program's spreading holdings across multiple categories (as part of the Full Position Size Approach). JPM believes that the use of these modified definitions under the Amended Liquidity Program will not adversely impact the likelihood that any Covered Fund will be able to meet redemptions or increase the risk that the interests of remaining shareholders will be significantly diluted or that remaining shareholders will be disproportionately exposed to illiquid investments.

24. Applicants state that the Amended Liquidity Program would provide investors with at least the same level of disclosure that they receive under the Existing 22e–4 Program to enable investors to understand the Amended Liquidity Program and its effect on the liquidity risk assessment of a Covered Fund's investments. Moreover, each Covered Fund would continue to provide appropriate disclosure in its annual or semi-annual shareholder reports regarding the operation and effectiveness of its liquidity risk management program (and, where applicable, would address any liquidity events that materially affected fund performance, as required by Form N–1A).

25. Applicants assert that the SEC and its staff will receive information, through the Covered Funds' public disclosures and reporting on Form N–PORT and, where applicable, Form N–LIQUID, necessary to assess the liquidity profiles of the Covered Funds, monitor the Covered Funds' compliance with the Amended Liquidity Program, and compare the liquidity risk management practices of the Covered Funds with those of other funds in the industry.

26. Applicants believe that the use of the Amended Liquidity Program's classification methodology would result in a similar level of transparency that will not adversely affect the SEC's ability to understand and monitor a Covered Fund's liquidity profile or conduct industry-wide surveillance.

27. Based on the foregoing, Applicants submit that the requested relief meets the standards for relief under section 6(c) of the Act.

VI. Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. Each Covered Fund will include an explanatory note with respect to the information reported in response to Items B.7, B.8 and C.7 of Form N–PORT substantively to the following effect:

''As permitted by an SEC exemptive order, the Funds use liquidity definitions and classification methodologies that differ from Rule 22e–4 requirements. Results shown on

[24] Item B.7 requires a fund to report, as applicable, its HLIM, the number of days the fund was below such HLIM, and any changes to the HLIM during the reporting period. Item B.8 requires disclosure of the percentage of a fund's highly liquid investment minimum assets that have been segregated or pledged in connection with certain derivatives transactions. For purposes of Item B.8 of Form N–PORT as amended, each Covered Fund that implements the Amended Liquidity Program and engages in derivatives transactions will provide the percentage of the Covered Fund's holdings that are ''highly liquid investments'' (as determined pursuant to the Amended Liquidity Program) that have been pledged as margin or collateral in connection with derivatives transactions that are ''moderately liquid investments,'' ''less liquid investments,'' or ''illiquid investments'' (as such classifications are determined pursuant to the Amended Liquidity Program, as described above, for purposes of Form N–PORT reporting).

Item C.7 requires funds to report the liquidity classification for each investment across the four buckets.

[25] For reporting on Form N–PORT, the funds would include an explanatory note regarding their modified reporting as described in condition 1 of the application. *See* section IV. of this Notice.

[26] As Applicants note, we have stated that funds that believe they would have to maintain dual liquidity classification programs as part of their liquidity risk management may choose to seek an exemption from the Commission from the classification requirements of rule 22e–4 if they believe that their existing systems would effectively accomplish the Commission's stated goals.

this Form could be different if the Funds did not rely on the exemptive order.''

2. Each Covered Fund will include explanatory notes in any Form N–LIQUID filing describing the classification methodology used to determine ''highly liquid investments'' or ''illiquid investments,'' as applicable, and any related assumptions.

3. The annual report provided to the board of trustees of each Covered Fund that implements the Amended Liquidity Program pursuant to rule 22e–4(b)(2)(iii) will include a certification with respect to compliance with the terms of the Order.

4. The Covered Funds that implement the Amended Liquidity Program will maintain records for a period of five years (the first two years in an easily accessible place) showing each instrument's classification under the Liquidity Risk Framework's five categories and each instrument's classification after it has been converted to four categories.

By the Commission.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2020–28764 Filed 12–28–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90768; File No. SR–NYSE–2019–67]

Self-Regulatory Organizations; New York Stock Exchange LLC; Order Setting Aside Action by Delegated Authority and Approving a Proposed Rule Change, as Modified by Amendment No. 2, To Amend Chapter One of the Listed Company Manual To Modify the Provisions Relating to Direct Listings

December 22, 2020.

I. Introduction

On December 11, 2019, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Chapter One of the Listed Company Manual (''Manual'') to modify the provisions relating to direct listings.[3] Pursuant to the proposal, NYSE would allow an issuer, at the time of an initial listing on the Exchange, to conduct a primary offering as part of a direct listing without conducting a firm commitment underwritten offering.

On August 26, 2020, the Commission, acting through authority delegated to the Division of Trading and Markets (''Division''),[4] approved the proposed rule change, as modified by Amendment No. 2 (''Approval Order'').[5] On September 8, 2020, the Council of Institutional Investors (''CII'' or ''Petitioner'') filed a petition for review of the Approval Order (''Petition for Review''). Pursuant to Commission Rule of Practice 431(e), the Approval Order was stayed by the filing with the Commission of a notice of intention to petition for review.[6] On September 25, 2020, the Commission issued a scheduling order, pursuant to Commission Rule of Practice 431, granting the Petition for Review of the Approval Order and providing until October 16, 2020, for any party or other person to file a written statement in support of, or in opposition to, the Approval Order.[7] On October 16, 2020, NYSE submitted a written statement in support of the Approval Order.[8]

The Commission has conducted a de novo review of NYSE's proposal, giving careful consideration to the entire record—including NYSE's amended proposal, the Petition for Review, and all comments and statements submitted—to determine whether the proposal is consistent with the Exchange Act and the rules and regulations issued thereunder. Under Section 19b(2)(C) of the Exchange Act, the Commission must approve the proposed rule change of a self-regulatory organization (''SRO'') if the Commission finds that the proposed rule change is consistent with the Exchange Act and the applicable rules and regulations thereunder; if it does not make such a finding, the Commission must disapprove the proposed rule change.[9] Additionally, under Rule 700(b)(3) of the Commission's Rules of Practice, the ''burden to demonstrate that a proposed rule change is consistent with the Exchange Act and the rules and regulations issued thereunder . . . is on the self-regulatory organization that proposed the rule change.'' [10] Further, ''the description of a proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently detailed and specific to support an affirmative Commission finding.'' [11] Finally, ''[a]ny failure of the self-regulatory organization to provide the information elicited by Form 19b–4 may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Exchange Act and the rules and regulations issued thereunder that are applicable to the self-regulatory organization.'' [12]

For the reasons discussed herein, the Commission has determined that NYSE has met its burden to show that the proposed rule change is consistent with the Exchange Act. We thus set aside the Approval Order and approve NYSE's proposed rule change, as amended. Section 6(b)(5) of the Exchange Act requires that the rules of a national securities exchange be designed to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] On December 13, 2019, the Exchange filed Amendment No. 1 to the proposed rule change, which amended and replaced the proposed rule change in its entirety. The proposed rule change, as modified by Amendment No. 1, was published for comment in the **Federal Register** on December 30, 2019. *See* Exchange Act Release No. 87821 (Dec. 20, 2019), 84 FR 72065. On February 13, 2020, pursuant to Section 19(b)(2) of the Exchange Act, the Commission designated a longer period within which to either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change. *See* Exchange Act Release No. 88190, 85 FR 9891 (Feb. 20, 2020). On March 26, 2020, the Commission instituted proceedings to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1. *See* Exchange Act Release No. 88485, 85 FR 18292 (Apr. 1, 2020) (''OIP''). On June 22, 2020, the Exchange filed Amendment No. 2 to the proposed rule change, which superseded the proposed rule change as modified by Amendment No. 1 (''Amendment No. 2''). On June 24, 2020, the Commission extended the time period for approving or disapproving the proposal to August 26, 2020. *See* Exchange Act Release No. 89147, 85 FR 39226 (June 30, 2020). The proposed rule change, as modified by Amendment No. 2, was published for comment in the **Federal Register** on June 30, 2020. *See* Exchange Act Release No. 89148 (June 24, 2020), 85 FR 39246 (''Notice'').

[4] 17 CFR 200.30–3(a)(12).

[5] *See* Exchange Act Release No. 89684, 85 FR 54454 (Sept. 1, 2020).

[6] 17 CFR 201.431(e). *See* Letter to John Carey, Senior Director, NYSE Group Inc. (Aug. 31, 2020) (providing notice of receipt of notice of intention for review of delegated action and stay of order), *available at https://www.sec.gov/rules/sro/nyse/2020/34-89684-carey-letter.pdf.* On September 4, 2020, NYSE filed a motion for the Commission to lift the automatic stay of the Approval Order and a brief in support of its motion to lift the stay. On September 8, 2020, CII filed a brief in opposition to NYSE's motion to lift the automatic stay. On September 11, 2020, NYSE filed a reply brief in support of its motion to lift the stay.

[7] *See* Exchange Act Release No. 90001, 85 FR 61793 (Sept. 30, 2020). In the scheduling order, the Commission also denied NYSE's motion to lift the automatic stay of the Approval Order and ordered that the proposed rule change, as modified by Amendment No. 2, remain stayed.

[8] *See* The New York Stock Exchange LLC's Statement in Support of Order Approving Proposed Rule Change (Oct. 16, 2020) (''NYSE Statement'').

[9] 15 U.S.C. 78s(b)(2)(C).

[10] 17 CFR 201.700(b)(3).

[11] *Id.*

[12] *Id.*

prevent fraudulent and manipulative acts and practices, 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 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 are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers, or to regulate by virtue of any authority conferred by the Exchange Act matters not related to the purposes of the Exchange Act or the administration of an exchange.[13]

The record supports a finding that NYSE's proposal is consistent with these requirements. In particular, based on that record, the Commission concludes that, consistent with Section 6(b)(5) of the Exchange Act, NYSE's proposal will prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, will protect investors and the public interest; and will not permit unfair discrimination between customers, issuers, brokers, or dealers, and is not designed to regulate by virtue of the Exchange Act matters not related to the purposes of the Exchange Act or the administration of an exchange.

II. Description of the Proposal

In an initial public offering (''IPO'') underwritten on a firm commitment basis, an underwriter or group of underwriters enter into an underwriting agreement with the issuer in which they commit to take and pay for a specified amount of shares at a set price. The underwriters' purchase price reflects a discount, or spread, to the public offering price, which is negotiated between the issuer and the underwriters. The underwriters purchase the securities at the agreed upon discount and then resell the securities to the initial investors at the public offering price prior to the opening of trading. The underwriters and the issuer generally determine the public offering price and the discount based on indications for interest from prospective initial purchasers, which typically are, in large part, institutional investors with ongoing relationships with the underwriters. When the securities begin trading on an exchange, the opening price is determined based on orders to buy and sell the securities and may vary significantly from the initial public offering price. In a direct listing, in contrast, there is no initial sale to an underwriter or pre-opening sale by the underwriter to the initial purchasers. Instead, initial sales are conducted through the exchange, with the prices determined based on matching buy and sell orders and in accordance with applicable listing rules.

Section 102.01B, Footnote (E) of the Manual states that the Exchange generally expects to list companies in connection with a firm commitment underwritten IPO, upon transfer from another market, or pursuant to a spin-off, but also allows for the possibility of using a direct listing, as described below.[14] Currently, Footnote (E) states that the Exchange recognizes that companies that have not previously had their common equity securities registered under the Exchange Act, but that have sold common equity securities in a private placement, may wish to list their common equity securities on the Exchange at the time of effectiveness of a registration statement[15] filed solely for the purpose of allowing existing shareholders to sell their shares.[16] The Exchange has proposed to define this type of direct listing already permitted by the Exchange's rules as a ''Selling Shareholder Direct Floor Listing.''[17] The Exchange has proposed to recognize an additional type of direct listing in which a company that has not previously had its common equity securities registered under the Exchange Act would list its common equity securities on the Exchange at the time of effectiveness of a registration statement pursuant to which the company itself would sell shares in the opening auction on the first day of trading on the Exchange in addition to, or instead of, facilitating sales by selling shareholders (a ''Primary Direct Floor Listing'').[18] Under the proposal, the Exchange would, on a case-by-case basis, exercise discretion to list companies through a Selling Shareholder Direct Floor Listing or a Primary Direct Floor Listing.[19]

With respect to a Selling Shareholder Direct Floor Listing, the Exchange proposal retains the existing standards regarding how the Exchange will determine whether a company has met its market value of publicly-held shares listing requirement. The Exchange will continue to determine that such company has met the $100 million aggregate market value of publicly-held shares requirement based on a combination of both (i) an independent third-party valuation (''Valuation'') of the company; and (ii) the most recent trading price for the company's common stock in a trading system for unregistered securities operated by a national securities exchange or a registered broker-dealer (''Private Placement Market'').[20] Alternatively, in the absence of any recent trading in a Private Placement Market, the Exchange will determine that such company has met its market value of publicly-held shares requirement if the company provides a Valuation evidencing a market value of publicly-held shares of at least $250 million.[21]

[13] 15 U.S.C. 78f(b)(5).

[14] *See* Section 102.01B, Footnote (E) of the Manual.

[15] The reference to a registration statement refers to an effective registration statement filed pursuant to the Securities Act of 1933 (''Securities Act'').

[16] *See* Section 102.01B, Footnote (E) of the Manual. *See also* Exchange Act Release No. 82627 (Feb. 2, 2018), 83 FR 5650 (Feb. 8, 2018) (SR–NYSE–2017–30) (''NYSE 2018 Order'') (approving proposed rule change to amend Section 102.01B of the Manual to modify the provisions relating to the qualifications of companies listing without a prior Exchange Act registration in connection with an underwritten IPO and amend the Exchange's rules to address the opening procedures on the first day of trading for such securities).

[17] *See* proposed Section 102.01B, Footnote (E) of the Manual. Under the proposal, the Exchange would specify that such company may have previously sold common equity securities in ''one or more'' private placements. The Exchange also has proposed to move the description of this type of direct listing as involving a company ''where such company is listing without a related underwritten offering upon effectiveness of a registration statement registering only the resale of shares sold by the company in earlier private placements'' so that this description appears in conjunction with the definition of ''Selling Shareholder Direct Floor Listing.'' *See id.*

[18] *See* proposed Section 102.01B, Footnote (E) of the Manual. A Primary Direct Floor Listing would include any such listing in which either (i) only the company itself is selling shares in the opening auction on the first day of trading; or (ii) the company is selling shares and selling shareholders may also sell shares in such opening auction. *See id.*

[19] *See* proposed Section 102.01B, Footnote (E) of the Manual.

[20] *See* proposed Section 102.01B, Footnote (E) of the Manual. The Exchange will attribute a market value of publicly-held shares to the company equal to the lesser of: (i) The value calculable based on the Valuation; and (ii) the value calculable based on the most recent trading price in a Private Placement Market. *See* Section 102.01B, Footnote (E) of the Manual. For specific requirements regarding the Valuation and the independence of the valuation agent conducting such Valuation, *see* Section 102.01B, Footnote (E) of the Manual. Section 102.01B, Footnote (E) of the Manual also sets forth specific factors for relying on a Private Placement Market price. Generally, the Exchange will only rely on a Private Placement Market price if it is consistent with a sustained history over a several month period prior to listing evidencing a market value in excess of the Exchange's market value requirement.

[21] *See* Section 102.01B, Footnote (E) of the Manual. Shares held by directors, officers, or their

With respect to a Primary Direct Floor Listing, the Exchange has proposed that it will deem a company to have met the applicable aggregate market value of publicly-held shares requirement if the company will sell at least $100 million in market value of the shares in the Exchange's opening auction on the first day of trading on the Exchange.[22] Alternatively, where a company is conducting a Primary Direct Floor Listing and will sell shares in the opening auction with a market value of less than $100 million, the Exchange will determine that such company has met its market value of publicly-held shares requirement if the aggregate market value of the shares the company will sell in the opening auction on the first day of trading and the shares that are publicly held immediately prior to the listing is at least $250 million, with such market value calculated using a price per share equal to the lowest price of the price range established by the issuer in its registration statement.[23]

According to the Exchange, a company may list on the Exchange in connection with a traditional IPO with a market value of publicly-held shares of $40 million and, in the Exchange's experience in listing IPOs, a liquid trading market develops after listing for issuers with a much smaller value of publicly-held shares than the Exchange anticipates would exist after the opening auction in a Primary Direct Floor Listing under the proposed market value of publicly-held shares requirements.[24] Consequently, the Exchange believes that these requirements would provide that any company conducting a Primary Direct Floor Listing would be of a suitable size for Exchange listing and that there would be sufficient liquidity for the security to be suitable for auction market trading.[25] The Exchange also states that, with the exception of the proposed requirement for Primary Direct Floor Listings, shares held by officers, directors, or owners of more than 10% of the company stock are not included in calculations of publicly-held shares for purposes of Exchange listing rules.[26] The Exchange states that such investors may acquire in secondary market trades shares sold by the issuer in a Primary Direct Floor Listing that were included when calculating whether the issuer meets the market value of publicly-held shares initial listing requirement.[27] The Exchange further states that it believes that because of the enhanced publicly-held shares requirement for listing in connection with a Primary Direct Floor Listing, which is much higher than the Exchange's $40 million requirement for a traditional underwritten IPO, and the neutral nature of the opening auction process, companies using a Primary Direct Floor Listing would have an adequate public float and liquid trading market after completion of the opening auction.[28]

The Exchange states that any company listing in connection with a Primary Direct Floor Listing or a Selling Shareholder Direct Floor Listing would continue to be subject to and need to meet all other applicable initial listing requirements. According to the Exchange, this would include the requirements of Section 102.01A of the Manual to have 400 round lot shareholders and 1.1 million publicly-held shares outstanding at the time of initial listing, and the requirement of Section 102.01B of the Manual to have a price per share of at least $4.00 at the time of initial listing.[29]

The Exchange has proposed a new order type to be used by the issuer in a Primary Direct Floor Listing and rules regarding how that new order type would participate in a Direct Listing Auction.[30] Specifically, the Exchange has proposed to introduce an Issuer Direct Offering Order (''IDO Order''), which would be a Limit Order to sell that is to be traded only in a Direct Listing Auction for a Primary Direct Floor Listing.[31] The IDO Order would have the following requirements: (1) Only one IDO Order may be entered on behalf of the issuer and only by one member organization; (2) the limit price of the IDO Order must be equal to the lowest price of the price range established by the issuer in its effective registration statement (the price range is defined as the ''Primary Direct Floor Listing Auction Price Range''); (3) the IDO Order must be for the quantity of shares offered by the issuer, as disclosed in the prospectus in the effective registration statement; (4) the IDO Order may not be cancelled or modified; and (5) the IDO Order must be executed in full in the Direct Listing Auction.[32] Consistent with current rules, a Designated Market Maker (''DMM'') would effectuate a Direct Listing Auction manually, and the DMM would be responsible for determining the Auction Price.[33] Under the proposal, the DMM would not conduct a Direct Listing Auction for a Primary Direct Floor Listing if (1) the Auction Price would be below the lowest price or above the highest price of the Primary Direct Floor Listing Auction Price Range; or (2) there is insufficient buy interest to satisfy both the IDO Order and all better-priced sell orders in full.[34] The Exchange states that if there is insufficient buy interest and the DMM cannot price the Auction and satisfy the IDO Order as required, the Direct Auction would not proceed and such security would not begin trading.[35] The Exchange represents that, if a Direct Listing Auction cannot be conducted, the Exchange would notify market participants via a Trader Update that the Primary Direct Floor Listing has been cancelled and any orders for that

immediate families and other concentrated holdings of 10 percent or more are excluded in calculating the number of publicly-held shares. *See* Section 102.01A, Footnote (B) of the Manual.

[22] *See* proposed Section 102.01B, Footnote (E) of the Manual.

[23] *See* proposed Section 102.01B, Footnote (E) of the Manual. The Exchange states that, for example, if the company is selling five million shares in the opening auction, there are 45 million publicly-held shares issued and outstanding immediately prior to listing, and the lowest price of the price range disclosed in the company's registration statement is $10 per share, then the Exchange will attribute to the company a market value of publicly-held shares of $500 million. *See* Notice, 85 FR at 39247.

[24] *See* Notice, 85 FR at 39250.

[25] *See* Notice, 85 FR at 39250.

[26] *See* Notice, 85 FR at 39247. The Exchange states that these types of inside investors may purchase shares sold by the company in the opening auction, and purchase shares sold by other shareholders or sell their own shares in the opening auction and in trading after the opening auction, to the extent not inconsistent with general anti-manipulation provisions, Regulation M, and other applicable securities laws. *See id.*

[27] *See* Notice, 85 FR at 39247.

[28] *See* Notice, 85 FR at 39247.

[29] *See* Notice, 85 FR at 39247.

[30] Under current Rule 1.1(f), the term ''Direct Listing'' means ''a security that is listed under Footnote (E) to Section 102.01B of the Listed Company Manual.'' The Exchange has proposed to modify this definition to specify that the term ''Direct Listing'' may refer to either a Selling Shareholder Direct Floor Listing or a Primary Direct Floor Listing. *See* proposed Rule 1.1(f). *See also* Rule 7.35(a)(1) for the definition of ''Auction'' and Rule 7.35(a)(1)(E) for the definition of ''Direct Listing Auction.''

[31] *See* proposed Rule 7.31(c)(1)(D). *See also* Rule 7.31(a)(2) for the definition of ''Limit Order.''

[32] *See* proposed Rule 7.31(c)(1)(D)(i)–(v).

[33] ''Auction Price'' is defined as the price at which an Auction is conducted. *See* Rule 7.35(a)(5). The Exchange states that because an IDO Order would not be entered by the DMM, the Exchange has proposed to include IDO Orders among the types of Auction-Only Orders that are not available to DMMs. *See* Notice, 85 FR at 39248, n.21. *See also* proposed Rule 7.31(c). An ''Auction-Only Order'' is a Limit or Market Order that is to be traded only in an auction pursuant to the Rule 7.35 Series (for Auction-Eligible Securities) or routed pursuant to Rule 7.34 (for UTP Securities). *See* Rule 7.31(c). *See also* Rule 7.31(a)(1) for the definition of ''Market Order.''

[34] *See* proposed Rule 7.35A(g)(2). A buy (sell) order is ''better-priced'' if it is priced higher (lower) than the Auction Price, and this includes all sell Market Orders and Market-on-Open Orders. *See* Rule 7.35(a)(5)(A). *See also* Rule 7.31(c)(1)(B) for the definition of ''Market-on-Open Order.'' A buy (sell) order is ''at-priced'' if it is priced equal to the Auction Price. *See* Rule 7.35(a)(5)(B).

[35] *See* Notice, 85 FR at 39249.

security that had been entered on the Exchange, including the IDO Order, would be cancelled back to the entering firms.[36]

Currently, Rule 7.35A(h) generally provides that, once an Auction Price has been determined, better-priced orders are guaranteed to participate in the Auction at the Auction Price, whereas at-priced orders are not guaranteed to participate and will be allocated according to specified priority rules.[37] The Exchange has proposed that an IDO Order would be guaranteed to participate in the Direct Listing Auction at the Auction Price.[38] If the limit price of the IDO Order is equal to the Auction Price, the IDO Order would have priority at that price.[39] The Exchange states that providing priority to an at-priced IDO Order would increase the potential for the IDO Order to be executed in full, and therefore for the Primary Direct Floor Listing to proceed.[40]

In addition, the Exchange has proposed to specify that two existing provisions would apply in the case of a Selling Shareholder Direct Floor Listing only. Currently, a DMM will publish a pre-opening indication if the Auction Price is anticipated to be a change of more than the Applicable Price Range[41] from a specified Indication Reference Price.[42] Under the proposal, the Indication Reference Price for a security that is a Selling Shareholder Direct Floor Listing that has had recent sustained trading in a Private Placement Market prior to listing would be the most recent transaction price in that market or, if none, would be a price determined by the Exchange in consultation with a financial advisor to the issuer of such security.[43] Further, when facilitating the opening on the first day of trading of a Selling Shareholder Direct Floor Listing that has not had a recent sustained history of trading in a Private Placement Market prior to listing, the DMM would consult with a financial advisor to the issuer of such security in order to effect a fair and orderly opening of such security.[44] The Exchange states that these provisions are not applicable to a Primary Direct Floor Listing because, unlike for a Selling Shareholder Direct Floor Listing, the registration statement for a Primary Direct Floor Listing would include a price range within which the company anticipates selling the shares it is offering.[45]

In the case of a Primary Direct Floor Listing, the Exchange has proposed a new measure of the Indication Reference Price. Specifically, for a security that is offered in a Primary Direct Floor Listing, the Indication Reference Price would be the lowest price of the Primary Direct Floor Listing Auction Price Range.[46]

The Exchange states that any services provided by a financial advisor to the issuer of a security listing in connection with a Selling Shareholder Direct Floor Listing or a Primary Direct Floor Listing (the ''financial advisor'') and the DMM assigned to that security must provide such services in a manner that is consistent with all federal securities laws, including Regulation M and other anti-manipulation requirements.[47] The Exchange states that, for example, when a financial advisor provides a consultation to the Exchange as required by Rule 7.35A(d)(2)(a)(iv), when the DMM consults with a financial advisor in connection with Rule 7.35A(g)(1), or when a financial advisor otherwise assists or consults with the DMM as to pricing or opening of trading in a Selling Shareholder Direct Floor Listing or Primary Direct Floor Listing, the financial advisor and DMM will not act inconsistent with Regulation M and other anti-manipulation provisions of the federal securities laws, or Exchange Rule 2020.[48] The Exchange represents that it has retained the Financial Industry Regulatory Authority (''FINRA'') pursuant to a regulatory services agreement to monitor such compliance with Regulation M and other anti-manipulation provisions of the federal securities laws, and Rule 2020.[49] The Exchange has proposed a new commentary that states that, in connection with a Selling Shareholder Direct Floor Listing, the financial advisor to the issuer of the security being listed and the DMM assigned to such security are reminded that any consultation that the financial advisor provides to the Exchange as required by Rule 7.35A(d)(2)(A)(iv) and any consultation between the DMM and financial advisor as required by Rule 7.35A(g)(1) is to be conducted in a manner that is consistent with the federal securities laws, including Regulation M and other anti-manipulation requirements.[50]

Finally, the Exchange has proposed to remove references to Direct Listing Auctions from Rule 7.35C, which concerns Exchange-facilitated auctions.[51] The Exchange states that, because of the importance of the DMM to the Direct Listing Auction, if a DMM is unable to manually facilitate a Direct Listing Auction, the Exchange would not proceed with a Selling Shareholder Direct Floor Listing or a Primary Direct Floor Listing.[52]

III. Discussion and Commission Findings

The Commission finds that the proposed rule change, as modified by Amendment No. 2, is consistent with Section 6(b)(5) of the Exchange Act,[53] 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 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 are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.[54]

The Commission has consistently recognized the importance and significance of national securities

[36] *See* Notice, 85 FR at 39249.

[37] *See* Rule 7.35A(h)(1) and (2).

[38] *See* proposed Rule 7.35A(h)(4).

[39] *See* proposed Rule 7.35A(h)(4).

[40] *See* Notice, 85 FR at 39249.

[41] The ''Applicable Price Range'' for determining whether to publish a pre-opening indication, with limited exception, is 5% for securities with an Indication Reference Price over $3.00 and $0.15 for securities with an Indication Reference Price equal to or lower than $3.00. *See* Rule 7.35A(d)(3)(A).

[42] *See* Rule 7.35A(d)(1)(A).

[43] *See* proposed Rule 7.35A(d)(2)(A)(iv).

[44] *See* proposed Rule 7.35A(g)(1). The Exchange has proposed a non-substantive change to this provision to modify a reference to ''Private Placement'' to utilize the defined term ''Private Placement Market.'' *See id.*

[45] *See* Notice, 85 FR at 39249.

[46] *See* proposed Rule 7.35A(d)(2)(A)(v). The Exchange states that, for example, if the Primary Direct Floor Listing Auction Price Range is $10.00 to $20.00, then the Indication Reference Price would be $10.00. *See* Notice, 85 FR at 39248, n.22.

[47] *See* Notice, 85 FR at 39249.

[48] *See* Notice, 85 FR at 39249 (citing Rule 2020, which provides that ''No member or member organization shall effect any transaction in, or induce the purchase or sale of, any security by means of any manipulative, deceptive or other fraudulent contrivance'').

[49] *See* Notice, 85 FR at 39249. The Exchange further represents that it expects to issue regulatory guidance in connection with a company conducting a Primary Direct Floor Listing, and that such regulatory guidance would include a reminder to member organizations that activities in connection with a Primary Direct Floor Listing, like activities in connection with other listings, must be conducted in a manner not inconsistent with Regulation M and other anti-manipulation provisions of the federal securities laws and Rule 2020. *See id.* at 39249, n.28.

[50] *See* proposed Rule 7.35A, Commentary .10.

[51] *See* proposed Rule 7.35C(a), (a)(3), (b)(1), and (b)(3).

[52] *See* Notice, 85 FR at 39249.

[53] 15 U.S.C. 78f(b)(5).

[54] 15 U.S.C. 78f(b). In approving this proposed rule change, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

exchange listing standards. Among other things, such listing standards help ensure that exchange listed companies will have sufficient public float, investor base, and trading interest to provide the depth and liquidity necessary to promote fair and orderly markets.[55] The standards, collectively, also provide investors and market participants with some level of assurance that the listed company has the resources, policies, and procedures to comply with the requirements of the Exchange Act and Exchange rules.[56]

The Exchange's listing standards currently provide the Exchange with discretion to list a company whose stock has not been previously registered under the Exchange Act, where such company is listing in connection with a Selling Shareholder Direct Floor Listing.[57] The Exchange has proposed to allow companies to list in connection with a Primary Direct Floor Listing, which would for the first time provide a company the option, without a firm commitment underwritten offering, of selling shares to raise capital in the opening auction upon initial listing on the Exchange.[58]

Several commenters expressed support for the proposed expansion of direct listings to permit a primary offering.[59] One commenter, for example, stated that it supports alternative formats for IPOs, including direct listing proposals like the one proposed by the Exchange, and expressed the view that issuers should be offered choices that match their objectives so long as they protect the integrity of the markets and are fair and clear to investors, using transparent processes.[60] Another commenter believed that allowing for multiple pathways for private companies to achieve exchange listing would encourage more companies to participate in public equity markets and provide investors a broader array of attractive investment opportunities.[61]

In Amendment No. 2, the Exchange made several modifications to its proposal that were designed to clarify the role of the issuer and financial advisor in a direct listing to explain how compliance with various rules and regulations will be addressed. As discussed in more detail below, these changes: (i) Help to ensure that the issuer cannot unduly influence the opening price through a new order type that cannot be modified or canceled; (ii) highlight that financial advisors involved with direct listings cannot violate the anti-manipulation provisions of the Exchange Act, including Regulation M; and (iii) highlight that the Exchange has retained FINRA pursuant to a regulatory services agreement to monitor compliance with Regulation M and other anti-manipulation provisions of the federal securities laws. We conclude that the proposal, as amended by Amendment No. 2, supports a finding that the proposal is consistent with the Exchange Act. More specifically, the following aspects of the proposal demonstrate that it is reasonably designed to be consistent with the protection of investors and the maintenance of fair and orderly markets, as well as the facilitation of capital formation: (i) Addition of the IDO Order type and other requirements which address how the issuer will participate in the opening auction; (ii) discussion of the role of financial advisors; (iii) addition of the Commentary that provides that specified activities are to be conducted in a manner that is consistent with the federal securities laws, including Regulation M and other anti-manipulation requirements; (iv) retaining FINRA to monitor compliance with Regulation M and other anti-manipulation provisions of the federal securities laws and NYSE Rule 2020; (v) clarification of how market value will be determined for qualifying the company's securities for listing; and (vi) elimination of the grace period for meeting certain listing requirements.

The Commission addresses below the relevant concerns, identified by either commenters or the Commission in the OIP, relating to NYSE's proposal to allow direct listings with a primary offering. First, the Commission addresses issues identified in the OIP related to the aggregate market value of publicly-held shares requirement and whether the proposed standards will help facilitate adequate liquidity for companies listing in a Primary Direct Floor Listing. Second, the Commission addresses issues identified in the OIP about the initial listing opening auction process for Primary Direct Floor Listings and discusses financial advisors. Finally, the Commission addresses commenters' concerns about whether the proposal is consistent with investor protection and the public interest given the lack of traditional underwriter

[55] The Commission has stated in approving national securities exchange listing requirements that the development and enforcement of adequate standards governing the listing of securities on an exchange is an activity of critical importance to the financial markets and the investing public. In addition, once a security has been approved for initial listing, maintenance criteria allow an exchange to monitor the status and trading characteristics of that issue to ensure that it continues to meet the exchange's standards for market depth and liquidity so that fair and orderly markets can be maintained. *See, e.g.,* NYSE 2018 Order, 83 FR at 5653, n.53; Exchange Act Release Nos. 81856 (Oct. 11, 2017), 82 FR 48296, 48298 (Oct. 17, 2017) (SR–NYSE–2017–31); 81079 (July 5, 2017), 82 FR 32022, 32023 (July 11, 2017) (SR–NYSE–2017–11). The Commission has stated that adequate listing standards, by promoting fair and orderly markets, are consistent with Section 6(b)(5) of the Exchange Act, in that they are, among other things, designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, and protect investors and the public interest. *See, e.g.,* NYSE 2018 Order, 83 FR at 5653, n.53; Exchange Act Release Nos. 87648 (Dec. 3, 2019), 84 FR 67308, 67314, n.42 (Dec. 9, 2019) (SR–NASDAQ–2019–059); 88716 (Apr. 21, 2020), 85 FR 23393, 23395, n.22 (Apr. 27, 2020) (SR–NASDAQ–2020–001).

[56] ''Meaningful listing standards also are important given investor expectations regarding the nature of securities that have achieved a national securities exchange listing, and the role of a national securities exchange in overseeing its market and assuring compliance with its listing standards.'' Exchange Act Release No. 65708 (Nov. 8, 2011), 76 FR 70799, 70802 (Nov. 15, 2011) (SR–NASDAQ–2011–073). *See also* Exchange Act Release Nos. 65709 (Nov. 8, 2011), 76 FR 70795 (Nov. 15, 2011) (SR–NYSE–2011–38); 88389 (Mar. 16, 2020), 85 FR 16163 (Mar. 20, 2020) (SR–NASDAQ–2019–089). The Exchange, in addition to requiring companies seeking to list to meet the quantitative listing standards and once listed the quantitative continued listing standards, also requires listed companies to meet other qualitative requirements. *See, e.g.,* Section 3, Corporate Responsibility, of the Manual.

[57] *See* Section 102.01B, Footnote (E) of the Manual. *See also* NYSE 2018 Order, 83 FR at 5654.

[58] *See* NYSE Listed Company Manual Section 102.01B, Footnote (E) of the Manual which states generally that the Exchange expects to list companies in connection with a firm commitment underwritten IPO, upon transfer from another market, or pursuant to a spin-off. Section 102.01B, Footnote (E) also states, however, that ''the Exchange recognizes that some companies that have not previously had their common equity securities registered under the Exchange Act, but which have sold common equity securities in a private placement, may wish to list their common equity securities on the Exchange at the time of effectiveness of a registration statement filed solely for the purpose of allowing existing shareholders to sell their shares.''

[59] *See* Letter from Stephen John Berger, Managing Director, Global Head of Government & Regulatory Policy, Citadel Securities (Feb. 18, 2020) (''Citadel Letter''), at 1; Letter from Paul Abrahimzadeh and Russell Chong, Co-Heads, U.S. Equity Capital Markets, Citigroup Capital Markets Inc. (Feb. 26, 2020) (''Citigroup Letter''); Letter from Matthew B. Venturi, Founder & CEO, ClearingBid, Inc. (Jan. 21, 2020) (''ClearingBid Letter''), at 5; Letter from David Ludwig, Head of Americas Equity Capital Markets, Goldman Sachs Group, Inc. (Feb. 7, 2020) (''Goldman Sachs Letter''); Letter from Burke Dempsey, Executive Vice President Head of Investment Banking, Wedbush Securities (Apr. 20, 2020) (''Wedbush Letter'').

[60] *See* Citigroup Letter. This commenter also stated its belief that the direct listing format would afford broad participation in the capital formation process and help establish a shareholder base that has a long-term interest in partnering with management teams. *See id.*

[61] *See* Goldman Sachs Letter. This commenter also referenced the recent direct listings by Spotify Technology S.A. and Slack Technologies, Inc., and expressed the view that the development of a direct listing approach to becoming a public company has been a significant step forward in providing companies greater choice in their path to going public, and that the ability to include a primary capital raise in a direct listing will further enhance this flexibility. *See id. See also* Citadel Letter, at 1; Wedbush Letter.

involvement in a Primary Direct Floor Listing, as well as concerns about Securities Act Section 11(a) liability. As discussed in greater detail below, the Commission concludes that the record addresses these concerns and that the Exchange has met its burden to demonstrate that its proposal is consistent with the Exchange Act, and therefore finds the proposed rule change to be consistent with the Exchange Act.

A. Aggregate Market Value of Publicly-Held Shares Requirement

With respect to the aggregate market value of publicly-held shares requirement, the Exchange proposes to require that it will deem a company to have met such requirement if the company will sell at least $100 million in market value of shares in the Exchange's opening auction on the first day of trading. Alternatively, where a company will sell shares in the opening auction with a market value of less than $100 million, the Exchange will deem the company to have met such requirement if the aggregate market value of the shares the company will sell in the opening auction on the first day of trading and the shares that are publicly held immediately prior to listing is at least $250 million. According to the Exchange, a company may list in connection with an IPO with a market value of publicly-held shares of $40 million and, ''in the Exchange's experience in listing IPOs, a liquid trading market develops after listing for issuers with a much smaller value of publicly-held shares than the Exchange anticipates would exist after the opening auction in a Primary Direct Floor Listing.'' [62] In Amendment No. 2, the Exchange clarified that market value would be calculated using a price per share equal to the lowest price of the price range multiplied by the number of shares being offered by the issuer.[63]

One commenter expressed the view that the proposal, as originally noticed for comment, appropriately updated the publicly-held shares and distribution requirements associated with direct listings in order to ensure the development of a liquid trading market.[64] Another commenter believed that the Exchange should provide data to support its conclusion that there would be adequate liquidity for a security listing in connection with a Primary Direct Floor Listing.[65] In its statement in support of its proposal, the Exchange stated that its proposal would impose a substantially higher capitalization requirement for Primary Direct Floor Listings than its rules require for traditional IPOs.[66]

The Commission has determined that the Exchange has met its burden to show that the proposed aggregate market value of publicly-held shares requirement provides the Exchange with a reasonable level of assurance that the company's market value supports listing on the Exchange and the maintenance of fair and orderly markets.[67] The Commission reaches this conclusion because the proposed market value standard for listing a Primary Direct Floor Listing is at least two and a half times greater than the market value standard that currently exists under Exchange rules for an Exchange listing of an IPO. The Commission also finds that the proposed requirements are also comparable to or higher than the aggregate market value of publicly-held shares required by the Exchange for initial listing in other contexts.[68] Specifically, the Exchange's proposed minimum market value requirements, which are designed in part to ensure sufficient liquidity, of $100 million and $250 million for Primary Direct Floor Listings are, in addition to being higher than the $40 million minimum market value requirement for IPOs,[69] comparable to (i) the $100 million and $250 million minimum market value requirements for listing a Selling Shareholder Direct Floor Listing; [70] and (ii) the $100 million requirement for aggregate market value of publicly-held shares for companies that list other than at the time of an IPO, spin-off, or initial firm commitment underwritten public offering.[71]

And as described below, using the lowest price in the price range established by the issuer in its registration statement to determine the minimum market value is a reasonable and conservative approach because the

[62] Notice, 85 FR at 39250. As described above, in determining that a company has met the market value of publicly-held shares standards the Exchange will consider the market value of all shares sold by the company in the opening auction, rather than excluding shares that may be purchased by officers, directors, or owners of more than 10% of the company's common stock, notwithstanding that generally the Exchange's listing standards exclude shares held by such insiders from its calculations of publicly-held shares. The Exchange believes that the Primary Direct Floor Listing will have an adequate public float and liquid trading market after completion of the opening auction given the higher market value requirement than that required for listing an underwritten IPO. *See* Notice, 85 FR at 39247.

[63] *See* Notice, 85 FR at 39247 and note 23, *supra,* and accompanying text.

[64] *See* Citadel Letter, at 1.

[65] *See* Letter from Jeffrey P. Mahoney, General Counsel, Council of Institutional Investors (July 16, 2020) (''CII Letter III''), at 5.

[66] *See* NYSE Statement, at 12 (citing Section 102.01B of the Manual; Approval Order at 16–17). According to the Exchange, it generally requires companies listing on the Exchange in connection with an IPO to have a market value of publicly-held shares of at least $40 million, whereas the proposal would require a company listing in conjunction with a Primary Direct Floor Listing to either (1) sell at least $100 million of its listed securities in the opening auction; or (2) have an aggregate market value of publicly-held shares immediately prior to listing, together with the market value of shares the company sells in the opening auction, of at least $250 million.

[67] Almost half of exchange-listed IPOs in the recent year had proceeds that fell below the $100 million threshold. Using information from Thomson Reuters SDC Platinum New Issues database, the Commission staff concluded that, among 146 exchange-listed IPOs conducted during the 2019 calendar year, the median offer size was $106.7 million. Further, staff concluded that approximately 47.9 percent of the companies that went public via IPO (12.8 percent for NYSE IPOs and 60.7 percent for NASDAQ IPOs) had an offer size that fell below $100 million. Similarly, an Ernst & Young report states that during 2019, the median proceeds raised in exchange-listed IPOs in the United States were approximately $110 million. *See* Global IPO trends: Q4 2019, Ernst & Young, *available at https://assets.ey.com/content/dam/ey-sites/ey-com/en_gl/topics/growth/ey-global-ipo-trends-q4-2019.pdf.*

[68] The Exchange did not provide the data specifically referenced by a commenter. *See supra* note 65 and accompanying text. However, the proposed minimum market value requirements are comparable to or higher than those listing standards applied by the Exchange in other contexts. *See supra* notes 20–21 and 66 and accompanying text.

[69] The existing $40 million market value requirement in Exchange Rules (Section 102.01B of the Manual) is a longstanding requirement that has supported the listing of companies on the Exchange that are suitable for listing and have existed since at least 2009. *See* Section 102.01B of the Manual. *See* Exchange Act Release No. 60501 (Aug. 13, 2009), 74 FR 42348 (Aug. 21, 2009) (SR–NYSE–2009–80) (lowering the aggregate market value of publicly-held shares for the listing of IPOs and spin-offs from $60 million to $40 million).

[70] The Commission previously approved the standards for Selling Shareholder Direct Floor Listings as supporting listing on the Exchange and the maintenance of fair and orderly markets thereby protecting investors and the public interest in accordance with Section 6(b)(5) of the Exchange Act. *See* NYSE 2018 Order, 83 FR at 5654.

[71] *See* Section 102.01B of the Manual. The Commission previously has found that this longstanding requirement is suitable for initial listing of companies on the Exchange and that the standard has supported listings of companies on the Exchange over many years. For example, in 1999 the Commission approved the existing $100 million aggregate market value standard of publicly-held shares standard that currently applies to listings other than IPOs and spin-offs. In approving this proposal, the Commission stated its belief that this threshold requirement, among others, should ''ensure that only companies of a certain minimum size are included among those listing on the Exchange, thereby protecting investors by raising the minimum standard for listed companies.'' Exchange Act Release No. 41502 (June 9, 1999), 64 FR 32588 (June 17, 1999) (SR–NYSE–99–13). The 1999 rule change also increased to $60 million the $40 million requirement that applied to IPOs and spin-offs, which is still significantly below the requirements being proposed for a Primary Direct Floor Listing. *Id.* As noted *supra* at note 69, the $60 million requirement was lowered back to $40 million in 2009. *See* Exchange Act Release No. 60501 (Aug. 13, 2009), 74 FR 42348 (Aug. 21, 2009) (SR–NYSE–2009–80).

Primary Direct Floor Listing will not proceed at a lower price.

B. Opening Auction Process for Primary Direct Floor Listings and Role of Financial Advisors

In the Order Instituting Proceedings, the Commission expressed concern that, with a Primary Direct Floor Listing, the company could be the only seller (or a dominant seller) participating in the opening auction and thus could be in a position to uniquely influence the price discovery process, and requested the Exchange to explain how its opening auction rules would apply in a Primary Direct Floor Listing.[72] In Amendment No. 2, the Exchange proposed to add the IDO Order as a new order type to be used by the issuer in a Primary Direct Floor Listing, and to clarify in its rules how the DMM would conduct the opening auction for such listings. As discussed above, the issuer would be required to submit an IDO Order in the opening auction with a limit price equal to the low end of the Primary Direct Floor Listing Auction Price Range, and for the full quantity of offered shares, as reflected in the registration statement. The IDO Order cannot be modified or canceled by the issuer once entered. Further, the DMM would conduct the opening auction only if the auction price is within the Primary Direct Floor Listing Auction Price Range disclosed in the registration statement, and the IDO Order and all better-priced sell orders can be satisfied in full. If the auction price is equal to the limit price of the IDO Order (*i.e.,* the low end of the Primary Direct Floor Listing Auction Price Range), the IDO Order would have priority over other sell orders at that price.[73]

The Commission finds that the IDO Order and related clarifications proposed by the Exchange help to clearly define the method by which the issuer participates in the opening auction, to prevent the issuer from being in a position to improperly influence the price discovery process,[74] and to design an auction that is otherwise consistent with the disclosures in the registration statement. Specifically, the issuer would be required to submit an IDO Order in the opening auction with a limit price equal to the low end of the Primary Direct Floor Listing Auction Price Range, and for the full quantity of offered shares, as reflected in the registration statement. Further, the IDO Order cannot be modified or canceled by the issuer once entered. The Commission further finds that it is appropriate for the IDO Order to have priority over other sell orders at the same price if the auction price is at the limit price of the IDO Order because the auction will not occur at all unless the IDO Order is satisfied in full. This provision therefore would allow for both the issuer's IDO Order and better-priced sell orders to be executed in the opening auction.[75] The IDO Order requirements described above mitigate concerns about the price discovery process in the opening auction and provide reasonable assurance that the opening auction and subsequent trading promote fair and orderly markets and that the proposed rules are designed to prevent manipulative acts and practices, and protect investors and the public interest in accordance with Section 6(b)(5) of the Exchange Act.

In Amendment No. 2, the Exchange added language to its proposal, discussed above, reminding a financial advisor to an issuer and the DMM that any consultations with the financial advisor must be conducted in a manner consistent with the federal securities laws, including Regulation M and other anti-manipulation requirements.[76] The Exchange also represents that it has retained FINRA to monitor such compliance and that it plans to issue regulatory guidance in this area. These steps will also help to ensure compliance by participants in the direct listing process with these important provisions of the federal securities laws and that the proposed changes are consistent with preventing manipulative acts and practices, and protecting investors and the public interest in accordance with Section 6(b)(5) of the Exchange Act.

C. Lack of Traditional Underwriter Involvement in a Primary Direct Floor Listing and Securities Act Section 11(a) Standing

1. Comments on the Proposal

Several commenters expressed concerns that the lack of traditional underwriter involvement in direct listings generally would increase risks for investors, suggesting that direct listings circumvent the traditional due diligence process and traditional underwriter liability.[77] One commenter stated that approval of the proposal would likely increase the number of companies that forgo the traditional IPO process, and significantly increase the risks for retail investors, including by circumventing the due diligence process.[78] This commenter expressed concern that direct listings could weaken certain investor protections, and recommended that the Commission make clear that financial advisors, exchanges, control shareholders, and directors involved in a direct listing automatically incur statutory underwriter liability under the Securities Act and are required to hold

[72] One commenter expressed general support for the proposal and offered a variety of observations beyond the scope of the proposal, including with respect to the importance of opening auction information. *See* ClearingBid Letter, at 1.

[73] In addition, as discussed above, the Exchange proposes that the DMM will publish a pre-opening indication in a Primary Direct Floor Listing if the auction price is expected to be outside a price range around an ''Indication Reference Price'' equal to the low end of the price range reflected in the registration statement. The Commission believes this is a reasonable and conservative reference price because the auction cannot occur at a lower price, and if the auction occurs at a higher price the proposal errs on the side of requiring opening indication information to be disseminated to market participants.

[74] *See supra* notes 72–73 and accompanying text. *See also* proposed Rule 7.31(c)(1)(D)(i)–(v) which sets forth the requirements the issuer must follow in entering the IDO Order and proposed Rule 7.35A(g)(2) which sets forth the requirements in order for the DMM to conduct the direct listing auction for a Primary Direct Floor Listing.

[75] In addition, the proposed changes to Rule 7.35C to remove the references to Direct Listing Auction would help ensure that all direct listings occur with a DMM that will facilitate the opening auction manually, and should help promote fair and orderly markets in connection with direct listings, because of the role of the DMM in ensuring that the conditions to conduct the auction, described above, have been met. The proposed changes to (i) Section 102.01B of the Manual, Footnote (E) to clarify the description of a Selling Shareholder Direct Floor Listing, (ii) Rule 1.1(f) to amend the definition of ''Direct Listing,'' and (iii) Rule 7.35A(g)(1) to use the defined term ''Private Placement Market'' will also provide clarity to the Exchange's rules, consistent with the protection of investors and the public interest under Section 6(b)(5) of the Exchange Act.

[76] *See* Notice, 85 FR at 39249, and proposed Rule 7.35A, Commentary .10. *See also supra* note 36 and accompanying text noting that the Exchange will issue a regulatory circular to remind member organizations that activities in connection with a Primary Direct Floor Listing, like activities in connection with other listings, must be conducted in a manner not inconsistent with Regulation M and other anti-manipulation provisions of the federal securities laws and NYSE Rule 2020.

[77] *See, e.g.,* Letter from Christopher A. Iacovella, Chief Executive Officer, ASA (December 12, 2019) (''ASA Letter I''), at 1.

[78] *See* ASA Letter I, at 1–2. This commenter believed that allowing companies to raise primary capital through a direct listing ''would be a complete end run around the traditional underwriting process and . . . create a massive loophole in the regulatory regime that governs the offerings of securities to the public.'' *Id.* at 1. In this commenter's view, two recent high-profile direct listings—Spotify and Slack—did not work out particularly well for retail investors, and a robust underwriting process would have uncovered more of these companies' vulnerabilities before these securities were offered to the public. *See id.* at 2. Another commenter stated that these direct listings may have been successes for private investors, but the retail and public investors that purchased stock in Spotify and Slack were under water for years, and one company is facing a lawsuit because of how direct listings are modeled. *See* Letter from Anonymous (June 30, 2020).

the regulatory capital necessary to act as a de facto underwriter.[79] On the other hand, one commenter supported direct listings as a suitable option for certain issuers, and stated that ''[d]ue diligence is already ably done by the legions of experienced accountants, lawyers, consultants, rating agencies, etc.'' [80]

Another commenter recommended that the Commission disapprove the proposal and expressed concern that shareholder legal rights under Section 11 of the Securities Act may be particularly vulnerable in the case of direct listings, and that investors in direct listings may have fewer legal protections than investors in IPOs.[81] The commenter stated that it could not support direct listings as an alternative to IPOs if public companies could limit their liability for damages caused by untrue statements of fact or material omissions of fact within registration statements associated with direct listings.[82]

The Petitioner's Petition for Review stated that the delegated order raises important policy issues that should be decided after plenary consideration by the Commission. In particular, the Petitioner expanded on its prior comments relating to claims under Section 11 of the Securities Act, stating that the proposal compounds the problems shareholders face in tracing their share purchases to a registration statement. As discussed in greater detail below, Section 11(a) of the Securities Act allows purchasers to bring claims for damages based on materially false or misleading registration statements. Courts have held that plaintiffs lack standing to pursue such claims if they cannot trace their purchased shares back to the offering covered by the false or misleading registration statement. The Petitioner stated that the proposal exacerbates concerns regarding the availability of Section 11 protections because it would ''make it possible for many more shares to be directly listed and sold without the protections offered by IPO regulations.'' [83] The Petitioner acknowledged that traceability problems may occur because of successive offerings—where first there is an offering under a registration statement and then there are unregistered offerings by company insiders after the expiration of any applicable lockup or Rule 144 holding periods.[84] The Petitioner also stated that traceability challenges may also arise in the context of simultaneous registered and unregistered sales.[85] The Petitioner also argued that the very purpose of the proposal is ''to facilitate, if not encourage, a significant increase in the number of securities that can be sold to the public without Section 11 protections'' and that it is hard to understand how that result poses no heightened risk to investors.[86] The Petitioner urged the Commission to explore a system of traceable shares before approving a direct listing regime.[87]

2. NYSE Response to Comments

In response, the Exchange stated that it does not believe that the absence of underwriters creates a gap in the regulatory regime that governs offerings of securities to the public.[88] According to the Exchange, while involvement of a traditional underwriter is often necessary to the success of an IPO or other public offering, underwriter participation in the public capital-raising process is not required by the Securities Act, and companies regularly access the public markets for capital raising and other purposes without using traditional underwriters.[89] In the Exchange's view, the due diligence process in Primary Direct Floor Listings is the responsibility of the gatekeepers who participate in the transaction, such as the company's board of directors, its senior management, and its independent accountants.[90] The Exchange further stated that a company pursuing a Primary Direct Floor Listing would go through the same process of publicly filing a registration statement as an underwritten offering, and if a company's business model exhibits weaknesses, they will be exposed to the public prior to listing.[91]

[79] *See* ASA Letter I, at 2; Letter from Christopher A. Iacovella, Chief Executive Officer, American Securities Association (Mar. 5, 2020) (''ASA Letter II''), at 2–3. Several additional commenters raised a variety of concerns with the use of a direct listing to conduct a primary offering. For example, one commenter expressed the view that ''bailing out'' private market investors with reduced offering requirements would incent companies to remain private longer, reduce transparency, and impair price discovery. *See* Letter from Anonymous (Dec. 4, 2019). Another commenter took the position that direct listings are a method for insiders to ''rip-off'' IPO investors. *See* Letter from Allan Rosenbalm (Dec. 4, 2019). Another commenter was critical of direct listings for a variety of reasons, and expressed the view, among other things, that they are ''an attempt to bypass the independent skilled investment banking and investment management professionals when establishing the initial market value of the company.'' Letter from Anonymous (Jan. 3, 2020). Another commenter stated that a primary capital raise would have many red flags, questioned how to trust a private company's accounting methods that are not consistent with the public markets, and stated that a direct listing is ''fraudulent with no liability.'' *See* Letter from Anonymous (July 1, 2020).

[80] Wedbush Letter.

[81] *See* Letter from Jeffrey P. Mahoney, General Counsel, Council of Institutional Investors (Jan. 16, 2020) (''CII Letter I''), at 2; Letter from Jeffrey P. Mahoney, General Counsel, Council of Institutional Investors (Apr. 16, 2020) (''CII Letter II''), at 2; CII Letter III, at 3–4, 6.

[82] *See* CII Letter I, at 2–3; CII Letter II, at 3; Petition for Review, at 9–10. This commenter was particularly concerned about positions taken by the issuer in a recent lawsuit relating to the direct listing of Slack, and expressed the view that the issuer ''relies on (1) attacking the right of secondary market purchasers to bring a Section 11 claim; and (2) the inability to determine what shares were 'covered' by Slack's registration statement.'' CII Letter I, at 2. *See also Pirani* v. *Slack Technologies, Inc.,* 445 F. Supp. 3d 367 (N.D. Cal. 2020).

[83] *See* Petition for Review, at 9.

[84] Although not required by federal securities laws or existing national securities exchange listing rules, a lockup period is an oft-included contractual agreement or provision negotiated with the underwriters of an initial public offering that restricts insiders and certain other pre-IPO security holders from selling, transferring, or otherwise disposing of their securities for a specified period—typically 90 to 180 days—following the initial public offering. As these provisions are not required by federal securities laws or existing national securities exchange listing rules, the specific terms of lockup agreements can and do vary between offerings. Rule 144 creates a safe harbor for the sale of restricted or control securities under the exemption in Section 4(a)(1) of the Securities Act if the seller complies with the conditions of the safe harbor, which includes a minimum holding period. *See* 17 CFR 230.144.

[85] The Petitioner stated that tracing shares to a registration statement immediately after an IPO may not be a significant concern but the situation becomes murkier when insiders are able to sell their shares in the company after the end of the lockup period. *See* Petition for Review, at 8. In discussing traceability issues, the Petitioner also stated that NYSE's proposal on Selling Shareholder Direct Floor Listings ''permitted not only the sale of shares covered by the registration statement, but also the simultaneous sale of unregistered shares held by insiders, assuming that the owner of those shares could satisfy the requirements of the Rule 144 exemption from registration.'' *See* Petition for Review, at 9.

[86] *See id.* at 14. The Petitioner stated with respect to the Slack case (see note 82, *supra*) that while the district court denied a motion to dismiss a Section 11 claim on the grounds that the plaintiff could not trace their purchase to Slack's registration statement, the court of appeals has agreed to hear the matter on an interlocutory basis so it is unclear whether the district court case will be upheld. *See Pirani* v. *Slack Technologies, Inc.,* No. 20–16419 (9th Cir. July 23, 2020), Docket No. 1. The Petitioner further argued that the Approval Order did not cite any cases where the sale of registered and unregistered shares shortly after an IPO and prior to the end of a lockup period was used as a basis to dismiss a claim of a Section 11 violation. *See* Petition for Review, at 14.

[87] *See* Petition for Review, at 12; CII Letter I, at 2–3; CII Letter III, at 4.

[88] *See* Letter from Elizabeth K. King, Chief Regulatory Officer, ICE, General Counsel & Corporate Secretary, NYSE (Mar. 16, 2020) (''NYSE Response Letter''), at 2.

[89] *See* NYSE Response Letter, at 2–3.

[90] *See* NYSE Response Letter, at 2–3. The Exchange took the position that IPOs carry a certain amount of risk for investors, that an underwritten IPO does not insulate investors from that risk, and that there is no reason to believe that companies with direct listings will perform any better or worse than companies with underwritten IPOs. *See id.* at 3.

[91] *See* NYSE Response Letter, at 4. The Exchange also took the position that the absence of lockup agreements with pre-IPO shareholders in Primary Direct Floor Listings does not create short-term

In response to the Petitioner's concern about the adequacy of investor protections under Section 11 of the Securities Act, the Exchange stated that these concerns flow from an extraneous factor—namely, lockup agreements. In particular, the Exchange contends that the Section 11 and traceability concerns are due to the potential lack of lockup agreements, which are neither prohibited nor required by the proposal or any other law or regulation, rather than to anything inherent in direct listings themselves or the Exchange rules permitting them to be listed.[92] The Exchange argued that the Petitioner assumes that because Primary Direct Floor Listings do not require underwriters, they will never involve lockup agreements, and therefore insider shareholders will sell their unregistered shares alongside the issuer's registered shares, potentially making it harder to trace purchased shares back to the registration statement.[93] Further, according to the Exchange, the traceability requirement may make it difficult for shareholders to establish standing under Section 11 in many situations that do not involve direct listings, including when a company has issued securities under more than one registration statement and distributed those securities through traditional, firm commitment underwritings.[94] The Exchange stated that in traditional, firm commitment underwritten IPOs there is no legal or regulatory requirement for the issuer to enter into lockup agreements with insiders, and conversely, there is nothing preventing an issuer in a direct listing from entering into a lockup agreement.[95]

According to the Exchange, the only courts to consider Section 11 standing in the context of a direct listing involved the Selling Shareholder Direct Floor Listing by Slack Technologies, Inc., where both a federal and a state court concluded that Section 11 did not preclude plaintiffs, at the pleading stage, from pursuing claims just because they could not definitively trace the securities they acquired to the registration statement.[96] The Exchange stated that for Petitioner's concerns to materialize, other courts in circumstances where there is no lockup agreement would need to reach the opposite conclusion.[97] Moreover, in response to the Petitioner's arguments that the Commission should delay implementation of the proposal until it addresses the traceability issue by enacting certain ''proxy plumbing'' reform measures, the Exchange stated that the Petitioner has pursued this goal for many years and the current proposal is not the proper vehicle to advance this agenda.[98]

3. Commission Discussion and Analysis

The Commission agrees with the Exchange that the Securities Act does not require the involvement of an underwriter in registered offerings.[99] Moreover, given the broad definition of ''underwriter'' [100] in the Securities Act, a financial advisor to an issuer engaged in a Primary Direct Floor Listing may, depending on the facts and circumstances including the nature and extent of the financial advisor's activities, be deemed a statutory ''underwriter'' with respect to the securities offering, with attendant underwriter liabilities.[101] Thus, the financial advisors to issuers in Primary Direct Floor Listings have incentives to engage in robust due diligence, given their reputational interests and potential liability, including as statutory underwriters under the broad definition of that term. Moreover, even absent the involvement of a statutory underwriter, investors would not be precluded from pursuing any claims they may have under the Securities Act for false or misleading offering documents, nor would the absence of a statutory underwriter affect the amount of damages investors may be entitled to recover.

In addition, issuers, officers, directors, and accountants, with their attendant liability, play important roles in assuring that disclosures provided to investors are materially accurate and complete. The Commission therefore does not view a firm commitment underwriting as necessary to provide adequate investor protection in the context of a registered offering. Indeed, exchange-listed companies often engage in offerings that do not involve a firm commitment underwriting.

The Commission finds that the proposed rule change is consistent with the protection of investors. First, the Commission disagrees with the concerns raised by commenters that direct listings would ''rip off'' investors, reduce transparency, or involve reduced offering requirements or accounting methods that are not ''up to code with the public markets.'' [102] The proposed rule change will require all Primary Direct Floor Listings to be registered under the Securities Act, and thus subject to the existing liability and disclosure framework under the Securities Act for registered offerings. Among other disclosures, these registration statements will require both bona fide price ranges [103] and audited financial statements prepared in accordance with either U.S. GAAP or International Financial Reporting Standards as issued by the International Accounting Standards Board.[104]

Second, Petitioner's concerns regarding shareholders' ability to pursue claims pursuant to Section 11 of the Securities Act due to traceability issues are not exclusive to nor necessarily inherent in Primary Direct Floor Listings. Rather, this issue is potentially implicated anytime securities that are not the subject of a recently effective

price instability, and that at most it shifts the timing of such instability from six months after the offering to closer to the time of listing. *See id. See also* NYSE Statement, at 20, stating that the same price volatility concerns that cause underwriters to request lockup agreements in a traditional IPO may apply to direct listings as well.

[92] *See* NYSE Statement, at 15.

[93] *See* NYSE Statement, at 18. The Exchange stated that tracing issues are very fact-dependent and turn on many factors so it is unclear whether Section 11 tracing difficulties will in fact occur. *See* NYSE Statement, at 17.

[94] *See* NYSE Statement, at 18–19 (citing *In re Century Aluminum Co. Sec. Litig.,* 729 F.3d 1104, 1107–08 (9th Cir 2013); *Krim* v. *pcOrder.com, Inc.,* 402 F.3d 489, 496–98 (5th Cir. 2005)).

[95] *See* NYSE Statement, at 20 (stating that in the recent Selling Shareholder Direct Floor Listing by Palantir, insider shareholders entered into lockup agreements with respect to certain shares). Further, the Exchange stated that even if lockup agreements did prove to be less common in direct listings, there is a market-based solution to this issue because shareholders will pay less for shares acquired with direct listings if they would face materially greater difficulty in pursuing Section 11 claims in connection with direct listings, and that in turn would incentivize issuers to structure their direct listings in a way that does not reduce the protections available under the federal securities laws. *See id.* at 21, n.67.

[96] *See* NYSE Statement, at 21–22 (citing *Pirani,* 445 F. Supp. 3d at 380–81; Case Management Order #5, *In re Slack Techs. Inc. S'holder Litig.,* Master File No. 19CIV005370, 2020 WL 4919555, at *3–5 (Cal. Super. Ct. Aug. 12, 2020)).

[97] *See* NYSE Statement, at 22.

[98] *See* NYSE Statement, at 22–24.

[99] *See, e.g.,* Item 508(c) of Regulation S–K (''Outline briefly the plan of distribution of any securities to be registered that are to be offered otherwise than through underwriters.'').

[100] Section 2(a)(11) of the Securities Act defines ''underwriter'' to mean ''any person who has purchased from an issuer with a view to, or offers or sells for an issuer in connection with, the distribution of any security, or participates, or has a direct or indirect participation in the direct or indirect underwriting of any such undertaking.''

[101] The Commission does not agree, as argued by one commenter, that financial advisors, exchanges, control shareholders, and directors involved in a direct listing will necessarily incur statutory underwriter liability under the Securities Act. *See* ASA Letter I, at 2; ASA Letter II, at 2–3. Whether or not any person would be considered a statutory underwriter would be evaluated based on the particular facts and circumstances, in light of the definition of underwriter contained in Section 2(a)(11).

[102] *See* note 79, *supra.*

[103] *See, e.g.,* Instruction 1 to Item 501(b)(3) of Regulation S–K.

[104] *See* Rule 4–01(a) of Regulation S–X.

registration statement trade in the same market as those that are so subject. Where a registration statement, at the time of effectiveness, contains an untrue statement of a material fact or omits to state a material fact required to be stated therein or necessary to make the statements therein not misleading, Section 11(a) of the Securities Act provides a cause of action to ''any person acquiring such security,'' unless it is proved that at the time of the acquisition the person ''knew of such untruth or omission.'' [105] Courts have interpreted this statutory provision to permit aftermarket purchasers (*i.e.,* those who acquire their securities in secondary market transactions rather than in the initial distribution from the issuer or underwriter) to recover damages under Section 11, but only if they can trace the acquired shares back to the offering covered by the false or misleading registration statement.[106] Tracing is not set forth in Section 11 and is a judicially-developed doctrine. As such, the application of this doctrine and, in particular, the pleading standards and factual proof that potential claimants must satisfy vary depending on the particular facts of the distribution and judicial district.[107]

Aftermarket purchasers following either firm commitment underwritten IPOs or direct listings may face similar difficulties in tracing their shares back to a misleading registration statement. In a number of litigated cases outside of the direct listing context, courts have denied plaintiffs standing to sue under Section 11 following registered public offerings on the basis that plaintiffs purchased their securities in secondary market transactions and could not directly trace their purchases to the allegedly defective registered offering because some portion [108] of the outstanding securities available for trading—sometimes a very small portion—were not issued pursuant to the allegedly defective registration statement. These situations arise where shares may have been issued pursuant to more than one registration statement, not all of which include material misstatements or omissions. Shares may have also entered the market prior to a potential claimant's purchase other than through the registered offering, such as through sales pursuant to Rule 144.[109] For example, the shares might have been sold by insiders or significant shareholders following the expiration of lockup agreements or applicable restricted periods, or could have also been sold by other shareholders who were never subject to any such agreement.[110] Furthermore, traceability concerns can arise when shares are held in fungible bulk—as they usually are—such that an investor is not able to establish that the particular shares it purchased were acquired pursuant to, or are traceable to, a particular misleading registration statement.[111]

Although it is possible that aftermarket purchases following a Primary Direct Floor Listing may present tracing challenges, this investor protection concern is not unique to Primary Direct Floor Listings, nor (based on the approaches taken by courts as described above) do we expect any such tracing challenges in this context to be of such magnitude as to render the proposal inconsistent with the Act. We expect judicial precedent on traceability in the direct listing context to continue to evolve,[112] but the Commission is not aware of, nor have commenters pointed to, any precedent to date in the direct listing context which prohibits plaintiffs from pursuing Section 11 claims.

The Commission further believes that Primary Direct Floor Listings will provide benefits to existing and potential investors relative to firm commitment underwritten offerings. First, because the securities to be issued by the company in connection with a Primary Direct Floor Listing would be allocated based on matching buy and sell orders, in accordance with the proposed rules, some investors may be able to purchase securities in a Primary Direct Floor Listing who might not otherwise receive an initial allocation in a firm commitment underwritten offering. The proposed rule change therefore has the potential to broaden the scope of investors that are able to purchase securities in an initial public offering, at the initial public offering price, rather than in aftermarket trading.

Second, because the price of securities issued by the company in a Primary Direct Floor Listing will be determined based on market interest and the matching of buy and sell orders, Primary Direct Floor Listings will provide an alternative way to price securities offerings that may better reflect prices in the aftermarket, and thus may allow for efficiencies in IPO pricing and allocation.[113] In a firm commitment underwritten offering, the offering price is informed by underwriter engagement with potential investors to gauge interest in the offering, but ultimately decided through negotiations between the issuer and the underwriters for the offering. The underwriters then sell the securities to the initial purchasers at the public offering price. When the securities begin trading on the listing exchange, however, the price often varies from the IPO price. The opening auction in a Primary Direct Floor Listing provides

[105] Section 11(a) of the Securities Act.

[106] *See, e.g., In re Century Aluminum Co. Sec. Litig.,* 729 F.3d 1104 (9th Cir. 2013).

[107] *See, e.g., Pirani* v. *Slack Techs., Inc.,* 2020 U.S. Dist. LEXIS 70177 (N.D. Cal., April 21, 2020) (addressing Securities Act Section 11 standing and stating that ''[i]f the text is ambiguous, the Court 'may [also] use canons of construction, legislative history, and the statute's overall purpose to illuminate Congress's intent.' '' (quoting *Pac. Coast Fed'n of Fishermen's Ass'ns* v. *Glaser,* 945 F.3d 1076 (9th Cir. 2019)).

[108] *See, e.g., Barnes* v. *Osofsky,* 373 F.2d 269 (2d Cir. 1967); *Krim* v. *PCOrder.com,* 402 F.3d 489 (5th Cir. 2005) (IPO stock represented 91% of shares trading in market); *In re Century Aluminum Co. Sec. Litig.,* 729 F.3d 1104 (9th Cir. 2013) (49 million shares were already trading in market prior to the issuance of 24.5 million shares pursuant to allegedly misleading registration statement).

[109] Rule 144 is a non-exclusive safe harbor that permits the resale of restricted securities, without Securities Act registration, if a number of conditions are met, including a holding period of either six months or one year, depending on the reporting status of the issuer. Non-affiliates of a newly-listed issuer may rely on Rule 144 to sell their securities provided they have held the securities for at least one year.

[110] While lockup agreements are customary in firm commitment initial public offerings, in the Commission's experience they often do not cover all of the outstanding shares. There is thus a risk that, even in the context of IPOs underwritten on a firm commitment basis, securities other than those issued pursuant to the related registration statement may enter the trading market prior to the expiration of any applicable lockup period and thus could raise questions regarding traceability of shares purchased on a national securities exchange. Additionally, as the Exchange noted, companies that pursue a direct listing may also enter into lockup agreements. Required disclosure in registration statements, for both direct listings and IPOs, may help investors assess the risk that shares other than those offered pursuant to the registration statement will be available for sale. For example, in registration statements for IPOs and direct listings, issuers are required to provide disclosure of the amount of shares that may be sold pursuant to Rule 144. *See* Item 201(a)(2) of Regulation S–K. Issuers also typically provide disclosure of the material terms of lockup agreements governing pre-IPO shares.

[111] *See, e.g., Krim* v. *PCOrder.com,* 402 F.3d 489 (5th Cir. 2005).

[112] For example, the Ninth Circuit Court of Appeals has agreed to consider the issue of Section 11 standing at issue in *Pirani* v. *Slack Techs., Inc.,* 2020 U.S. Dist. LEXIS 70177 (N.D. Cal., April 21, 2020) on an interlocutory basis. *See Pirani* v. *Slack Technologies, Inc.,* No. 20–16419 (9th Cir., July 23, 2020), Docket No. 1.

[113] A frequent academic observation of traditional firm commitment underwritten offerings is that the IPO price, established through negotiation between the underwriters and the issuer, is often lower than the price that the issuer could have obtained for the securities, based on a comparison of the IPO price to the closing price on the first day of trading. *See, e.g.,* Patrick M. Corrigan, Article: The Seller's Curse and the Underwriter's Pricing Pivot: A Behavioral Theory of IPO Pricing, 13 Va. L. & Bus. Rev 335; Jay R. Ritter, Initial Public Offerings: Underpricing tbl.1a (June 17, 2020), *https://site.warrington.ufl.edu/ritter/files/IPOs2019_Underpricing.pdf.*

for a different price discovery method for IPOs which may reduce the spread between the IPO price and subsequent market trades, a potential benefit to existing and potential investors. In this way, the proposed rule change may result in additional investment opportunities while providing companies more options for becoming publicly traded.[114]

The Commission finds that the Exchange's proposal will facilitate the orderly distribution and trading of shares, as well as foster competition, which is clearly consistent with the purposes of the Exchange Act. The orderly distribution of, and trading of shares, promotes fair and orderly markets, and is one of the important roles of a national securities exchange in ensuring that its rules prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade and protect investors and the public interest.[115] The proposal also fosters competition by providing an alternate method for companies of sufficient size that decide they would rather not conduct a firm commitment underwritten offering to list on the Exchange, thereby removing potential impediments to free and open markets consistent with Section 6(b)(5) of the Exchange Act while also supporting capital formation. For the reasons discussed above, the Commission finds that, on balance, the proposed rule change to permit Primary Direct Floor Listings is designed to, among other things, prevent fraudulent and manipulative acts and practices and to protect investors and the public interest.

IV. Conclusion

For foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment No. 2, is consistent with the Exchange Act and the rules and regulations thereunder applicable to a national securities exchange.

It is therefore ordered, pursuant to Rule 431 of the Commission's Rules of Practice, that the earlier action taken by delegated authority, Exchange Act Release No. 89684 (August 26, 2020), 85 FR 54454 (September 1, 2020), is set aside and, pursuant to Section 19(b)(2) of the Exchange Act, the proposed rule change (SR–NYSE–2019–67), as modified by Amendment No. 2, hereby is approved.

By the Commission.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2020–28709 Filed 12–28–20; 8:45 am]

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[114] While the Commission acknowledges the possibility that some companies may pursue a Primary Direct Floor Listing instead of a traditional IPO, these two listing methods may not be substitutable in a wide variety of instances. For example, some issuers may require the assistance of underwriters to develop a broad investor base sufficient to support a liquid trading market; others may believe a traditional firm commitment IPO is preferable given the benefits to brand recognition that can result from roadshows and other marketing efforts that often accompany such offerings. Thus, we do not anticipate that all companies that are eligible to go public through a Primary Direct Floor Listing will choose to do so; the method chosen will depend on each issuer's unique characteristics.

[115] *See* 15 U.S.C. 78f(b)(5). *See also* 15 U.S.C. 78k–1(a)(1)(C)(i).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90756; File No. SR–ISE–2020–42]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Harmonize Exchange Rule General 3, Section 2 With Recent Changes by the Financial Industry Regulatory Authority, Inc.

December 21, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 11, 2020, Nasdaq ISE, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and II below, which Items have been prepared substantially 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 proposes to harmonize Exchange Rule General 3, Section 2 with recent changes by the Financial Industry Regulatory Authority, Inc. (''FINRA''). This amendment would temporarily grant the Exchange Review Council (''ERC'') authority[3] to conduct hearings in connection with appeals of Membership Application Program decisions by video conference, if warranted by the current COVID–19-related public health risks posed by an in-person hearing. As proposed, the temporary amendment would be in effect through April 30, 2021.[4]

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/ise/rules,* at the principal office of the Exchange, 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 proposes to harmonize Exchange Rule General 3, Section 2 with recent changes to FINRA Rule 1015 in order to temporarily grant the ERC authority to conduct hearings in connection with appeals of Membership Application Program decisions by video conference, if warranted by the current COVID–19-related public health risks posed by an in-person hearing.[5] As proposed, these temporary amendments would be in effect through April 30, 2021.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] For ERC hearings under Exchange Rule General 3, Section 2(g), this temporary authority is granted to the ERC or relevant Subcommittee.

[4] If the Exchange requires temporary relief from the rule requirements identified in this proposal beyond April 30, 2021, the Exchange may submit a separate rule filing to extend the expiration date of the temporary amendments under these rules. The amended Exchange rules will revert back to their original state at the conclusion of the temporary relief period and any extension thereof.

[5] *See* Exchange Act Release No. 89737 (September 2, 2020), 85 FR 55712 (September 9, 2020) (SR–FINRA–2020–027) (''FINRA Filing''). *See also* Exchange Act Release No. 90619 (December 9, 2020), 85 FR 81250 (December 15, 2020) (SR–FINRA–2020–042) (extending the relief in the FINRA Filing through April 30, 2021). The Exchange notes that the FINRA Filing also proposed to temporarily amend FINRA Rules 9261, 9524, and 9830, which govern hearings in connection with appeals of disciplinary actions, eligibility proceedings, and temporary and permanent cease and desist orders. The Exchange's Rules 9261, 9524, and 9830 incorporate by reference The Nasdaq Stock Market LLC rules, which are the subject of a separate filing. *See* SR–NASDAQ–2020–076 (November 5, 2020). Therefore, the Exchange is not proposing to adopt that aspect of the FINRA Filing.

Background

The Exchange's rule regarding the hearing and evidentiary process for appeals of Membership Application Program decisions as set forth in Rule General 3, Section 2(g) is based on FINRA's Rule 1015. As adopted, the text of Exchange Rule General 3, Section 2(g) is substantially the same as FINRA Rule 1015, with the exception of conforming and technical differences.

In view of the ongoing spread of COVID–19 and its effect on FINRA's adjudicatory functions nationwide, FINRA recently filed a temporary rule change to grant the National Adjudicatory Council (''NAC'') the authority to conduct certain hearings by video conference, if warranted by the current COVID–19-related public health risks posed by in-person hearings.[6] Accordingly, the Exchange proposes to file this temporary rule change to align with the temporary rule change filed by FINRA.

Mirroring FINRA's NAC, the ERC is the Exchange's appellate body, which reviews initial decisions issued by FINRA's Office of Hearing Officers (''OHO'') and—through Subcommittees—holds evidentiary hearings for Membership Application Program decision appeals and eligibility proceedings under Exchange Rule General 3, Section 2(g). This temporary proposed rule change will allow the ERC or relevant Subcommittee to make an assessment as to whether an in-person hearing would compromise the health and safety of the hearing participants such that the hearing should proceed by video conference.

Proposed Rule Change

Consistent with FINRA's temporary amendment to FINRA Rule 1015, the Exchange proposes to temporarily grant the ERC authority to conduct hearings in connection with appeals of Membership Application Program decisions by video conference, if warranted by the current COVID–19-related public health risks posed by an in-person hearing. The proposed change will permit the ERC to make an assessment, based on critical COVID–19 data and criteria, as to whether an in-person hearing would compromise the health and safety of the hearing participants such that the hearing should proceed by video conference. The Exchange believes that this is a reasonable procedure to follow in hearings under Rule General 3, Section 2(g).

To effectuate these changes, the Exchange proposes to add the following sentence to General 3, Section 2(g)(6):

> Upon consideration of the current public health risks presented by an in-person hearing, the Exchange Review Council or Subcommittee may, on a temporary basis, determine that the hearing shall be conducted, in whole or in part, by video conference.

The proposed text is substantially the same as the language adopted by FINRA, excepting conforming and technical differences.[7]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Section 6(b)(5) of the Act,[9] in particular, 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, by providing greater harmonization between the Exchange rules and FINRA rules of similar purpose, resulting in less burdensome and more efficient regulatory compliance.

As previously noted, the text of Exchange Rule General 3, Section 2(g) is substantially the same as FINRA's rule. As such, the proposed rule change will foster cooperation and coordination with persons engaged in facilitating transactions in securities and will remove impediments to and perfect the mechanism of a free and open market and a national market system.

The Exchange believes that the proposed temporary rule change will permit the Exchange to effectively conduct hearings during the COVID–19 pandemic in situations where in-person hearings present likely public health risks. The ability to conduct hearings by video conference will thereby permit the Exchange's adjudicatory functions to continue unabated, thereby avoiding protracted delays. Conducting hearings via video conference will give the parties and adjudicators simultaneous visual and oral communication without the risks inherent in physical proximity during a pandemic.

The Exchange believes that the temporary proposed rule change strikes an appropriate balance between providing fair process and enabling the Exchange to fulfill its statutory obligations to protect investors and maintain fair and orderly markets while accounting for the significant health and safety risks of in-person hearings stemming from the outbreak of COVID–19.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the temporary proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but is rather intended solely to provide temporary relief given the impacts of the COVID–19 pandemic. In its filing, FINRA provides an abbreviated economic impact assessment maintaining that the changes are necessary to temporarily rebalance the attendant benefits and costs of the obligations under FINRA Rule 1015 in response to the impacts of the COVID–19 pandemic that is equally applicable to the changes the Exchange proposes.[10] The Exchange accordingly incorporates FINRA's abbreviated economic impact assessment by reference.

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

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[11] and subparagraph (f)(6) of Rule 19b–4 thereunder.[12]

The Exchange believes that this filing is non-controversial and eligible to become effective immediately because the proposal promotes uniformity in rules across self-regulatory organizations thereby enabling the Exchange to conduct hearings during

[6] *See* FINRA Filing, 85 FR at 55712.

[7] *See id.* at 55712.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] *See* FINRA Filing, 85 FR at 55716.

[11] 15 U.S.C. 78s(b)(3)(A).

[12] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

the COVID–19 pandemic by video conference where the health risks of in-person hearings are significant. The proposed rule change is based on, and similar to, recent changes made to FINRA Rule 1015 that addressed the issue of balancing public health risks with conducting hearings during the COVID–19 pandemic. The Exchange proposes to adopt the rule change in substantially the same form as it was adopted by FINRA. The Exchange further believes that the proposed rule change would not significantly affect the protection of investors or the public interest or impose any significant burden on competition because the changes are based on the rules of FINRA. Moreover, the proposed rule change is not intended to address competitive issues but rather is concerned solely with providing temporary relief given the impacts of the COVID–19 pandemic.

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–ISE–2020–42 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–ISE–2020–42. 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, on business days between the hours of 10:00 a.m. and 3:00 p.m., located at 100 F Street NE, Washington, DC 20549. 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–ISE–2020–42 and should be submitted on or before January 19, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28682 Filed 12–28–20; 8:45 am]

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[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90755; File No. SR–GEMX–2020–21]

Self-Regulatory Organizations; Nasdaq GEMX, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Harmonize Exchange Rule General 3, Section 2 With Recent Changes by the Financial Industry Regulatory Authority, Inc.

December 21, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 11, 2020, Nasdaq GEMX, LLC (''GEMX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared substantially by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to harmonize Exchange Rule General 3, Section 2 with recent changes by the Financial Industry Regulatory Authority, Inc. (''FINRA''). This amendment would temporarily grant the Exchange Review Council (''ERC'') authority[3] to conduct hearings in connection with appeals of Membership Application Program decisions by video conference, if warranted by the current COVID–19-related public health risks posed by an in-person hearing. As proposed, the temporary amendment would be in effect through April 30, 2021.[4]

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/gemx/rules,* at the principal office of the Exchange, 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 proposes to harmonize Exchange Rule General 3, Section 2 with recent changes to FINRA Rule 1015 in order to temporarily grant the ERC authority to conduct hearings in connection with appeals of Membership

[3] For ERC hearings under Exchange Rule General 3, Section 2(g), this temporary authority is granted to the ERC or relevant Subcommittee.

[4] If the Exchange requires temporary relief from the rule requirements identified in this proposal beyond April 30, 2021, the Exchange may submit a separate rule filing to extend the expiration date of the temporary amendments under these rules. The amended Exchange rules will revert back to their original state at the conclusion of the temporary relief period and any extension thereof.

Application Program decisions by video conference, if warranted by the current COVID–19-related public health risks posed by an in-person hearing.[5] As proposed, these temporary amendments would be in effect through April 30, 2021.

Background

The Exchange's rule regarding the hearing and evidentiary process for appeals of Membership Application Program decisions as set forth in Rule General 3, Section 2(g) is based on FINRA's Rule 1015. As adopted, the text of Exchange Rule General 3, Section 2(g) is substantially the same as FINRA Rule 1015, with the exception of conforming and technical differences.

In view of the ongoing spread of COVID–19 and its effect on FINRA's adjudicatory functions nationwide, FINRA recently filed a temporary rule change to grant the National Adjudicatory Council (''NAC'') the authority to conduct certain hearings by video conference, if warranted by the current COVID–19-related public health risks posed by in-person hearings.[6] Accordingly, the Exchange proposes to file this temporary rule change to align with the temporary rule change filed by FINRA.

Mirroring FINRA's NAC, the ERC is the Exchange's appellate body, which reviews initial decisions issued by FINRA's Office of Hearing Officers (''OHO'') and—through Subcommittees—holds evidentiary hearings for Membership Application Program decision appeals and eligibility proceedings under Exchange Rule General 3, Section 2(g). This temporary proposed rule change will allow the ERC or relevant Subcommittee to make an assessment as to whether an in-person hearing would compromise the health and safety of the hearing participants such that the hearing should proceed by video conference.

Proposed Rule Change

Consistent with FINRA's temporary amendment to FINRA Rule 1015, the Exchange proposes to temporarily grant the ERC authority to conduct hearings in connection with appeals of Membership Application Program decisions by video conference, if warranted by the current COVID–19-related public health risks posed by an in-person hearing. The proposed change will permit the ERC to make an assessment, based on critical COVID–19 data and criteria, as to whether an in-person hearing would compromise the health and safety of the hearing participants such that the hearing should proceed by video conference. The Exchange believes that this is a reasonable procedure to follow in hearings under Rule General 3, Section 2(g).

To effectuate these changes, the Exchange proposes to add the following sentence to General 3, Section 2(g)(6):

> Upon consideration of the current public health risks presented by an in-person hearing, the Exchange Review Council or Subcommittee may, on a temporary basis, determine that the hearing shall be conducted, in whole or in part, by video conference.

The proposed text is substantially the same as the language adopted by FINRA, excepting conforming and technical differences.[7]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Section 6(b)(5) of the Act,[9] in particular, 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, by providing greater harmonization between the Exchange rules and FINRA rules of similar purpose, resulting in less burdensome and more efficient regulatory compliance.

As previously noted, the text of Exchange Rule General 3, Section 2(g) is substantially the same as FINRA's rule. As such, the proposed rule change will foster cooperation and coordination with persons engaged in facilitating transactions in securities and will remove impediments to and perfect the mechanism of a free and open market and a national market system.

The Exchange believes that the proposed temporary rule change will permit the Exchange to effectively conduct hearings during the COVID–19 pandemic in situations where in-person hearings present likely public health risks. The ability to conduct hearings by video conference will thereby permit the Exchange's adjudicatory functions to continue unabated, thereby avoiding protracted delays. Conducting hearings via video conference will give the parties and adjudicators simultaneous visual and oral communication without the risks inherent in physical proximity during a pandemic.

The Exchange believes that the temporary proposed rule change strikes an appropriate balance between providing fair process and enabling the Exchange to fulfill its statutory obligations to protect investors and maintain fair and orderly markets while accounting for the significant health and safety risks of in-person hearings stemming from the outbreak of COVID–19.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the temporary proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but is rather intended solely to provide temporary relief given the impacts of the COVID–19 pandemic. In its filing, FINRA provides an abbreviated economic impact assessment maintaining that the changes are necessary to temporarily rebalance the attendant benefits and costs of the obligations under FINRA Rule 1015 in response to the impacts of the COVID–19 pandemic that is equally applicable to the changes the Exchange proposes.[10] The Exchange accordingly incorporates FINRA's abbreviated economic impact assessment by reference.

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

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant

[5] *See* Exchange Act Release No. 89737 (September 2, 2020), 85 FR 55712 (September 9, 2020) (SR–FINRA–2020–027) (''FINRA Filing''). *See also* Exchange Act Release No. 90619 (December 9, 2020), 85 FR 81250 (December 15, 2020) (SR–FINRA–2020–042) (extending the relief in the FINRA Filing through April 30, 2021). The Exchange notes that the FINRA Filing also proposed to temporarily amend FINRA Rules 9261, 9524, and 9830, which govern hearings in connection with appeals of disciplinary actions, eligibility proceedings, and temporary and permanent cease and desist orders. The Exchange's Rules 9261, 9524, and 9830 incorporate by reference The Nasdaq Stock Market LLC rules, which are the subject of a separate filing. *See* SR–NASDAQ–2020–076 (November 5, 2020). Therefore, the Exchange is not proposing to adopt that aspect of the FINRA Filing.

[6] *See* FINRA Filing, 85 FR at 55712.

[7] *See id.* at 55712.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] FINRA Filing, 85 FR at 55716.

burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [11] and subparagraph (f)(6) of Rule 19b–4 thereunder.[12]

The Exchange believes that this filing is non-controversial and eligible to become effective immediately because the proposal promotes uniformity in rules across self-regulatory organizations thereby enabling the Exchange to conduct hearings during the COVID–19 pandemic by video conference where the health risks of in-person hearings are significant. The proposed rule change is based on, and similar to, recent changes made to FINRA Rule 1015 that addressed the issue of balancing public health risks with conducting hearings during the COVID–19 pandemic. The Exchange proposes to adopt the rule change in substantially the same form as it was adopted by FINRA. The Exchange further believes that the proposed rule change would not significantly affect the protection of investors or the public interest or impose any significant burden on competition because the changes are based on the rules of FINRA. Moreover, the proposed rule change is not intended to address competitive issues but rather is concerned solely with providing temporary relief given the impacts of the COVID–19 pandemic.

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.

[11] 15 U.S.C. 78s(b)(3)(A)(iii).

[12] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

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–GEMX–2020–21 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–GEMX–2020–21. 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–GEMX–2020–21 and should be submitted on or before January 19, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28668 Filed 12–28–20; 8:45 am]

BILLING CODE 8011–01–P

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90754; File No. SR–NYSEAMER–2020–85]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Effective Date in Commentary .10 Under NYSE American Rule 2.1210

December 21, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 15, 2020, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II 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 proposes a rule change to extend the effective date in Commentary .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE American Rule 2.1210 (Registration Requirements) applicable to member organizations, Equity Trading Permit (''ETP'') Holders and American Trading Permit (''ATP'') Holders, from December 31, 2020 to April 30, 2021. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, 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 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend the effective date in Commentary .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE American Rule 2.1210 (Registration Requirements) applicable to member organizations, ETP Holders and ATP Holders (collectively, ''Members'') [3] from December 31, 2020 to April 30, 2021. The proposed rule change would extend the 120-day period that certain individuals can function as a principal without having successfully passed an appropriate qualification examination through April 30, 2021,[4] and would apply only to those individuals who were designated to function as a principal prior to January 1, 2021. This proposed rule change is based on a filing recently submitted by the Financial Regulatory Authority, Inc. (''FINRA'') [5] and is intended to harmonize the Exchange's registration rules with those of FINRA so as to promote uniform standards across the securities industry.

The COVID–19 pandemic is an unpredictable, exogenous event that has resulted in unavoidable disruptions to the securities industry and impacted member firms, regulators, investors and other stakeholders. In response to COVID–19, earlier this year FINRA began providing temporary relief by way of frequently asked questions (''FAQs'') [6] to address disruptions to the administration of FINRA qualification examinations caused by the pandemic that have significantly limited the ability of individuals to sit for examinations due to Prometric test center capacity issues.[7]

FINRA published the first FAQ on March 20, 2020, providing that individuals who were designated to function as principals under FINRA Rule 1210.04 [8] prior to February 2, 2020, would be given until May 31, 2020, to pass the appropriate principal qualification examination.[9] On May 19, 2020, FINRA extended the relief to pass the appropriate examination until June 30, 2020. On June 29, 2020, FINRA again extended the temporary relief providing that individuals who were designated to function as principals under FINRA Rule 1210.04 prior to May 4, 2020, would be given until August 31, 2020, to pass the appropriate principal qualification examination.

On September 25, 2020, NYSE American filed with the Commission a proposed rule change for immediate effectiveness to extend the temporary relief provided via the FAQ by adopting temporary Commentary .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE American Rule 2.1210 (Registration Requirements).[10] Pursuant to this rule filing, individuals who were designated prior to September 3, 2020, to function as a principal under NYSE American Rule 2.1210.10 have until December 31, 2020, to pass the appropriate qualification examination.

The COVID–19 conditions necessitating the extension of relief provided in the FAQ and SR–NYSEAMER–2020–71 persist and in fact appear to be worsening.[11] One of the impacts of COVID–19 continues to be serious interruptions in the administration of FINRA qualification examinations at Prometric test centers and the limited ability of individuals to sit for the examinations.[12] Although Prometric has been reopening its test centers, Prometric's safety practices mean that currently not all test centers are open, some of the open test centers are at limited capacity, and some open test centers are delivering only certain examinations that have been deemed essential by the local government.[13] Furthermore, Prometric has had to close some reopened test centers due to incidents of COVID–19 cases. The initial nationwide closure in March along with the inability to fully reopen all Prometric test centers due to COVID–19 have led to a significant backlog of individuals who are waiting to sit for FINRA examinations that are not available online, including the General Securities Principal Exam (Series 24).[14]

In addition, firms are continuing to experience operational challenges with

[3] The term ''member organization'' is defined in Rule 24 (Office Rules) as ''a partnership, corporation or such other entity as the Exchange may, by Rule, permit to become a member organization, and which meets the qualifications specified in the Rules.'' The term ''member organization'' is defined in Rule 2(b)(i) (Equities Rules) as a registered broker or dealer (unless exempt pursuant to the Exchange Act that is a member of the Financial Industry Regulatory Authority, Inc. (''FINRA'') or another registered securities exchange. Member organizations that transact business with public customers or conduct business on the Floor of the Exchange shall at all times be members of FINRA. A registered broker or dealer must also be approved by the Exchange and authorized to designate an associated natural person to effect transactions on the floor of the Exchange or any facility thereof. This term shall include a natural person so registered, approved and licensed who directly effects transactions on the floor of the Exchange or any facility thereof.'' The term ''member organization'' also includes any registered broker or dealer that is a member of FINRA or a registered securities exchange, consistent with the requirements of section 2(b)(i) of this Rule, which does not own a trading license and agrees to be regulated by the Exchange as a member organization and which the Exchange has agreed to regulate.'' *See* Rule 2(a)(ii) (Equities Rules). The term ''ETP Holder'' means a member organization that has been issued an ETP. An ETP Holder will agree to be bound by the Rules of the Exchange, and by all applicable rules and regulations of the Securities and Exchange Commission. *See* Rule 1.1E(n). References to ''member organization'' as used in Exchange rules include ATP Holders, which are registered brokers or dealers approved to effect transactions on the Exchange's options marketplace. Under the Exchange's rules, an ATP Holder has the status as a ''member'' of the Exchange as that term is defined in Section 3 of the Act. *See* Rule 900.2NY(4) & (5).

[4] If NYSE American seeks to provide additional temporary relief from the rule requirements identified in this proposed rule change beyond April 30, 2021, NYSE American will submit a separate rule filing to further extend the temporary extension of time.

[5] *See* Exchange Act Release No. 90617 (December 9, 2020), 85 FR 81258 (December 15, 2020) (SR–FINRA–2020–043) (the ''FINRA Filing''). The Exchange notes that the FINRA Filing also provides temporary relief to individuals registered with FINRA as Operations Professionals under FINRA Rule 1220. The Exchange does not have a registration category for Operations Professionals and therefore, the Exchange is not proposing to adopt that aspect of the FINRA Filing.

[6] *See https://www.finra.org/rules-guidance/key-topics/covid-19/faq#qe.*

[7] At the outset of the COVID–19 pandemic, all FINRA qualification examinations were administered at test centers operated by Prometric. Based on the health and welfare concerns resulting from COVID–19, in March Prometric closed all of its test centers in the United States and Canada and began to slowly reopen some of them at limited capacity in May. Currently, Prometric has resumed testing in many of its United States and Canada test centers, at either full or limited occupancy, based on local and government mandates.

[8] NYSE American Rule 2.1210.03 is the corresponding rule to FINRA Rule 1210.04.

[9] FINRA Rule 1210.04 (Requirements for Registered Persons Functioning as Principals for a Limited Period) allows a member firm to designate certain individuals to function in a principal capacity for 120 calendar days before having to pass an appropriate principal qualification examination. NYSE American Rule 2.1210.03 provides the same allowance to Members.

[10] *See* Exchange Act Release No. 90115 (October 7, 2020), 85 FR 64595 (October 13, 2020) (Notice of Filing and Immediate Effectiveness of SR–NYSEAMER–2020–71).

[11] *See, e.g.,* Meryl Kornfield, Jacqueline Dupree, Marisa Iati, Paulina Villegas, Siobhan O'Grady and Hamza Shaban, New daily coronavirus cases in U.S. rise to 145,000, latest all-time high, Wash. Post, November 11, 2020, *https://www.washingtonpost.com/nation/2020/11/11/coronavirus-covid-live-updates-us/.*

[12] Information about the continued impact of COVID–19 on FINRA-administered examinations is available at *https://www.finra.org/rules-guidance/key-topics/covid-19/exams.*

[13] Information from Prometric about its safety practices and the impact of COVID–19 on its operations is available at *https://www.prometric.com/corona-virus-update. See also supra* note 12.

[14] Earlier this year, an online test delivery service was launched for candidates seeking to take qualification examination remotely. Only certain qualification examinations are available online. *See supra* note 12. FINRA is considering making additional qualification examinations available remotely on a limited basis.

much of their personnel working from home due to shelter-in-place orders, restrictions on businesses and social activity imposed in various states, and adherence to other social distancing guidelines consistent with the recommendations of public health officials.[15] As a result, firms continue to face potentially significant disruptions to their normal business operations that may include a limitation of in-person activities and staff absenteeism as a result of the health and welfare concerns stemming from COVID–19. Such potential disruptions may be further exacerbated and may even affect client services if firms cannot continue to keep principal positions filled as they may have difficulty finding other qualified individuals to transition into these roles or may need to reallocate employee time and resources away from other critical responsibilities at the firm.

These ongoing, extenuating circumstances make it impracticable for Members to ensure that the individuals whom they have designated to function in a principal capacity, as set forth in NYSE American Rule 2.1210.03, are able to successfully sit for and pass an appropriate qualification examination within the 120-calendar day period required under the rule, or to find other qualified staff to fill this position. The ongoing circumstances also require individuals to be exposed to the health risks associated with taking an in-person examination, because the General Securities Principal examination is not available online. Therefore, NYSE American is proposing to extend the effective date of the temporary relief provided through SR–NYSEAMER–2020–71 until April 30, 2021. The proposed rule change would apply only to those individuals who were designated to function as a principal prior to January 1, 2021. Any individuals designated to function as a principal on or after January 1, 2021, would need to successfully pass an appropriate qualification examination within 120 days.

NYSE American believes that this proposed continued extension of time is tailored to address the needs and constraints on a Member's operations during the COVID–19 pandemic, without significantly compromising critical investor protection. The proposed extension of time will help to minimize the impact of COVID–19 on Members by providing continued flexibility so that Members can ensure that principal positions remain filled. The potential risks from the proposed extension of the 120-day period are mitigated by the Member's continued requirement to supervise the activities of these designated individuals and ensure compliance with federal securities laws and regulations, as well as NYSE American rules.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[16] in general, and furthers the objectives of Section 6(b)(5),[17] 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 proposed rule change is intended to minimize the impact of COVID–19 on Member operations by extending the 120-day period certain individuals may function as a principal without having successfully passed an appropriate qualification examination under NYSE American Rule 2.1210.03 until April 30, 2021. The proposed rule change does not relieve Members from maintaining, under the circumstances, a reasonably designed system to supervise the activities of their associated persons to achieve compliance with applicable securities laws and regulations, and with applicable NYSE American rules that directly serve investor protection. In a time when faced with unique challenges resulting from the COVID–19 pandemic, NYSE American believes that the proposed rule change is a sensible accommodation that will continue to afford Members the ability to ensure that critical positions are filled and client services maintained, while continuing to serve and promote the protection of investors and the public interest in this unique environment.

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. As set forth in SR–NYSEAMER–2020–71, the proposed rule change is intended solely to extend temporary relief necessitated by the continued impacts of the COVID–19 pandemic and the related health and safety risks of conducting in-person activities. In its filing, FINRA notes that the proposed rule change is necessary to temporarily rebalance the attendant benefits and costs of the obligations under FINRA Rule 1210 in response to the impacts of the COVID–19 pandemic that would otherwise result if the temporary amendments were to expire on December 31, 2020.[18] The Exchange accordingly incorporates FINRA's abbreviated economic impact assessment by reference.

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. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [19] and Rule 19b–4(f)(6) thereunder.[20]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii), the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately upon filing. As noted above, the Exchange stated that the proposed extension of time will help minimize the impact of the COVID–19 outbreak on Members' operations by allowing them to keep principal positions filled and minimizing disruptions to client services and other critical responsibilities. The Exchange further stated that the ongoing

[15] *See, e.g.,* Centers for Disease Control and Prevention, How to Protect Yourself & Others, *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html.*

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

[18] *See* FINRA Filing, 85 FR at 81260.

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

extenuating circumstances of the COVID–19 pandemic make it impractical to ensure that individuals designated to act in these capacities are able to take and pass the appropriate qualification examination during the 120-calendar day period required under the rules. The Exchange also explained that shelter-in-place orders, quarantining, restrictions on business and social activity and adherence to social distancing guidelines consistent with the recommendations of public officials remain in place in various states.[21] In addition, the Exchange observed that, following a nationwide closure of all test centers earlier in the year, some test centers have re-opened, but are operating at limited capacity or are only delivering certain examinations that have been deemed essential by the local government.[22] Although, as the Exchange noted, FINRA has launched an online test delivery service to help address this backlog, the General Securities Principal (Series 24) Examination is not available online.[23] Nevertheless, the Exchange explained that the proposed rule change will provide needed flexibility to ensure that these positions remain filled and is tailored to address the constraints on Members' operations during the COVID–19 pandemic without significantly compromising critical investor protection.[24]

The Commission observes that the Exchange's proposal, like the FINRA Filing, provides only an extension to temporary relief from the requirement to pass certain qualification examinations within the 120-day period in the rules. As proposed, this relief would extend the 120-day period that certain individuals can function as principals through April 30, 2021. If a further extension of temporary relief from the rule requirements identified in this proposal beyond April 30, 2021 is required, the Exchange noted that it may submit a separate rule filing to extend the effectiveness of the temporary relief under these rules.[25] For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest.[26] Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[27]

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–NYSEAMER–2020–85 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–2020–85. 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–NYSEAMER–2020–85 and should be submitted on or before January 19, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

J. Matthew DeLesDernier,

Assistant Secretary.

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[21] *See supra* note 15.

[22] *See supra* notes 12 and 13. The Exchange states that Prometric has also had to close some reopened test centers due to incidents of COVID–19 cases.

[23] *See supra* note 14. FINRA is considering making additional qualification examinations available remotely on a limited basis.

[24] The Exchange states that Members remain subject to the continued requirement to supervise the activities of these designated individuals and ensure compliance with federal securities laws and regulations, as well as NYSE American rules.

[25] *See supra* note 4.

[26] As noted above by NYSE American, this proposal is an extension of temporary relief provided in a prior filing where NYSE American also requested and the Commission granted a waiver of the 30-day operative delay. *See supra* note 10, 85 FR at 64597.

[27] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[28] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90752; File No. SR–IEX–2020–20]

Self-Regulatory Organizations; Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend IEX Rule 2.160 (Registration Requirements and Restrictions on Membership) To Adopt Temporary Supplementary Material .02 (Temporary Extension of the Limited Period for Registered Persons To Function as Principals) Under the Rule

December 21, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 15, 2020, the Investors Exchange LLC (''IEX'' or the ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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

Pursuant to the provisions of Section 19(b)(1) under the Act,[3] and Rule 19b–4 thereunder,[4] IEX is filing with the Commission a proposed rule change to amend IEX Rule 2.160 (Registration Requirements and Restrictions on Membership) to adopt temporary Supplementary Material .02 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under paragraph (i) of the Rule. The proposed rule change would harmonize the IEX Rule with a Financial Industry Regulatory Authority, Inc. (''FINRA'') rule amendment that extended the 120-day period during which certain individuals can function as a principal without having successfully passed an appropriate qualifying examination, through April 30, 2021.[5]

The text of the proposed rule change is available at the Exchange's website at *www.iextrading.com,* at the principal office of the Exchange, 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 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 Statutory Basis for, the Proposed Rule Change

1. Purpose

Currently, IEX Rule 2.160(i), Supplementary Material .01 provides, *inter alia,* that an IEX Member (''Member'') may designate any person currently registered, or who becomes registered with the Member as a representative to function as a principal for 120 calendar days prior to passing an appropriate principal qualification examination and that, in no event, may such person function as a principal beyond the initial 120 calendar day period without having passed an appropriate principal qualifying examination.

The Exchange is proposing to amend IEX Rule 2.160(i) to adopt Supplementary Material .02 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals). Under the proposed amendment, a person designated to function as a principal prior to January 1, 2021 may continue to function as a principal without having successfully passed an appropriate qualifying examination until April 30, 2021. The proposed amendment will align IEX's rule with FINRA Rule 1210, which was recently amended to provide the same temporary extension for principals due to the continuing impact of the COVID–19 pandemic.[6] FINRA performs certain functions related to the qualification, registration and continuing education requirements for registered persons pursuant to a regulatory services agreement with the Exchange.

In response to COVID–19, earlier this year FINRA began providing temporary relief to member firms from FINRA rules and requirements via frequently asked questions (''FAQs'') on its website.[7] Two of these FAQs[8] provided temporary relief to address disruptions to the administration of FINRA qualification examinations caused by the pandemic that have significantly limited the ability of individuals to sit for these examinations due to Prometric test center capacity issues.[9]

FINRA published the first FAQ on March 20, 2020, providing that individuals whom were designated to function as principals under FINRA Rule 1210.04 prior to February 2, 2020, would be given until May 31, 2020, to pass the appropriate principal qualification examination.[10] On May 19, 2020, FINRA extended the relief to pass the appropriate examination until June 30, 2020. On June 29, 2020, FINRA again extended the temporary relief providing that individuals who were designated to function as principals under FINRA Rule 1210.04 prior to May 4, 2020, would be given until August 31, 2020, to pass the appropriate principal qualification examination.[11]

On August 28, 2020, FINRA filed with the Commission a proposed rule change for immediate effectiveness to extend the temporary relief provided via the two FAQs by adopting temporary Supplementary Material .12 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under FINRA Rule 1210 (Registration Requirements).[12] Pursuant to this rule filing, individuals who were designated prior to September 3, 2020, to function as a principal under FINRA Rule 1210.04 would have until December 31, 2020, to pass the appropriate qualification examination.

Thereafter, on December 9, 2020, FINRA filed with the Commission a proposed rule change for immediate effectiveness to extend the limited period for registered persons to function as a principal through April 30, 2021.[13] Pursuant to this rule filing, individuals who were designated prior to January 1, 2021 to function as a principal would have until April 30, 2021 to pass the appropriate qualifying examination.

The Exchange continues to closely monitor the impact of the COVID–19 pandemic on Members, investors, and other stakeholders. The COVID–19 conditions necessitating the extension of relief provided in FINRA's FAQs and rule amendments persist and, in fact, appear to be worsening.[14] One of the impacts of COVID–19 continues to be serious interruptions in the administration of FINRA qualification examinations at Prometric test centers

[3] 15 U.S.C. 78s(b)(1).

[4] 17 CFR 240.19b–4.

[5] *See* Exchange Act Release No. 89732 (September 1, 2020), 85 FR 55535 (September 8, 2020) (SR–FINRA–2020–26); Exchange Act Release No. 90617 (December 9, 2020), 85 FR 81258 (December 15, 2020) (SR–FINRA–2020–43).

[6] *See supra* note 5.

[7] *See* Frequently Asked Questions Related to Regulatory Relief Due to the Coronavirus Pandemic, available at *https://www.finra.org/rules-guidance/key-topics/covid-19/faq.*

[8] *See https://www.finra.org/rules-guidance/key-topics/covid-19/faq#qe.*

[9] At the outset of the COVID–19 pandemic, all FINRA qualification examinations were administered at test centers operated by Prometric. Based on the health and welfare concerns resulting from COVID–19, in March Prometric closed all its test centers in the United States and Canada and began to slowly reopen some of them at limited capacity in May. At this time, not all of these Prometric test centers have reopened at full capacity.

[10] FINRA Rule 1210.04 (Requirements for Registered Persons Functioning as Principals for a Limited Period) allows a member firm to designate certain individuals to function in a principal capacity for 120 calendar days before having to pass an appropriate principal qualification examination. IEX Rule 2.160(i) Supplementary Material .01 provides the same allowance to Members.

[11] *See supra* note 8.

[12] *See supra* note 5. FINRA's proposed rule changes also provided for a similar temporary extension of the limited period for persons to function as an Operations Professional under FINRA Rule 1220(b)(3)(B) to December 31, 2020, and later to April 30, 2021, to pass the appropriate qualification examination. IEX does not have Operations Professional as a registration category.

[13] *See supra* note 5.

[14] *See, e.g.,* Meryl Kornfield, Jacqueline Dupree, Marisa Iati, Paulina Villegas, Siobhan O'Grady and Hamza Shaban, *New daily coronavirus cases in U.S. rise to 145,000, latest all-time high,* Wash. Post, November 11, 2020, *https://www.washingtonpost.com/nation/2020/11/11/coronavirus-covid-live-updates-us/.*

and the limited ability of individuals to sit for the examinations.[15] Although Prometric has begun reopening test centers, Prometric's safety practices mean that currently not all test centers are open, some of the open test centers are at limited capacity, and some open test centers are delivering only certain examinations that have been deemed essential by the local government.[16] Furthermore, Prometric has had to close some reopened test centers due to incidents of COVID–19 cases. The initial nationwide closure in March along with the inability to fully reopen all Prometric test centers due to COVID–19 have led to a significant backlog of individuals who are waiting to sit for FINRA examinations.[17] In addition, Members are continuing to experience operational challenges with much of their personnel working from home due to shelter-in-place orders, restrictions on businesses and social activity imposed in various states, and adherence to other social distancing guidelines consistent with the recommendations of public health officials.[18]

As a result, Members continue to face potentially significant disruptions to their normal business operations that may include a limitation of in-person activities and staff absenteeism as a result of the health and welfare concerns stemming from COVID–19. Such potential disruptions may be further exacerbated and may even affect client services if Members cannot continue to keep principal positions filled as they may have difficulty finding other qualified individuals to transition into these roles or may need to reallocate employee time and resources away from other critical responsibilities at the Member.

These ongoing, extenuating circumstances make it impracticable for Members to ensure that the individuals whom they have designated to function as a principal as set forth in IEX Rule 2.160(i) are able to successfully sit for and pass an appropriate qualification examination within the 120-calendar day period required by Supplementary Material .01 under Rule 2.160(i), or to find other qualified staff to fill these positions. The ongoing circumstances also require individuals to be exposed to the health risks associated with taking an in-person examination, because the General Securities Principal examination is not available online. Therefore, IEX is proposing to extend the 120-day period during which an individual can function as a principal before having to pass an applicable qualification examination until April 30, 2021.[19] The proposed rule change would apply only to those individuals who were designated to function as a principal prior to January 1, 2021. Any individuals designated to function as a principal on or after January 1, 2021 would need to successfully pass an appropriate qualification examination within 120 days.

The Exchange believes that this proposed extension of time is tailored to address the needs and constraints on a Member's operations during the COVID–19 pandemic, without significantly compromising critical investor protection. The proposed extension of time will help to minimize the impact of COVID–19 on Members by providing continued flexibility so that Members can ensure that principal positions remain filled. The potential risks from the proposed extension of the 120-day period are mitigated by the ongoing requirement that Members supervise the activities of these designated individuals and ensure compliance with federal securities laws and regulations, as well as IEX Rules.

As noted below, IEX has filed the proposed rule change for immediate effectiveness and has requested that the SEC waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, so IEX can implement the proposed rule change immediately.

2. Statutory Basis

IEX believes that the proposed rule change is consistent with the provisions of Section 6(b)[20] of the Act in general, and furthers the objectives of Section 6(b)(5) of the Act[21] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, 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 by harmonizing the Exchange's registration rules with those of FINRA, on which they are based. Consequently, the proposed change will conform the Exchange's rules to changes made to corresponding FINRA rules, thus promoting application of consistent regulatory standards with respect to rules that FINRA enforces pursuant to its regulatory services agreement with the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

IEX does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issue but to align the Exchange's rules with those of FINRA, which will assist FINRA in its oversight work done pursuant to a regulatory services agreement with IEX. The proposed rule change will also provide for consistent application of the Exchange's registration rules with those of FINRA, on which they are based. The Exchange believes that the proposed rule change is necessary to temporarily rebalance the attendant benefits and costs of the obligations under Rule 2.160 in response to the impacts of the COVID–19 pandemic that would otherwise result if the temporary rule amendment was not adopted. Consequently, the Exchange believes that the proposed temporary relief afforded by the proposed rule change and the benefit of harmonizing the Exchange's registration and qualification rules with those of FINRA does not present any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has

[15] Information about the continued impact of COVID–19 on FINRA-administered examinations is available at *https://www.finra.org/rules-guidance/key-topics/covid-19/exams.*

[16] Information from Prometric about its safety practices and the impact of COVID- 19 on its operations is available at *https://www.prometric.com/corona-virus-update.*

[17] Although an online test delivery service has been launched to help address the backlog, the General Securities Principal Exam (Series 24) is not available online. *See supra* note 12. FINRA is considering making additional qualifications examinations available remotely on a limited basis.

[18] *See, e.g.,* Centers for Disease Control and Prevention, How to Protect Yourself & Others, *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html.*

[19] If IEX seeks to provide additional temporary relief from the rule requirements identified in this proposed rule change beyond April 30, 2021, IEX will submit a separate rule filing to further extend the temporary extension of time.

[20] 15 U.S.C. 78f.

[21] 15 U.S.C. 78f(b)(5).

become effective pursuant to Section 19(b)(3)(A) of the Act[22] and Rule 19b–4(f)(6) thereunder.[23]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii), the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately upon filing. As noted above, the Exchange stated that the proposed extension of time will help minimize the impact of the COVID–19 outbreak on Members' operations by allowing them to keep principal positions filled and minimizing disruptions to client services and other critical responsibilities. The Exchange further stated that the ongoing extenuating circumstances of the COVID–19 pandemic make it impractical to ensure that individuals designated to act in these capacities are able to take and pass the appropriate qualification examination during the 120-calendar day period required under the rules. The Exchange also explained that shelter-in-place orders, quarantining, restrictions on business and social activity and adherence to social distancing guidelines consistent with the recommendations of public officials remain in place in various states.[24] In addition, the Exchange observed that, following a nationwide closure of all test centers earlier in the year, some test centers have re-opened, but are operating at limited capacity or are only delivering certain examinations that have been deemed essential by the local government.[25] Although, as the Exchange noted, FINRA has launched an online test delivery service to help address this backlog, the General Securities Principal (Series 24) Examination is not available online.[26] Nevertheless, the Exchange explained that the proposed rule change will provide needed flexibility to ensure that these positions remain filled and is tailored to address the constraints on Members' operations during the COVID–19 pandemic without significantly compromising critical investor protection.[27]

The Commission observed that the Exchange's proposal, like FINRA's analogous filing, provides only temporary relief from the requirement to pass certain qualification examinations within the 120-day period in the rules. As proposed, this relief would extend the 120-day period that certain individuals can function as principals through April 30, 2021. If a further extension of temporary relief from the rule requirements identified in this proposal beyond April 30, 2021 is required, the Exchange noted that it may submit a separate rule filing to extend the effectiveness of the temporary relief under these rules.[28] For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest.[29] Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[30]

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–IEX–2020–20 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–IEX–2020–20. 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 such filing also will be available for inspection and copying at the principal office of IEX. 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–IEX–2020–20 and should be submitted on or before January 19, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28658 Filed 12–28–20; 8:45 am]

BILLING CODE 8011–01–P

[22] 15 U.S.C. 78s(b)(3)(A).

[23] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[24] *See supra* note 18.

[25] *See supra* notes 15 and 16. The Exchange states that Prometric has also had to close some reopened test centers due to incidents of COVID–19 cases.

[26] *See supra* note 17. FINRA is considering making additional qualification examinations available remotely on a limited basis.

[27] The Exchange states that Members remain subject to the continued requirement to supervise the activities of these designated individuals and ensure compliance with federal securities laws and regulations, as well as IEX rules.

[28] *See supra* note 19.

[29] As noted above by the Exchange, this proposed temporary change is based on a recent filing by FINRA that the Commission approved with a waiver of the 30-day operative delay. *See supra* note 5, 85 FR at 81260.

[30] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[31] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90760; File No. SR–NYSEARCA–2020–112]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Effective Date in Commentary .10 Under NYSE Arca Rule 2.1210

December 21, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 15, 2020, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II 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 proposes a rule change to extend the effective date in Commentary .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE Arca Rule 2.1210 (Registration Requirements) applicable to Equity Trading Permit (''ETP'') Holders, Options Trading Permit (''OTP'') Holders and OTP Firms, from December 31, 2020 to April 30, 2021. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, 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 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend the effective date in Commentary .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE Arca Rule 2.1210 (Registration Requirements) applicable to ETP Holders, OTP Holders and OTP Firms (collectively, ''Members''),[3] from December 31, 2020 to April 30, 2021. The proposed rule change would extend the 120-day period that certain individuals can function as a principal without having successfully passed an appropriate qualification examination through April 30, 2021,[4] and would apply only to those individuals who were designated to function as a principal prior to January 1, 2021. This proposed rule change is based on a filing recently submitted by the Financial Regulatory Authority, Inc. (''FINRA'') [5] and is intended to harmonize the Exchange's registration rules with those of FINRA so as to promote uniform standards across the securities industry.

The COVID–19 pandemic is an unpredictable, exogenous event that has resulted in unavoidable disruptions to the securities industry and impacted member firms, regulators, investors and other stakeholders. In response to COVID–19, earlier this year FINRA began providing temporary relief by way of frequently asked questions (''FAQs'') [6] to address disruptions to the administration of FINRA qualification examinations caused by the pandemic that have significantly limited the ability of individuals to sit for examinations due to Prometric test center capacity issues.[7]

FINRA published the first FAQ on March 20, 2020, providing that individuals who were designated to function as principals under FINRA Rule 1210.04 [8] prior to February 2, 2020, would be given until May 31, 2020, to pass the appropriate principal qualification examination.[9] On May 19, 2020, FINRA extended the relief to pass the appropriate examination until June 30, 2020. On June 29, 2020, FINRA again extended the temporary relief providing that individuals who were designated to function as principals under FINRA Rule 1210.04 prior to May 4, 2020, would be given until August 31, 2020, to pass the appropriate principal qualification examination.

On September 25, 2020, NYSE Arca filed with the Commission a proposed rule change for immediate effectiveness to extend the temporary relief provided via the FAQ by adopting temporary Commentary .10 (Temporary Extension of the Limited Period for Registered Persons to Function as Principals) under NYSE Arca Rule 2.1210 (Registration Requirements).[10] Pursuant to this rule

[3] The term ''ETP Holder'' refers to a sole proprietorship, partnership, corporation, limited liability company or other organization in good standing that has been issued an ETP. An ETP Holder must be a registered broker or dealer pursuant to Section 15 of the Act. *See* Rule 1.1(o). The term ''ETP'' refers to an Equity Trading Permit issued by the Exchange for effecting approved securities transactions on the Exchange's Trading Facilities. *See* Rule 1.1(n). The term ''OTP Holder'' refers to a natural person, in good standing, who has been issued an OTP. An OTP Holder must be a registered broker or dealer pursuant to Section 15 of the Act. Under the Exchange's rules, an OTP Holder has the status as a ''member'' of the Exchange as that term is defined in Section 3 of the Act. *See* Rule 1.1(nn). The term ''OTP'' refers to an Options Trading Permit issued by the Exchange for effecting approved securities transactions on the Exchange's Trading Facilities. *See* Rule 1.1(mm). The term ''OTP Firm'' refers to a sole proprietorship, partnership, corporation, limited liability company or other organization in good standing who holds an OTP or upon whom an individual OTP Holder has conferred trading privileges on the Exchange's Trading Facilities pursuant to and in compliance with Exchange rules. An OTP Firm must be a registered broker or dealer pursuant to Section 15 of the Act. *See* Rule 1.1(oo).

[4] If NYSE Arca seeks to provide additional temporary relief from the rule requirements identified in this proposed rule change beyond April 30, 2021, NYSE Arca will submit a separate rule filing to further extend the temporary extension of time.

[5] *See* Exchange Act Release No. 90617 (December 9, 2020), 85 FR 81258 (December 15, 2020) (SR–FINRA–2020–043) (the ''FINRA Filing''). The Exchange notes that the FINRA Filing also provides temporary relief to individuals registered with FINRA as Operations Professionals under FINRA Rule 1220. The Exchange does not have a registration category for Operations Professionals and therefore, the Exchange is not proposing to adopt that aspect of the FINRA Filing.

[6] *See https://www.finra.org/rules-guidance/key-topics/covid-19/faq#qe.*

[7] At the outset of the COVID–19 pandemic, all FINRA qualification examinations were administered at test centers operated by Prometric. Based on the health and welfare concerns resulting from COVID–19, in March Prometric closed all of its test centers in the United States and Canada and began to slowly reopen some of them at limited capacity in May. Currently, Prometric has resumed testing in many of its United States and Canada test centers, at either full or limited occupancy, based on local and government mandates.

[8] NYSE Arca Rule 2.1210.03 is the corresponding rule to FINRA Rule 1210.04.

[9] FINRA Rule 1210.04 (Requirements for Registered Persons Functioning as Principals for a Limited Period) allows a member firm to designate certain individuals to function in a principal capacity for 120 calendar days before having to pass an appropriate principal qualification examination. NYSE Arca Rule 2.1210.03 provides the same allowance to Members.

[10] *See* Exchange Act Release No. 90113 (October 7, 2020), 85 FR 65110 (October 14, 2020) (Notice of Filing and Immediate Effectiveness of SR–NYSEARCA–2020–87).

filing, individuals who were designated prior to September 3, 2020, to function as a principal under NYSE Arca Rule 2.1210.10 have until December 31, 2020, to pass the appropriate qualification examination.

The COVID–19 conditions necessitating the extension of relief provided in the FAQ and SR–NYSEARCA–2020–87 persist and in fact appear to be worsening.[11] One of the impacts of COVID–19 continues to be serious interruptions in the administration of FINRA qualification examinations at Prometric test centers and the limited ability of individuals to sit for the examinations.[12] Although Prometric has been reopening its test centers, Prometric's safety practices mean that currently not all test centers are open, some of the open test centers are at limited capacity, and some open test centers are delivering only certain examinations that have been deemed essential by the local government.[13] Furthermore, Prometric has had to close some reopened test centers due to incidents of COVID–19 cases. The initial nationwide closure in March along with the inability to fully reopen all Prometric test centers due to COVID–19 have led to a significant backlog of individuals who are waiting to sit for FINRA examinations that are not available online, including the General Securities Principal Exam (Series 24).[14]

In addition, firms are continuing to experience operational challenges with much of their personnel working from home due to shelter-in-place orders, restrictions on businesses and social activity imposed in various states, and adherence to other social distancing guidelines consistent with the recommendations of public health officials.[15] As a result, firms continue to face potentially significant disruptions to their normal business operations that may include a limitation of in-person activities and staff absenteeism as a result of the health and welfare concerns stemming from COVID–19. Such potential disruptions may be further exacerbated and may even affect client services if firms cannot continue to keep principal positions filled as they may have difficulty finding other qualified individuals to transition into these roles or may need to reallocate employee time and resources away from other critical responsibilities at the firm.

These ongoing, extenuating circumstances make it impracticable for Members to ensure that the individuals whom they have designated to function in a principal capacity, as set forth in NYSE Arca Rule 2.1210.03, are able to successfully sit for and pass an appropriate qualification examination within the 120-calendar day period required under the rule, or to find other qualified staff to fill this position. The ongoing circumstances also require individuals to be exposed to the health risks associated with taking an in-person examination, because the General Securities Principal examination is not available online. Therefore, NYSE Arca is proposing to extend the effective date of the temporary relief provided through SR–NYSEARCA–2020–87 until April 30, 2021. The proposed rule change would apply only to those individuals who were designated to function as a principal prior to January 1, 2021. Any individuals designated to function as a principal on or after January 1, 2021, would need to successfully pass an appropriate qualification examination within 120 days.

NYSE Arca believes that this proposed continued extension of time is tailored to address the needs and constraints on a Member's operations during the COVID–19 pandemic, without significantly compromising critical investor protection. The proposed extension of time will help to minimize the impact of COVID–19 on Members by providing continued flexibility so that Members can ensure that principal positions remain filled. The potential risks from the proposed extension of the 120-day period are mitigated by the Member's continued requirement to supervise the activities of these designated individuals and ensure compliance with federal securities laws and regulations, as well as NYSE Arca rules.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[16] in general, and furthers the objectives of Section 6(b)(5),[17] 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 proposed rule change is intended to minimize the impact of COVID–19 on Member operations by extending the 120-day period certain individuals may function as a principal without having successfully passed an appropriate qualification examination under NYSE Arca Rule 2.1210.03 until April 30, 2021. The proposed rule change does not relieve Members from maintaining, under the circumstances, a reasonably designed system to supervise the activities of their associated persons to achieve compliance with applicable securities laws and regulations, and with applicable NYSE Arca rules that directly serve investor protection. In a time when faced with unique challenges resulting from the COVID–19 pandemic, NYSE Arca believes that the proposed rule change is a sensible accommodation that will continue to afford Members the ability to ensure that critical positions are filled and client services maintained, while continuing to serve and promote the protection of investors and the public interest in this unique environment.

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. As set forth in SR–NYSEARCA–2020–87, the proposed rule change is intended solely to extend temporary relief necessitated by the continued impacts of the COVID–19 pandemic and the related health and safety risks of conducting in-person activities. In its filing, FINRA notes that the proposed rule change is necessary to temporarily rebalance the attendant benefits and costs of the obligations under FINRA Rule 1210 in response to the impacts of the COVID–19 pandemic that would otherwise result if the temporary amendments were to expire

[11] *See, e.g.,* Meryl Kornfield, Jacqueline Dupree, Marisa Iati, Paulina Villegas, Siobhan O'Grady and Hamza Shaban, New daily coronavirus cases in U.S. rise to 145,000, latest all-time high, Wash. Post, November 11, 2020, *https://www.washingtonpost.com/nation/2020/11/11/coronavirus-covid-live-updates-us/.*

[12] Information about the continued impact of COVID–19 on FINRA-administered examinations is available at *https://www.finra.org/rules-guidance/key-topics/covid-19/exams.*

[13] Information from Prometric about its safety practices and the impact of COVID–19 on its operations is available at *https://www.prometric.com/corona-virus-update. See also supra* note 12.

[14] Earlier this year, an online test delivery service was launched for candidates seeking to take qualification examination remotely. Only certain qualification examinations are available online. *See supra* note 12. FINRA is considering making additional qualification examinations available remotely on a limited basis.

[15] *See, e.g.,* Centers for Disease Control and Prevention, How to Protect Yourself & Others, *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html.*

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

on December 31, 2020.[18] The Exchange accordingly incorporates FINRA's abbreviated economic impact assessment by reference.

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. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[19] and Rule 19b–4(f)(6) thereunder.[20]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b–4(f)(6)(iii), the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative immediately upon filing. As noted above, the Exchange stated that the proposed extension of time will help minimize the impact of the COVID–19 outbreak on Members' operations by allowing them to keep principal positions filled and minimizing disruptions to client services and other critical responsibilities. The Exchange further stated that the ongoing extenuating circumstances of the COVID–19 pandemic make it impractical to ensure that individuals designated to act in these capacities are able to take and pass the appropriate qualification examination during the 120-calendar day period required under the rules. The Exchange also explained that shelter-in-place orders, quarantining, restrictions on business and social activity and adherence to social distancing guidelines consistent with the recommendations of public officials remain in place in various states.[21] In addition, the Exchange observed that, following a nationwide closure of all test centers earlier in the year, some test centers have re-opened, but are operating at limited capacity or are only delivering certain examinations that have been deemed essential by the local government.[22] Although, as the Exchange noted, FINRA has launched an online test delivery service to help address this backlog, the General Securities Principal (Series 24) Examination is not available online.[23] Nevertheless, the Exchange explained that the proposed rule change will provide needed flexibility to ensure that these positions remain filled and is tailored to address the constraints on Members' operations during the COVID–19 pandemic without significantly compromising critical investor protection.[24]

The Commission observes that the Exchange's proposal, like the FINRA Filing, provides only an extension to temporary relief from the requirement to pass certain qualification examinations within the 120-day period in the rules. As proposed, this relief would extend the 120-day period that certain individuals can function as principals through April 30, 2021. If a further extension of temporary relief from the rule requirements identified in this proposal beyond April 30, 2021 is required, the Exchange noted that it may submit a separate rule filing to extend the effectiveness of the temporary relief under these rules.[25] For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest.[26] Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[27]

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–NYSEARCA–2020–112 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–NYSEARCA–2020–112. 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

[18] *See* FINRA Filing, 85 FR at 81260.

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[21] *See supra* note 15.

[22] *See supra* notes 12 and 13. The Exchange states that Prometric has also had to close some reopened test centers due to incidents of COVID–19 cases.

[23] *See supra* note 14. FINRA is considering making additional qualification examinations available remotely on a limited basis.

[24] The Exchange states that Members remain subject to the continued requirement to supervise the activities of these designated individuals and ensure compliance with federal securities laws and regulations, as well as NYSE Arca rules.

[25] *See supra* note 4.

[26] As noted above by NYSE Arca, this proposal is an extension of temporary relief provided in a prior filing where NYSE Arca also requested and the Commission granted a waiver of the 30-day operative delay. *See supra* note 10, 85 FR at 65112.

[27] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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–2020–112 and should be submitted on or before January 19, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28659 Filed 12–28–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Form 2–E, Report pursuant to rule 609 of Regulation E, SEC File No. 270–222, OMB Control No. 3235–0233

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 609 (17 CFR 230.609) under the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) requires small business investment companies and business development companies that have engaged in offerings of securities that are exempt from registration pursuant to Regulation E under the Securities Act of 1933 (17 CFR 230.601 to 610a) to report semi-annually on Form 2–E (17 CFR 239.201) the progress of the offering. The form solicits information such as the dates an offering commenced and was completed (if completed), the number of shares sold and still being offered, amounts received in the offering, and expenses and underwriting discounts incurred in the offering. The information provided on Form 2–E assists the staff in monitoring the progress of the offering and in determining whether the offering has stayed within the limits set for an offering exempt under Regulation E.

The Commission estimates that, on average, approximately one respondent submits a Form 2–E filing each year. The Commission further estimates that this information collection imposes an annual burden of four hours and imposes an annual external cost burden of zero.

The collection of information under Form 2–E is mandatory. The information provided by the form will not be kept confidential. 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.

Written comments are invited on: (a) 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; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: December 22, 2020.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2020–28769 Filed 12–28–20; 8:45 am]

BILLING CODE 8011–01–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Notice of Product Exclusion Extensions and Additional Modifications: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation

AGENCY: Office of the United States Trade Representative (USTR).

ACTION: Notice of product exclusion extensions and additional modifications.

SUMMARY: In prior notices, the U.S. Trade Representative modified the action in the Section 301 investigation of China's acts, policies, and practices related to technology transfer, intellectual property, and innovation by excluding from additional duties certain medical-care products needed to address the COVID–19 outbreak. On March 25, 2020, the U.S. Trade Representative sought public comment on additional modifications in this investigation in order to address COVID–19. This notice announces the U.S. Trade Representative's determination to extend certain product exclusions and to make further modifications to remove Section 301 duties from additional medical-care products to address COVID–19.

DATES: The product exclusion extensions announced in this notice will extend the exclusions through March 31, 2021. The modifications to exclude additional products will apply as of January 1, 2021 until March 31, 2021. U.S. Customs and Border Protection will issue instructions on entry guidance and implementation.

FOR FURTHER INFORMATION CONTACT: For general questions about this notice, contact Associate General Counsel Philip Butler, Assistant General Counsels Benjamin Allen or Susie Park Hodge, or Director of Industrial Goods Justin Hoffmann at (202) 395–5725. For specific questions on customs classification or implementation of the product exclusions identified in the Annexes to this notice, contact *traderemedy@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

At the direction of the President, the U.S. Trade Representative imposed additional duties on products of China in order to obtain the elimination of the unfair and damaging acts, policies, and practices identified in this investigation. These additional duties were imposed in four tranches. *See* 83 FR 28719 (June 20, 2018), 83 FR 40823 (August 16, 2018), 83 FR 47974 (September 21, 2018), as modified by 83 FR 49153 (September 28, 2018), and 84 FR 43304 (August 20, 2019), as modified by 84 FR 69447 and 85 FR 3741.

For each tranche, the U.S. Trade Representative established a process by which U.S. stakeholders could request the exclusion of particular products subject to the action. Additionally, the U.S. Trade Representative later established a process by which U.S. stakeholders could request the extension of particular exclusions.

Throughout the exclusion process, USTR assessed medical necessity in granting exclusions, consistent with its published criteria. In addition, the U.S.

[28] 17 CFR 200.30–3(a)(12).

Trade Representative, in consultation with the Department of Health and Human Services (HHS), prioritized the review and exclusion of requests addressing medical-care products related to the U.S. response to COVID–19. *See* 85 FR 13970 (March 10, 2020), 85 FR 15015 (March 16, 2020), and 85 FR 15244 (March 17, 2020). These exclusions covered personal protective equipment products and other medical-care related products.

On March 25, 2020, in order to reflect developments in the efforts to respond to COVID–19, the U.S. Trade Representative requested public comments on possible further modifications to remove Section 301 duties from additional medical-care products to address the COVID–19 outbreak. 85 FR 16987 (March 25, 2020). This docket was open from March 25–June 25, 2020, and each commenter was required to identify the particular product of concern and explain how it relates to the response to COVID–19. USTR accepted comments regarding any product covered by the action in the investigation, regardless of whether the product was subject to a pending or denied exclusion request.

B. Determination To Extend Certain Exclusions and Make Additional Modifications

In light of the rising spread and ongoing efforts to combat COVID–19, the U.S. Trade Representative has determined that maintaining or re-imposing additional duties on certain products subject to the action no longer is appropriate and that the application of additional duties to these products could impact U.S. preparedness to address COVID–19.

Pursuant to sections 301(b), 301(c), and 307(a) of the Trade Act of 1974, as amended, and in accordance with the advice of the interagency Section 301 Committee, the U.S. Trade Representative has determined to extend certain product exclusions on medical-care products and to remove the duties from additional medical-care products. The medical-care products covered by this determination are set out in the annexes to this notice. In light of the evolving nature of the battle against COVID–19, the U.S. Trade Representative has determined to extend the exclusions in the annexes until March 31, 2021, and the modifications will be effective from January 1, 2021, to March 31, 2021. The U.S. Trade Representative may consider further extensions and/or additional modifications as appropriate. The U.S. Trade Representative's determination also takes into account advice from advisory committees and any public comments.

The exclusions and modifications are available for any product that meets the description in the Annexes. Further, the scope of each exclusion and modification is governed by the scope of the ten-digit Harmonized Tariff Schedule of the United States (HTSUS) subheadings and product descriptions in the annexes to this notice.

Joseph Barloon,

General Counsel, Office of the United States Trade Representative.

BILLING CODE 3290–F0–P

ANNEX A

A. Effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on January 1, 2021 and before 11:59 p.m. eastern daylight time on March 31, 2021, subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States (HTSUS) is modified:

1. by inserting the following new heading 9903.88.62 in numerical sequence, with the material in the new heading inserted in the columns of the HTSUS labeled "Heading/Subheading", "Article Description", and "Rates of Duty 1-General", respectively:

Heading/ Subheading	Article Description	Rates of Duty		
		1		2
		General	Special	
"9903.88.62	Effective with respect to entries on or after January 1, 2021, and through March 31, 2021, articles the product of China, as provided for in U.S. note 20(ooo) to this subchapter, each covered by an exclusion granted by the U.S. Trade Representative	The duty provided in the applicable subheading"		

2. by inserting the following new U.S. note 20(ooo) to subchapter III of chapter 99 in numerical sequence:

"(ooo) The U.S. Trade Representative determined to establish a process by which particular products classified in heading 9903.88.01 and provided for in U.S. notes 20(a) and 20(b) to this subchapter could be excluded from the additional duties imposed by heading 9903.88.01. See 83 Fed. Reg. 28710 (June 20, 2018) and 83 Fed. Reg. 32181 (July 11, 2018). Subsequently, the U.S. Trade Representative sought public comment on additional modifications in this investigation in order to address COVID-19. See 85 FR 16987 (March 25, 2020). The U.S. Trade Representative has determined that, as provided in heading 9903.88.62, the additional duties provided for in heading 9903.88.01 shall not apply to the following particular products, which are provided for in the enumerated statistical reporting numbers:

1) Disposable plastic filters of a kind suitable for filtering and dehumidifying a patient's breath in a medical device such as a gas analyzer (described in statistical reporting number 8421.39.8090)
2) S-band and X-band linear accelerators designed for use in radiation surgery or radiation therapy equipment (described in statistical reporting number 8543.10.0000)
3) Disposable electrocardiograph (ECG) electrodes (described in statistical reporting number 9018.11.9000)
4) Ultrasonic scanning apparatus, each having dimensions not exceeding 122 cm by 77 cm by 127 cm, whether or not presented with transducer (described in statistical reporting number 9018.12.0000)

5) Blood pressure monitors suitable for use by medical professionals (described in statistical reporting number 9018.19.9530)
6) Digital peak flow meters suitable for use by medical professionals (described in statistical reporting number 9018.19.9550)
7) Fingertip pulse oximeters suitable for use by medical professionals (described in statistical reporting number 9018.19.9550)
8) Bismuth germanate crystals with set dimensional and surface finish requirements and used as a detection element in Positron Emission Tomography (PET) detectors (described in statistical reporting number 9018.19.9560)
9) Magnetic resonance imaging ("MRI") patient enclosure devices, each incorporating radio frequency and gradient coils (described in statistical reporting number 9018.19.9560)
10) Parts and accessories of capnography monitors (described in statistical reporting number 9018.19.9560)
11) Disposable surface electrodes for Intra-operative neuromonitoring ("IONM") systems, each composed of a surface electrode pad, an insulated wire, and a standard DIN 42802 connector (described in statistical reporting number 9018.19.9560)
12) Otoscopes (described in statistical reporting number 9018.90.2000)
13) Anesthesia masks (described in statistical reporting number 9018.90.3000)
14) Anesthetic instruments and appliances suitable for use in medical or surgical sciences, and parts and accessories of the foregoing (described in statistical reporting number 9018.90.3000)
15) Electrosurgical cautery pencils with electrical connectors (described in statistical reporting number 9018.90.6000)
16) Printed circuit board assemblies designed for use in displaying operational performance of medical infusion equipment (described in statistical reporting number 9018.90.7580)
17) Combined positron emission tomography/computed tomography (PET/CT) scanners which utilize multiple PET gantries (frames) on a common base (described in statistical reporting number 9022.12.0000)
18) X-ray tables (described in statistical reporting number 9022.90.2500)
19) X-ray tube housings and parts thereof (described in statistical reporting number 9022.90.4000)
20) Multi-leaf collimators of radiotherapy systems based on the use of X-ray (described in statistical reporting number 9022.90.6000)
21) Parts and accessories, of metal, for mobile X-ray apparatus (described in statistical reporting number 9022.90.6000)
22) Vertical stands specially designed to support, contain or adjust the movement of X-ray digital detectors, or the X-ray tube and collimator in complete X-ray diagnostic systems (described in statistical reporting number 9022.90.6000)
23) Thermoplastic masks of polycaprolactone for the use of immobilizing patients, during the use of alpha, beta or gamma radiations, for radiography or radiotherapy (described in statistical reporting number 9022.90.9500)
24) Inoculator sets of plastics, each consisting of a plate with multiple wells, a display tray, and a lid; when assembled, the set measuring 105 mm or more but not exceeding 108 mm in width, 138 mm or more but not exceeding 140 mm in depth, and 6.5 mm or less in thickness (described in statistical reporting number 9027.90.5650)".

3. by amending the last sentence of the first paragraph of U.S. note 20(a) to subchapter III of chapter 99 by:

   a. by deleting "or (12)" and by inserting "(12)" in lieu thereof; and

b. by inserting "; or (13) heading 9903.88.62 and U.S. note 20(ooo) to subchapter III of chapter 99" after the phrase "U.S. note 20(mmm) to subchapter III of chapter 99", where it appears at the end of the sentence.

4. by amending U.S. note 20(b) to subchapter III of chapter 99 by:

a. by deleting "or (12)" and by inserting "(12)" in lieu thereof; and

b. by inserting "; or (13) heading 9903.88.62 and U.S. note 20(ooo) to subchapter III of chapter 99" after the phrase "U.S. note 20(mmm) to subchapter III of chapter 99", where it appears at the end of the sentence.

5. by amending the Article Description of heading 9903.88.01:

a. by deleting "9903.88.58 or";

b. by inserting in lieu thereof "9903.88.58,"; and

c. by inserting "or 9903.88.62," after "9903.88.60,".

B. Effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on January 1, 2021, the exclusion for certain inoculator sets of plastics that is provided for in heading 9903.88.06 and U.S. note 20(i)(32) to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States is deleted.

ANNEX B

Effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on January 1, 2021 and before 11:59 p.m. eastern daylight time on March 31, 2021, subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States (HTSUS) is modified:

a. by inserting the following new heading 9903.88.63 in numerical sequence, with the material in the new heading inserted in the columns of the HTSUS labeled "Heading/Subheading", "Article Description", and "Rates of Duty 1-General", respectively:

Heading/ Subheading	Article Description	Rates of Duty		
		1		2
		General	Special	
"9903.88.63	Effective with respect to entries on or after January 1, 2021, and through March 31, 2021, articles the product of China, as provided for in U.S. note 20(ppp) to this subchapter, each covered by an exclusion granted by the U.S. Trade Representative	The duty provided in the applicable subheading"		

b. by inserting the following new U.S. note 20(ppp) to subchapter III of chapter 99 in numerical sequence:

"(ppp) The U.S. Trade Representative determined to establish a process by which particular products classified in heading 9903.88.02 and provided for in U.S. notes 20(c) and 20(d) to this subchapter could be excluded from the additional duties imposed by heading 9903.88.02. See 83 Fed. Reg. 40823 (August 16, 2018) and 83 Fed. Reg. 47326 (September 18, 2018). Subsequently, the U.S. Trade Representative sought public comment on additional modifications in this investigation in order to address COVID-19. See 85 FR 16987 (March 25, 2020). The U.S. Trade Representative has determined that, as provided in heading 9903.88.63, the additional duties provided for in heading 9903.88.02 shall not apply to the following particular products, which are provided for in the enumerated statistical reporting numbers:

1) 9025.19.8010
2) 9025.19.8020
3) 9025.19.8060
4) 9025.19.8085
5) Molded acrylonitrile-butadiene-styrene (ABS) tubes, of a kind used to effect the sterile transfer of fluid from a bag or vial to another container, each tube measuring 7.5 cm or more but not exceeding 23 cm in length, with an inner diameter of less than 0.65 cm and an outer diameter of less than 9 cm, one end having been angle-cut to form a spike, and having an integrated flange, less than 3 cm in diameter (splash guard) near the spike end and removable polyethylene caps on each end, put up in sterile packing (described in statistical reporting number 3917.29.0090)
6) Polyethylene film, 20.32 to 198.12 cm in width, and 30.5 to 2000.5 m in length, coated on one side with solvent acrylic adhesive, clear or in transparent colors, whether or not printed, in rolls (described in statistical reporting number 3919.90.5060)
7) Rectangular sheets of high-density or low-density polyethylene, 111.75 cm to 215.9 cm in width, and 152.4 cm to 304.8 cm in length, with a sticker attached to mark the center of each sheet, of a kind used in hospital or surgery center operating rooms (described in statistical reporting number 3920.10.0000)
8) Sheets and strips consisting of both cross-linked polyethylene and ethylene vinyl acetate, of a width greater than 1 m but not greater than 1.5 m, and a length greater than 1.75 m but not greater than 2.6 m (described in statistical reporting number 3921.19.0000)
9) Polyethylene sheet and film laminated with spunbond-spunbond-spunbond nonwoven polypropylene fabric, measuring 1.12 m or more but not over 1.52 m in width and 1.93 m or more but not over 2.29 m in length, and weighing 55 g/m^2 or more but not exceeding 88 g/m^2 (described in statistical reporting number 3921.90.1500)
10) Dispensers of hand-cleaning or hand-sanitizing solutions, whether employing a manual pump or a proximity-detecting battery-operated pump, each article weighing not more than 3 kg (described in statistical reporting number 8424.89.9000)".

c. by amending the last sentence of the first paragraph of U.S. note 20(c) to subchapter III of chapter 99 by:

1. by deleting "or (6)" and by inserting "(6)" in lieu thereof; and

2. by inserting "; or (7) heading 9903.88.63 and U.S. note 20(ppp) to subchapter III of chapter 99" after the phrase "U.S. note 20(nnn) to subchapter III of chapter 99", where it appears at the end of the sentence.

d. by amending U.S. note 20(d) to subchapter III of chapter 99 by:

1. by deleting "or (6)" and by inserting "(6)" in lieu thereof; and

2. by inserting "; or (7) heading 9903.88.63 and U.S. note 20(ppp) to subchapter III of chapter 99" after the phrase "U.S. note 20(nnn) to subchapter III of chapter 99", where it appears at the end of the sentence.

e. by amending the Article Description of heading 9903.88.02:

1. by deleting "9903.88.59 or";

2. by inserting in lieu thereof "9903.88.59,"; and

3. by inserting "or 9903.88.63," after "9903.88.61,".

ANNEX C

Effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on January 1, 2021 and before 11:59 p.m. eastern daylight time on March 31, 2021, subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States (HTSUS) is modified:

1. by inserting the following new heading 9903.88.64 in numerical sequence, with the material in the new heading inserted in the columns of the HTSUS labeled "Heading/Subheading", "Article Description", and "Rates of Duty 1-General", respectively:

Heading/ Subheading	Article Description	Rates of Duty		
		1		2
		General	Special	
"9903.88.64	Effective with respect to entries on or after January 1, 2021, and through March 31, 2021, articles the product of China, as provided for in U.S. note 20(qqq) to this subchapter, each covered by an exclusion granted by the U.S. Trade Representative	The duty provided in the applicable subheading"		

2. by inserting the following new U.S. note 20(qqq) to subchapter III of chapter 99 in numerical sequence:

"(qqq) The U.S. Trade Representative determined to establish a process by which particular products classified in heading 9903.88.03 and provided for in U.S. notes 20(e) and 20(f) to this subchapter could be excluded from the additional duties imposed by heading 9903.88.03,

and by which particular products classified in heading 9903.88.04 and provided for in U.S. note 20(g) to this subchapter could be excluded from the additional duties imposed by heading 9903.88.04. See 83 Fed. Reg. 47974 (September 21, 2018) and 84 Fed. Reg. 29576 (June 24, 2019). Subsequently, the U.S. Trade Representative sought public comment on additional modifications in this investigation in order to address COVID-19. See 85 FR 16987 (March 25, 2020). The U.S. Trade Representative has determined that, as provided in heading 9903.88.64, the additional duties provided for in heading 9903.88.03 or in heading 9903.88.04 shall not apply to the following particular products, which are provided for in the enumerated statistical reporting numbers:

1) 3808.94.1000
2) 3808.94.5010
3) 3808.94.5050
4) 3808.94.5090
5) 3923.21.0095
6) 3926.20.9050
7) 4015.19.1010
8) 4819.50.4060
9) 5603.12.0090
10) 5603.14.9090
11) 5603.92.0090
12) 5603.93.0090
13) 6505.00.8015
14) 8424.90.9080
15) Sodium metal (CAS No. 7440-23-5), in bulk solid form (described in statistical reporting number 2805.11.0000)
16) Disposable cloths of nonwoven textile materials impregnated, coated or covered with organic surface-active preparations for washing the skin, put up for retail sale (described in statistical reporting number 3401.30.5000)
17) Hand soaps and hand sanitizers in the form of liquid or cream put up for retail sale, other than hand sanitizers of heading 3808 (described in statistical reporting number 3401.30.5000)
18) Organic surface-active liquid for washing the skin, not containing any aromatic or modified aromatic surface-active agent, put up for retail sale in a bottle of plastics with pump-action top, each bottle measuring not more than 17 cm in width, not more than 27 cm in height and not more than 6.5 cm in length and with a net weight of not more than 0.5 kg (described in statistical reporting number 3401.30.5000)
19) Mixtures containing 2-(dimethylamino)ethanol (CAS No. 108-01-0) (described in statistical reporting number 3824.99.9297)
20) Silicon monoxide (SiO) (CAS No. 10097-28-6) in powder form (described in statistical reporting number 3824.99.9297)
21) Flexible gas sampling tubes, pipes and hoses, of polyvinyl chloride, with lock connectors at each end (described in statistical reporting number 3917.33.0000)
22) Flexible oxygen tubes, pipes and hoses presented with integrated molded connectors, of polyvinyl chloride (described in statistical reporting number 3917.33.0000)
23) Container units of plastics, each comprising a tub and lid therefore, configured or fitted for the conveyance, packing, or dispensing of wet wipes (described in statistical reporting number 3923.10.9000)

24) Sacks and bags of polymers of ethylene, reclosable, qualifying as Class 1 medical devices by the U.S. Food and Drug Administration under product code NNI (described in statistical reporting number 3923.21.0030)
25) Injection molded polypropylene plastic caps or lids each weighing not over 24 grams designed for dispensing wet wipes (described in statistical reporting number 3923.50.0000)
26) Aprons, of plastics, of a kind used as personal protection equipment (described in statistical reporting number 3926.20.9010)
27) Seamless disposable gloves of acrylonitrile butadiene rubber, other than for surgical or medical use (described in statistical reporting number 4015.19.1010)
28) Seamless disposable gloves of natural rubber latex, other than for surgical or medical use (described in statistical reporting number 4015.19.1010)
29) Nonwoven fabrics of man-made fibers, weighing more than 25 g/m² but not more than 70 g/m², with a smooth or embossed texture (not impregnated, coated or covered with material other than or in addition to rubber, plastics, wood pulp or glass fibers), in rolls that are pre-slitted in lengths of not less than 15 cm to not more than 107 cm, for use in the manufacture of personal care wipes (described in statistical reporting number 5603.12.0090)
30) Hand pumps (other than for fuel or lubricants, not fitted or designed to be fitted with a metering device), each used to dispense a metered quantity of liquid soap or sanitizer (described in statistical reporting number 8413.20.0000)
31) Hand pumps for liquids (other than those of subheading 8413.11 or 8413.19) of acrylonitrile butadiene styrene (ABS) plastics (described in statistical reporting number 8413.20.0000)
32) Indicator panels incorporating LEDs, designed for use in medical infusion equipment (described in statistical reporting number 8531.20.0040)
33) Data input devices each with display capabilities of a kind used for magnetic resonance imaging ("MRI") equipment, computed tomography ("CT") equipment, intraoperative X-ray ("IXR") equipment or patient monitors (described in statistical reporting number 8537.10.9170)
34) Compound binocular optical microscopes (other than stereoscopic microscopes and microscopes for photomicrography, cinemicrography or microprojection), each with magnification of 40X or more but not exceeding 1,000X, weighing not more than 3 kg (described in statistical reporting number 9011.80.0000)
35) Compound optical microscopes (other than stereoscopic microscopes and microscopes for photomicrography, cinemicrography or microprojection), each with magnification of 40X or more but not exceeding 400X, weighing not more than 15 kg (described in statistical reporting number 9011.80.0000)".

3. by amending the last sentence of the first paragraph of U.S. note 20(e) to subchapter III of chapter 99 by:

   a. by deleting "or (15)" and by inserting "(15)" in lieu thereof; and

   b. by inserting "; or (16) heading 9903.88.64 and U.S. note 20(qqq) to subchapter III of chapter 99" after the phrase "U.S. note 20(iii) to subchapter III of chapter 99", where it appears at the end of the sentence.

4. by amending U.S. note 20(f) to subchapter III of chapter 99 by:

a. by deleting "or (15)" and by inserting "(15)" in lieu thereof; and

b. by inserting "; or (16) heading 9903.88.64 and U.S. note 20(qqq) to subchapter III of chapter 99" after the phrase "U.S. note 20(iii) to subchapter III of chapter 99", where it appears at the end of the sentence.

5. by amending the first sentence of U.S. note 20(g) to subchapter III of chapter 99:

a. by deleting "or (8)" and by inserting "(8)" in lieu thereof; and

b. by inserting "; or (9) heading 9903.88.64 and U.S. note 20(qqq) to subchapter III of chapter 99" after the phrase "U.S. note 20(aaa) to subchapter III of chapter 99", where it appears at the end of the sentence.

6. by amending the Article Description of heading 9903.88.03:

a. by deleting "9903.88.48 or";

b. by inserting in lieu thereof "9903.88.48,"; and

c. by inserting "or 9903.88.64," after "9903.88.56,".

7. by amending the Article Description of heading 9903.88.04:

a. by deleting "9903.88.48 or";

b. by inserting in lieu thereof "9903.88.48, "; and

c. by inserting "or 9903.88.64" after "9903.88.56".

ANNEX D

Effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on January 1, 2021, and before 11:59 p.m. eastern daylight time on March 31, 2021, subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States (HTSUS) is modified:

1. by inserting the following new heading 9903.88.65 in numerical sequence, with the material in the new heading inserted in the columns of the HTSUS labeled "Heading/Subheading", "Article Description", and "Rates of Duty 1-General", respectively:

Heading/ Subheading	Article Description	Rates of Duty		
		1		2
		General	Special	
"9903.88.65	Effective with respect to entries on or after January 1, 2021, and through March 31, 2021, articles the product of China, as provided for in U.S. note 20(rrr) to this subchapter, each covered by an exclusion granted by the U.S. Trade Representative.	The duty provided in the applicable subheading "		

2. by inserting the following new U.S. note 20(rrr) to subchapter III of chapter 99 in numerical sequence:

"(rrr) The U.S. Trade Representative determined to establish a process by which particular products classified in heading 9903.88.15 and provided for in U.S. notes 20(r) and (s) to this subchapter could be excluded from the additional duties imposed by heading 9903.88.15. See 84 Fed. Reg. 43304 (August 20, 2019), 84 Fed. Reg. 45821 (August 30, 2019), 84 Fed. Reg. 57144 (October 24, 2019) and 85 Fed. Reg. 3741 (January 22, 2020). Subsequently, the U.S. Trade Representative sought public comment on additional modifications in this investigation in order to address COVID-19. See 85 FR 16987 (March 25, 2020). The U.S. Trade Representative has determined that, as provided in heading 9903.88.65, the additional duties provided for in heading 9903.88.15 shall not apply to the following particular products, which are provided for in the following enumerated statistical reporting numbers:

1) 3401.19.0000
2) 3926.90.9910
3) 4015.19.0510
4) 4015.19.0550
5) 4818.90.0000 prior to July 1, 2020; 4818.90.0020 or 4818.90.0080 effective July 1, 2020
6) 5210.11.4040
7) 5210.11.6020
8) 5504.10.0000
9) 6210.10.5010
10) 6210.10.5090
11) 6307.90.6090
12) 6307.90.6800
13) 6307.90.7200
14) Face shields of transparent plastics, whether or not assembled (described in statistical reporting number 3926.90.9950)
15) Bowls of molded plastics, with clips for retaining guide wires during surgical procedures (described in statistical reporting number 3926.90.9990 prior to July 1, 2020; described in statistical reporting number 3926.90.9985 effective July 1, 2020)

16) Coverings, of plastics, designed to fit over wound sites or casts thereby forming a protective seal for keeping the covered area dry and debris free while showering or bathing (described in statistical reporting number 3926.90.9990 prior to July 1, 2020; described in statistical reporting number 3926.90.9985 effective July 1, 2020)
17) Disposable graduated medicine dispensing cups of plastics (described in statistical reporting number 3926.90.9990 prior to July 1, 2020; described in statistical reporting number 3926.90.9985 effective July 1, 2020)
18) Single-use sterile drapes and covers of plastics, of a kind used to protect the sterile field in surgical operating rooms (described in statistical reporting number 3926.90.9990 prior to July 1, 2020; described in statistical reporting number 3926.90.9985 effective July 1, 2020)
19) Sterile decanters of polystyrene plastics, each of a kind used to transfer aseptic fluids or medication to and from sterile bags, vials or glass containers (described in statistical reporting number 3926.90.9990 prior to July 1, 2020; described in statistical reporting number 3926.90.9985 effective July 1, 2020)
20) Gloves, containing less than 50 percent by weight of textile fibers, coated with rubber or plastics designed for enhanced grip (described in statistical reporting number 6116.10.6500)
21) Cold packs consisting of a single-use, instant, endothermic chemical reaction cold pack combined with a textile exterior lining (described in statistical reporting number 6307.90.9889 prior to July 1, 2020; described in statistical reporting number 6307.90.9891 effective July 1, 2020)
22) Disposable shoe and boot covers of man-made fiber fabrics (described in statistical reporting number 6307.90.9889 prior to July 1, 2020; described in statistical reporting number 6307.90.9891 effective July 1, 2020)
23) Face masks and particulate facepiece respirators, of textile fabrics (described in statistical reporting number 6307.90.9889 prior to July 1, 2020; described in statistical reporting number 6307.90.9845, 6307.90.9850, 6307.90.9870, or 6307.90.9875 effective July 1, 2020)
24) Hot packs of textile material, single-use (exothermic chemical reaction) (described in statistical reporting number 6307.90.9889 prior to July 1, 2020; described in statistical reporting number 6307.90.9891 effective July 1, 2020)
25) Laparotomy sponges of cotton (described in statistical reporting number 6307.90.9889 prior to July 1, 2020; described in statistical reporting number 6307.90.9891 effective July 1, 2020)
26) Single-use blood pressure cuff sleeves of textile materials (described in statistical reporting number 6307.90.9889 prior to July 1, 2020; described in statistical reporting number 6307.90.9891 effective July 1, 2020)
27) Single-use medical masks of textile material (described in statistical reporting number 6307.90.9889 prior to July 1, 2020; described in statistical reporting number 6307.90.9845, 6307.90.9850, or 6307.90.9870 effective July 1, 2020)
28) Single-use stethoscope covers (described in statistical reporting number 6307.90.9889 prior to July 1, 2020; described in statistical reporting number 6307.90.9891 effective July 1, 2020)
29) Woven gauze sponges of cotton in square or rectangular sizes (described in statistical reporting number 6307.90.9889 prior to July 1, 2020; described in statistical reporting number 6307.90.9891 effective July 1, 2020)
30) Protective Articles (described in statistical reporting number 9004.90.0000 prior to January 1, 2021; described in statistical reporting number 9004.90.0010 or 9004.90.0090 effective January 1, 2021)".

3. by amending the last sentence of the first paragraph of U.S. note 20(r):

   a. by deleting "or (9)" and by inserting "(9)" in lieu thereof; and

   b. by inserting ", or (10) heading 9903.88.65 and U.S. note 20(rrr) to subchapter III of chapter 99" after "U.S. note 20(jjj) to subchapter III of chapter 99".

4. by amending the article description of heading 9903.88.15:

   a. by deleting "9903.88.55 or" and by inserting "9903.88.55," in lieu thereof; and

   b. by inserting "or 9903.88.65," after "9903.88.57,".

ANNEX E

The following tables are provided for informational purposes only. Table A contains a list of the original exclusions and corresponding Chapter 99 Heading and Note 20 Subdivision for the first extension and the current extension. Additionally, the table indicates which Annex to this notice the extension appears. Table B contains a list of new products excluded from Section 301 duties.

Table A. Extensions of Exclusions

Original Exclusion		First Extension		Current Extension		
Chapter 99 Heading	Note 20 Subdivision	Chapter 99 Heading	Note 20 Subdivision	Chapter 99 Heading	Note 20 Subdivision	Annex
9903.88.14	20(q)(61)	9903.88.58	20(kkk)(7)	9903.88.62	20(ooo)(1)	Annex A
9903.88.14	20(q)(254)	9903.88.58	20(kkk)(39)	9903.88.62	20(ooo)(2)	Annex A
9903.88.14	20(q)(274)	9903.88.58	20(kkk)(43)	9903.88.62	20(ooo)(3)	Annex A
9903.88.14	20(q)(276)	9903.88.58	20(kkk)(45)	9903.88.62	20(ooo)(6)	Annex A
9903.88.14	20(q)(277)	9903.88.58	20(kkk)(46)	9903.88.62	20(ooo)(7)	Annex A
9903.88.14	20(q)(278)	9903.88.58	20(kkk)(47)	9903.88.62	20(ooo)(8)	Annex A
9903.88.14	20(q)(279)	9903.88.58	20(kkk)(48)	9903.88.62	20(ooo)(9)	Annex A
9903.88.14	20(q)(280)	9903.88.58	20(kkk)(49)	9903.88.62	20(ooo)(10)	Annex A
9903.88.10	20(m)(88)	9903.88.50	20(ccc)(16)	9903.88.62	20(ooo)(11)	Annex A
9903.88.14	20(q)(281)	9903.88.58	20(kkk)(50)	9903.88.62	20(ooo)(12)	Annex A
9903.88.14	20(q)(282)	9903.88.58	20(kkk)(51)	9903.88.62	20(ooo)(13)	Annex A
9903.88.14	20(q)(283)	9903.88.58	20(kkk)(52)	9903.88.62	20(ooo)(15)	Annex A
9903.88.14	20(q)(284)	9903.88.58	20(kkk)(53)	9903.88.62	20(ooo)(16)	Annex A
9903.88.19	20(x)(89)	9903.88.60	20(mmm)(9)	9903.88.62	20(ooo)(17)	Annex A
9903.88.14	20(q)(285)	9903.88.58	20(kkk)(54)	9903.88.62	20(ooo)(18)	Annex A
9903.88.14	20(q)(286)	9903.88.58	20(kkk)(55)	9903.88.62	20(ooo)(19)	Annex A
9903.88.11	20(n)(106)	9903.88.52	20(eee)(12)	9903.88.62	20(ooo)(20)	Annex A
9903.88.14	20(q)(287)	9903.88.58	20(kkk)(56)	9903.88.62	20(ooo)(21)	Annex A
9903.88.14	20(q)(290)	9903.88.58	20(kkk)(58)	9903.88.62	20(ooo)(22)	Annex A
9903.88.14	20(q)(291)	9903.88.58	20(kkk)(59)	9903.88.62	20(ooo)(23)	Annex A
9903.88.06	20(i)(32)	9903.88.06	20(i)(32)	9903.88.62	20(ooo)(24)	Annex A
9903.88.17	20(v)(6)	9903.88.59	20(lll)(2)	9903.88.63	20(ppp)(5)	Annex B
9903.88.12	20(o)(6)	9903.88.54	20(ggg)(2)	9903.88.63	20(ppp)(6)	Annex B

Original Exclusion		First Extension		Current Extension		
Chapter 99 Heading	Note 20 Subdivision	Chapter 99 Heading	Note 20 Subdivision	Chapter 99 Heading	Note 20 Subdivision	Annex
9903.88.12	20(o)(12)	9903.88.54	20(ggg)(3)	9903.88.63	20(ppp)(7)	Annex B
9903.88.17	20(v)(34)	9903.88.59	20(lll)(9)	9903.88.63	20(ppp)(8)	Annex B
9903.88.17	20(v)(36)	9903.88.59	20(lll)(10)	9903.88.63	20(ppp)(9)	Annex B
9903.88.12	20(o)(24)	9903.88.54	20(ggg)(5)	9903.88.63	20(ppp)(10)	Annex B
9903.88.41	20(tt)(2)	9903.88.56	20(iii)(7)	9903.88.64	20(qqq)(5)	Annex C
9903.88.41	20(tt)(3)	9903.88.56	20(iii)(8)	9903.88.64	20(qqq)(6)	Annex C
9903.88.41	20(tt)(4)	9903.88.56	20(iii)(9)	9903.88.64	20(qqq)(7)	Annex C
9903.88.46	20(yy)(1)	9903.88.56	20(iii)(10)	9903.88.64	20(qqq)(8)	Annex C
9903.88.41	20(tt)(5)	9903.88.56	20(iii)(11)	9903.88.64	20(qqq)(9)	Annex C
9903.88.48	20(aaa)(14)	9903.88.56	20(iii)(12)	9903.88.64	20(qqq)(10)	Annex C
9903.88.48	20(aaa)(15)	9903.88.56	20(iii)(13)	9903.88.64	20(qqq)(11)	Annex C
9903.88.48	20(aaa)(16)	9903.88.56	20(iii)(14)	9903.88.64	20(qqq)(12)	Annex C
9903.88.40	20(ss)(1)	9903.88.56	20(iii)(15)	9903.88.64	20(qqq)(13)	Annex C
9903.88.45	20(xx)(1)	9903.88.56	20(iii)(16)	9903.88.64	20(qqq)(14)	Annex C
9903.88.35	20(nn)(2)	9903.88.56	20(iii)(32)	9903.88.64	20(qqq)(15)	Annex C
9903.88.46	20(yy)(15)	9903.88.56	20(iii)(37)	9903.88.64	20(qqq)(16)	Annex C
9903.88.48	20(aaa)(28)	9903.88.56	20(iii)(38)	9903.88.64	20(qqq)(18)	Annex C
9903.88.45	20(xx)(13)	9903.88.56	20(iii)(57)	9903.88.64	20(qqq)(20)	Annex C
9903.88.48	20(aaa)(33)	9903.88.56	20(iii)(58)	9903.88.64	20(qqq)(21)	Annex C
9903.88.13	20(p)(1)	9903.88.56	20(iii)(59)	9903.88.64	20(qqq)(24)	Annex C
9903.88.13	20(p)(2)	9903.88.56	20(iii)(60)	9903.88.64	20(qqq)(26)	Annex C
9903.88.38	20(qq)(29)	9903.88.56	20(iii)(63)	9903.88.64	20(qqq)(28)	Annex C
9903.88.38	20(qq)(30)	9903.88.56	20(iii)(64)	9903.88.64	20(qqq)(29)	Annex C
9903.88.33	20(ll)(15)	9903.88.56	20(iii)(97)	9903.88.64	20(qqq)(30)	Annex C
9903.88.37	20(pp)(34)	9903.88.56	20(iii)(134)	9903.88.64	20(qqq)(31)	Annex C
9903.88.38	20(qq)(56)	9903.88.56	20(iii)(135)	9903.88.64	20(qqq)(32)	Annex C
9903.88.43	20(vv)(128)	9903.88.56	20(iii)(197)	9903.88.64	20(qqq)(33)	Annex C
9903.88.37	20(pp)(58)	9903.88.56	20(iii)(231)	9903.88.64	20(qqq)(35)	Annex C
9903.88.37	20(pp)(59)	9903.88.56	20(iii)(232)	9903.88.64	20(qqq)(36)	Annex C
9903.88.39	20(rr)(1)	9903.88.57	20(jjj)((3)	9903.88.65	20(rrr)(1)	Annex D
9903.88.39	20(rr)(2)	9903.88.57	20(jjj)((4)	9903.88.65	20(rrr)(2)	Annex D
9903.88.39	20(rr)(3)	9903.88.57	20(jjj)((5)	9903.88.65	20(rrr)(3)	Annex D
9903.88.39	20(rr)(4)	9903.88.57	20(jjj)((6)	9903.88.65	20(rrr)(4)	Annex D
9903.88.39	20(rr)(5)	9903.88.57	20(jjj)((7)	9903.88.65	20(rrr)(5)	Annex D
9903.88.49	20(bbb)(1)	9903.88.57	20(jjj)(8)	9903.88.65	20(rrr)(6)	Annex D
9903.88.49	20(bbb)(2)	9903.88.57	20(jjj)((9)	9903.88.65	20(rrr)(7)	Annex D
9903.88.53	20(fff)(2)	9903.88.57	20(jjj)(10)	9903.88.65	20(rrr)(8)	Annex D
9903.88.39	20(rr)(6)	9903.88.57	20(jjj)((11)	9903.88.65	20(rrr)(9) 20(rrr)(10)	Annex D
9903.88.39	20(rr)(7)	9903.88.57	20(jjj)((12)	9903.88.65	20(rrr)(11)	Annex D
9903.88.39	20(rr)(8)	9903.88.57	20(jjj)((13)	9903.88.65	20(rrr)(12)	Annex D
9903.88.42	20(uu)(1)	9903.88.57	20(jjj)((20)	9903.88.65	20(rrr)(15)	Annex D

Original Exclusion		First Extension		Current Extension		
Chapter 99 Heading	Note 20 Subdivision	Chapter 99 Heading	Note 20 Subdivision	Chapter 99 Heading	Note 20 Subdivision	Annex
9903.88.44	20(ww)(6)	9903.88.57	20(jjj)((21)	9903.88.65	20(rrr)(16)	Annex D
9903.88.42	20(uu)(2)	9903.88.57	20(jjj)((22)	9903.88.65	20(rrr)(17)	Annex D
9903.88.42	20(uu)(4)	9903.88.57	20(jjj)((23)	9903.88.65	20(rrr)(18)	Annex D
9903.88.42	20(uu)(5)	9903.88.57	20(jjj)((24)	9903.88.65	20(rrr)(19)	Annex D
9903.88.49	20(bbb)(10)	9903.88.57	20(jjj)((33)	9903.88.65	20(rrr)(20)	Annex D
9903.88.42	20(uu)(6)	9903.88.57	20(jjj)((43)	9903.88.65	20(rrr)(21)	Annex D
9903.88.42	20(uu)(7)	9903.88.57	20(jjj)((44)	9903.88.65	20(rrr)(22)	Annex D
9903.88.42	20(uu)(9)	9903.88.57	20(jjj)((45)	9903.88.65	20(rrr)(23)	Annex D
9903.88.42	20(uu)(11)	9903.88.57	20(jjj)((46)	9903.88.65	20(rrr)(24)	Annex D
9903.88.42	20(uu)(12)	9903.88.57	20(jjj)((47)	9903.88.65	20(rrr)(25)	Annex D
9903.88.42	20(uu)(14)	9903.88.57	20(jjj)((48)	9903.88.65	20(rrr)(26)	Annex D
9903.88.42	20(uu)(15)	9903.88.57	20(jjj)((49)	9903.88.65	20(rrr)(27)	Annex D
9903.88.42	20(uu)(16)	9903.88.57	20(jjj)((50)	9903.88.65	20(rrr)(28)	Annex D
9903.88.42	20(uu)(17)	9903.88.57	20(jjj)((51)	9903.88.65	20(rrr)(29)	Annex D
9903.88.42	20(uu)(19)	9903.88.57	20(jjj)((62)	9903.88.65	20(rrr)(30)	Annex D

Table B. Additional Products Excluded from Section 301 Duties

Chapter 99 Heading	Note 20 Subdivision	Annex	Product Description
9903.88.62	20(ooo)(4)	Annex A	Ultrasonic scanning apparatus, each having dimensions not exceeding 122 cm by 77 cm by 127 cm, whether or not presented with transducer (described in statistical reporting number 9018.12.0000)
9903.88.62	20(ooo)(5)	Annex A	Blood pressure monitors suitable for use by medical professionals (described in statistical reporting number 9018.19.9530)
9903.88.62	20(ooo)(14)	Annex A	Anesthetic instruments and appliances suitable for use in medical or surgical sciences, and parts and accessories of the foregoing (described in statistical reporting number 9018.90.3000)
9903.88.63	20(ppp)(1)	Annex B	9025.19.8010
9903.88.63	20(ppp)(2)	Annex B	9025.19.8020
9903.88.63	20(ppp)(3)	Annex B	9025.19.8060
9903.88.63	20(ppp)(4)	Annex B	9025.19.8085
9903.88.64	20(qqq)(1)	Annex C	3808.94.1000
9903.88.64	20(qqq)(2)	Annex C	3808.94.5010
9903.88.64	20(qqq)(3)	Annex C	3808.94.5050
9903.88.64	20(qqq)(4)	Annex C	3808.94.5090
9903.88.64	20(qqq)(17)	Annex C	Hand soaps and hand sanitizers in the form of liquid or cream put up for retail sale, other than hand sanitizers of heading 3808 (described in statistical reporting number 3401.30.5000)

Chapter 99 Heading	Note 20 Subdivision	Annex	Product Description
9903.88.64	20(qqq)(22)	Annex C	Flexible oxygen tubes, pipes and hoses presented with integrated molded connectors, of polyvinyl chloride (described in statistical reporting number 3917.33.0000)
9903.88.64	20(qqq)(24)	Annex C	Sacks and bags of polymers of ethylene, reclosable, qualifying as Class 1 medical devices by the U.S. Food and Drug Administration under product code NNI (described in statistical reporting number 3923.21.0030)
9903.88.64	20(qqq)(26)	Annex C	Aprons, of plastics, of a kind used as personal protection equipment (described in statistical reporting number 3926.20.9010)
9903.88.64	20(qqq)(33)	Annex C	Data input devices each with display capabilities of a kind used for magnetic resonance imaging ("MRI") equipment, computed tomography ("CT") equipment, intraoperative X-ray ("IXR") equipment or patient monitors (described in statistical reporting number 8537.10.9170)
9903.88.65	20(rrr)(13)	Annex D	6307.90.7200
9903.88.65	20(rrr)(14)	Annex D	Face shields of transparent plastics, whether or not assembled (described in statistical reporting number 3926.90.9950)
9903.88.62	20(ooo)(4)	Annex A	Ultrasonic scanning apparatus, each having dimensions not exceeding 122 cm by 77 cm by 127 cm, whether or not presented with transducer (described in statistical reporting number 9018.12.0000)

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2020–1199; Airspace Docket No. 20–AEA–21]

Notice of Availability of Written Re-Evaluation and Record of Decision; New York/New Jersey/Philadelphia Metropolitan Area Airspace Redesign

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces the availability of a Written Re-evaluation and Record of Decision (WR/ROD) for the New York/New Jersey/Philadelphia (NY/NJ/PHL) Metropolitan Area Airspace Redesign project. This 2020 WR/ROD follows the issuance of a Final Environmental Impact Statement (EIS) for the project, issued in July 2007, and a subsequent ROD (September 2007) that approved the Integrated Airspace Alternative with Integrated Control Complex for implementation. The September 2007 ROD was followed by a corrected ROD (October 2007), as well as a WR/ROD (July 2008) that re-affirmed the original decision in light of new schedule limits at John F. Kennedy International Airport (JFK) and Newark Liberty International Airport (EWR).

DATES: The FAA's WR/ROD for the NY/NJ/PHL Metropolitan Airspace Redesign is effective December 22, 2020.

FOR FURTHER INFORMATION CONTACT: For additional information, contact Matthew Cathcart, Acting Manager, Operations Support Group, in writing to Federal Aviation Administration, Eastern Service Center, Operations Support Group, AJV–E2, FAA Southern Regional Office, P.O. Box 20636, Atlanta, GA 30320; by telephone, at (404) 305–5624; or, by electronic mail, at *Matthew.Cathcart@faa.gov.*

SUPPLEMENTARY INFORMATION: The purpose of the NY/NJ/PHL Metropolitan Area Airspace Redesign project was to increase the efficiency and reliability of the airspace structure and the Air Traffic Control (ATC) system, thereby accommodating growth while enhancing safety and reducing delays in air travel for the NY/NJ/PHL Metropolitan Area. The Airspace Redesign project was intended to modernize the structure of the NY/NJ/PHL air traffic environment while laying a foundation for achieving the Next Generation Air Transportation System (NextGen) in an environmentally responsible manner.

While four stages of implementation were originally planned, FAA paused the project in 2012 in light of air transportation system changes in the intervening years. While several beneficial elements of the project were implemented, the National Airspace System evolved significantly between the 2007 EIS and 2012. New NextGen capabilities, such as Time Based Metering and advanced satellite based navigation procedures, and increasing consolidation of the airline industry, changes in system use, and evolving traffic projections resulted in new and different airspace and procedures requirements. As a result, the FAA suspended the Airspace Redesign project in May 2013. The FAA has determined it is appropriate to end implementation and has prepared the aforementioned December 2020 WR/ROD. The WR/ROD may be accessed on the FAA's public website: *https://*

www.faa.gov/air_traffic/nas/nynjphl_redesign/documentation/.

This Notice of Availability of the December 2020 WR/ROD also serves as the response to Section 560 of the FAA Reauthorization Act of 2018, which imposed the following requirement:

Not later than 90 days after the date of enactment of this Act, the Administrator shall develop and publish in the **Federal Register** *a work plan for the New York/New Jersey/Philadelphia Metropolitan Area Airspace Project.*

As discussed above, work on the NY/NJ/PHL Metropolitan Area Airspace Redesign project was suspended in May 2013, and the FAA has determined it is appropriate to end implementation. There is no work plan for the project beyond the preparation of the December 2020 WR/ROD and this Notice.

Issued in Atlanta, Georgia, on December 22, 2020.

Ryan W. Almasy,

Director (Acting), Eastern Service Center, Mission Support Services, Air Traffic Organization, Federal Aviation Administration.

[FR Doc. 2020–28745 Filed 12–28–20; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[FMCSA Docket No. FMCSA–2020–0051]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt five individuals from the requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) that interstate commercial motor vehicle (CMV) drivers have ''no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV.'' The exemptions enable these individuals who have had one or more seizures and are taking anti-seizure medication to operate CMVs in interstate commerce.

DATES: The exemptions were applicable on November 27, 2020. The exemptions expire on November 27, 2022.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 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. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to *http://www.regulations.gov/docket?D=FMCSA-2020-0051* and choose the document to review. 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.

B. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. 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.transportation.gov/privacy.*

II. Background

On October 28, 2020, FMCSA published a notice announcing receipt of applications from five individuals requesting an exemption from the epilepsy and seizure disorders prohibition in 49 CFR 391.41(b)(8) and requested comments from the public (85 FR 68407). The public comment period ended on November 27, 2020, and 10 comments were received.

FMCSA has evaluated the eligibility of these applicants and determined that granting exemptions to these individuals would achieve a level of safety equivalent to, or greater than, the level that would be achieved by complying with § 391.41(b)(8).

The physical qualification standard for drivers regarding epilepsy found in § 391.41(b)(8) states that a person is physically qualified to drive a CMV if that person has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a CMV.

In addition to the regulations, FMCSA has published advisory criteria [1] to assist medical examiners (MEs) in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce.

III. Discussion of Comments

FMCSA received 10 comments in this proceeding. Of the 10 comments received, nine were in support of the exemptions and one was outside the scope of this notice.

IV. Basis for Exemption Determination

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 Agency's decision regarding these exemption applications is based on the 2007 recommendations of the Agency's Medical Expert Panel. The Agency conducted an individualized assessment of each applicant's medical information, including the root cause of the respective seizure(s) and medical information about the applicant's seizure history, the length of time that has elapsed since the individual's last seizure, the stability of each individual's treatment regimen and the duration of time on or off of anti-seizure medication. In addition, the Agency reviewed the treating clinician's medical opinion related to the ability of the driver to safely operate a CMV with a history of seizure and each applicant's driving record found in the Commercial Driver's License Information System for commercial driver's license (CDL) holders, and interstate and intrastate inspections recorded in the Motor Carrier Management Information System. For non-CDL holders, the Agency reviewed the driving records from the State Driver's Licensing Agency. A summary of each applicant's seizure history was discussed in the October 28, 2020, **Federal Register**

[1] These criteria may be found in APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section H. Epilepsy: § 391.41(b)(8), paragraphs 3, 4, and 5, which is available on the internet at *https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol5/pdf/CFR-2015-title49-vol5-part391-appA.pdf.*

notice (85 FR 68407) and will not be repeated in this notice.

These five applicants have been seizure-free over a range of eight to 14 years while taking anti-seizure medication and maintained a stable medication treatment regimen for the last 2 years. In each case, the applicant's treating physician verified his or her seizure history and supports the ability to drive commercially.

The Agency acknowledges the potential consequences of a driver experiencing a seizure while operating a CMV. However, the Agency believes the drivers granted this exemption have demonstrated that they are unlikely to have a seizure and their medical condition does not pose a risk to public safety.

Consequently, FMCSA finds that in each case exempting these applicants from the epilepsy and seizure disorder prohibition in § 391.41(b)(8) is likely to achieve a level of safety equal to that existing without the exemption.

V. Conditions and Requirements

The terms and conditions of the exemption are provided to the applicants in the exemption document and includes the following: (1) Each driver must remain seizure-free and maintain a stable treatment during the 2-year exemption period; (2) each driver must submit annual reports from their treating physicians attesting to the stability of treatment and that the driver has remained seizure-free; (3) each driver must undergo an annual medical examination by a certified ME, as defined by § 390.5; and (4) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy of his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

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 five exemption applications, FMCSA exempts the following drivers from the epilepsy and seizure disorder prohibition, § 391.41(b)(8), subject to the requirements cited above:

Scott Baggarley (WA)
Keith E. Hubbard (WV)
Billy R. Hunter (KY)
Devyn R. Roberts (KY)
Saundra Wesselman (IN)

In accordance with 49 U.S.C. 31315(b), each exemption will be valid for 2 years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (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 prior to being 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).

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2020–28609 Filed 12–28–20; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket Number NHTSA–2020–0101]

Agency Information Collection Activities; Notice and Request for Comment; Reporting of Information and Documents About Potential Defects

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for public comments on a reinstatement with modification of a previously approved collection of information.

SUMMARY: The National Highway Traffic Safety Administration (NHTSA) invites public comments about our intention to request Office of Management and Budget (OMB) approval for a reinstatement with modification of a currently approved information collection. Before a Federal agency can collect certain information from the public, it must receive approval from OMB. Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatements of previously approved collections. This document describes a collection of information for which NHTSA intends to seek OMB approval.

DATES: Comments must be received on or before March 1, 2021.

ADDRESSES: You may submit comments identified by the Docket No. NHTSA–2020–0101 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, 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) 366–9322 before coming.
- *Fax:* 202–493–2251.

Instructions: All submissions must include the agency name and docket number for this proposed collection of information. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *https://www.transportation.gov/privacy.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or the street address listed above. To be sure someone is there to help you, please call (202) 366–9322 before coming. Follow the online instructions for accessing the dockets.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact, Tanya Topka, Trends Analysis Division (NEF–108), Room W48–337, National Highway Traffic Safety Administration, 1200 New Jersey Ave., Washington, DC 20590. Telephone: (202) 366–9590. Please identify the relevant collection of information by referring to its OMB Control Number.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must first publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information.

The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulation, *see* 5 CFR 1320.8(d), an agency must ask for public comment on the following: (a) 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; (b) 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; (c) how to enhance the quality, utility, and clarity of the information to be collected; and (d) how to minimize the burden of the collection of information on those who are to respond, including 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. In compliance with these requirements, NHTSA asks for public comments on the following collection of information:

Title: Reporting of Information and Documents About Potential Defects.

OMB Control Number: 2127–0616.

Type of Request: Reinstatement with modification of a previously approved information collection.

Type of Review Requested: Regular.

Requested Expiration Date of Approval: 3 years from date of approval.

Background and Summary of the Collection of Information: This notice requests comment on NHTSA's intention to seek approval from OMB to reinstate with modification a previously approved collection of information, OMB No. 2127–0616, covering requirements in 49 CFR 579, *Reporting of Information and Communications about Potential Defects.* Part 579 implements, and addresses with more specificity, requirements from the Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act (Pub. L. 106–414), which was enacted on November 1, 2000, and are codified at 49 U.S.C. 30166.

The purpose of part 579 is to enhance motor vehicle safety by specifying information and documents that manufacturers of motor vehicles and motor vehicle equipment must provide to NHTSA with respect to possible safety-related defects and non-compliances in their products, including the reporting of safety recalls and other safety campaigns the manufacturers conduct outside the United States. Under part 579, there are three categories of reporting requirements: (1) Requirements at § 579.5 to submit notices, bulletins, customer satisfaction campaigns, consumer advisories, and other communications (found in Subpart A of part 579); (2) requirements at § 579.11 to submit information related to safety recalls and other safety campaigns in foreign countries (found in Subpart B of part 579); and (3) requirements at §§ 579.21–28 to submit Early Warning Information (found in Subpart C of part 579). The Early Warning Reporting (EWR) requirements (49 U.S.C. 30166(m); 49 CFR part 579, subpart C) specify that manufacturers of motor vehicles and motor vehicle equipment must submit to NHTSA information, periodically or upon NHTSA's request, that includes claims for deaths and serious injuries, property damage data, communications from customers and others, information on incidents resulting in fatalities or serious injuries from possible defects in vehicles or equipment in the United States or in identical or substantially similar vehicles or equipment in a foreign country, and other information that assists NHTSA in identifying potential safety-related defects. The intent of this information collection is to provide early warning of such potential safety-related defects to NHTSA.

Description of the Need for the Information and Proposed Use of the Information: The information required under 49 U.S.C. 30166 and 49 CFR part 579 is used by NHTSA to promptly identify potential safety-related defects in motor vehicles and motor vehicle equipment in the United States. When a trend in incidents arising from a potentially safety-related defect is discovered, NHTSA relies on this information, along with other agency data, to determine whether or not to open a defect investigation.

Affected Public: Manufacturers of motor vehicles and motor vehicle equipment.

Estimated Number of Respondents: NHTSA receives part 579 submissions from approximately 337 manufacturers per year. We estimate that there will be a total of 337 respondents per year associated with OMB No. 2127–0616.

Estimated Total Annual Burden Hours: When this approved information collection was last renewed in June 2017, NHTSA estimated the annual burden associated with this collection to be 49,243 burden hours. NHTSA is updating these estimates to better align with the current volume of submissions and to include reporting for common green tires and follow-up sequences (per § 579.28(l)) that were left out of the previous information collection request. NHTSA now estimates that the annual burden hours associated with this collection are 53,810 hours and that the collection requires no additional costs to the respondents beyond the labor costs associated with the burden hours.

NHTSA estimated the burdens associated with this labor by calculating the burden associated with submitting information under each subpart of part 579. In addition to these burdens, NHTSA also estimates that manufacturers will incur computer maintenance burden hours, which are estimated on a per manufacturer basis.

Requirements Under Part 579, Subpart A

The first component of this collection request covers the requirements found in part 579 Subpart A, § 579.5, Notices, bulletins, customer satisfaction campaigns, consumer advisories, and other communications. Section 579.5 requires manufactures to furnish (1) a copy of all notices, bulletins, and other communications sent to more than one manufacturer, distributor, dealer, lessor, lessee, owner, or purchaser, in the United States, regarding any defect in its vehicles or items of equipment (including any failure or malfunction beyond normal deterioration in use, or any failure of performance, or any flaw or unintended deviation from design specifications), whether or not such defect is safety-related and (2) a copy of each communication relating to a customer satisfaction campaign, consumer advisory, recall, or other safety activity involving the repair or replacement of motor vehicles or equipment, that the manufacturer issued to, or made available to, more than one dealer, distributor, lessor, lessee, other manufacturer, owner, or purchaser, in the United States. Manufacturers are required to submit this information monthly. However, Section 579.5 does not require manufacturers to create these documents. Instead, only copies of these documents must be submitted to NHTSA and manufacturers must index these communications and email them to NHTSA within 5 working days after the end of the month in which they were issued. Therefore, the burden hours are only those associated with collecting the documents and submitting copies to NHTSA.

NHTSA estimates that it receives approximately 24,884 notices a year. We estimate that it takes about 5 minutes to collect, index, and send each notice to NHTSA. Therefore, we estimate that it takes 2,074 hours for manufacturers to submit notices as required under Section 579.5 (24,884 notices × 5 minutes = 124,420 minutes or 2,074 hours).

To calculate the labor cost associated with submitting Section 579.5 notices, bulletins, customer satisfaction campaigns, consumer advisories and other communications that are sent to more than one dealer or owner, NHTSA looked at wage estimates for the type of personnel submitting the documents. While some manufacturers employ clerical staff to collect and submit the documents, others use technical computer support staff to complete the task. Because we do not know what percent of the work is completed by clerical or technical computer support staff, NHTSA estimates the total labor costs associated with these burden hours by looking at the average wage for the higher paid technical computer support staff. The Bureau of Labor Statistics (BLS) estimates that the average hourly wage for Computer Support Specialists (BLS Occupation code 15–1230) in the Motor Vehicle Manufacturing Industry is $31.39.[1] The Bureau of Labor Statistics estimates that private industry workers' wages represent 70.2% of total labor compensation costs.[2] Therefore, NHTSA estimates the hourly labor costs to be $44.72 for Computer Support Specialists. The labor cost per submission is estimated to be $3.73 ($44.72 × 5 minutes). NHTSA estimates the total labor cost associated with the 2,074 burden hours for § 579.5 submissions to be $92,817.32 ($3.73 × 24,884 submissions). Table 1 provides a summary of the burden estimates using the average annual submission count for monthly reports submitted pursuant to § 579.5 and the estimated burden hours and labor costs associated with those submissions.

TABLE 1—BURDEN ESTIMATES FOR § 579.5 SUBMISSIONS

Average annual § 579.5 submissions	Estimated burden per submission	Average hourly labor cost	Labor cost per submission	Total burden hours	Total labor costs
24,884	5 minutes	$44.72	$3.73	2,074	$92,817.32 or $92,817

Requirements Under Part 579, Subpart B (Foreign Reporting)

The second component of this information collection request covers the requirements found in part 579 Subpart B, ''Reporting of Safety Recalls and Other Safety Campaigns in Foreign Countries.'' Pursuant to § 579.11, whenever a manufacturer determines to conduct a safety recall or other safety campaign in a foreign country, or whenever a foreign government has determined that a safety recall or other safety campaign must be conducted, covering a motor vehicle, item of motor vehicle equipment, or tire that is identical or substantially similar to a vehicle, item of equipment, or tire sold or offered for sale in the United States, the manufacturer must report to NHTSA not later than 5 working days after the manufacturer makes such determination or receives written notification of the foreign government's determination. Section 579.11(e) also requires each manufacturer of motor vehicles to submit, not later than November 1 of each year, a document that identifies foreign products and their domestic counterparts.

In order to provide the information required for foreign safety campaigns, manufacturers must (1) determine whether vehicles or equipment that are covered by a foreign safety recall or other safety campaign are identical or substantially similar to vehicles or equipment sold in the United States, (2) prepare and submit reports of these campaigns to the agency, and (3) where a determination or notice has been made in a language other than English, translate the determination or notice into English before transmitting it to the agency.

NHTSA estimates that there is no burden associated with determining whether an individual safety recall covers a foreign motor vehicle or item of motor vehicle equipment that is identical or substantially similar to those sold in the United States because manufacturers can simply consult the list that they are required to submit each year. Therefore, the only burden associated with making the determination of whether a foreign safety recall or other safety campaign is required to be reported to NHTSA is the burden associated with creating the annual list. NHTSA continues to estimate that it takes approximately 9 hours per manufacturer to develop and submit the list. The 9 hours are comprised of 8 attorney hours and 1 hour for IT work. NHTSA receives these lists from 101 manufacturers, on average, resulting in 909 burden hours (101 vehicle manufacturers × 8 hours for attorney support = 808 hours) + (101 vehicle manufacturers × 1 hour for IT support = 101 hours).

NHTSA estimates that preparing and submitting each foreign defect report (foreign recall campaign) requires 1 hour of clerical staff and that translation of determinations into English requires 2 hours of technical staff (note: This assumes that all foreign campaign reports require translation, which is unlikely). Between 2016 and 2018, NHTSA received a yearly average of 227 foreign recall reports. NHTSA estimates that in each of the next three years, NHTSA will receive, on average, 227 foreign recall reports. NHTSA estimates that each report will take 3 hours (1 hour to prepare by a clerical employee and 2 hours for translation). Therefore, NHTSA estimates that the burden hours associated with submitting these reports will be 681 hours (3 hours per report × 227 reports).

Therefore, NHTSA estimates the total annual burden hours on manufacturers for reporting foreign safety campaigns and substantially similar vehicles/equipment is 1,590 hours (909 hours for submitting annual lists + 681 hours for submitting foreign recall and safety campaign reports). This is an increase of 444 burden hours from our previous estimate (1,590 hours for current estimate − 1,146 hours for previous estimate). Table 2 provides a summary of the estimated burden hours for part 579 Subpart B submissions.

[1] May 2019 National Industry-Specific Occupational Employment and Wage Estimates NAICS 336100—Motor Vehicle Manufacturing, U.S. Bureau of Labor Statistics, *https://www.bls.gov/oes/current/naics4_336100.htm#15-0000*. Last Accessed June 17, 2020.

[2] Employer Costs for Employee Compensation, U.S. Bureau of Labor Statistics, *https://www.bls.gov/news.release/ecec.t01.htm*. Last Accessed July 30, 2020.

TABLE 2—BURDEN HOUR ESTIMATES FOR FOREIGN REPORTING

Submission type	Annual number of submissions	Burden hours per report	Total burden hours
Foreign Recall/Safety-Related Campaign Report	227	1 hour clerical + 2 hours translation = 3 hours	681
Annual List	101	8 hours attorney + 1 hour IT = 9 hours	909
Total			1,590

To calculate the labor cost associated with part 579 foreign reporting submissions, NHTSA looked at wage estimates for the type of personnel submitting the documents. As stated above, NHTSA estimates that submitting annual lists under § 579.11(e) will involve 8 hours of attorney time and 1 hour of IT work. The Bureau of Labor Statistics (BLS) estimates that the average hourly wage for Lawyers (BLS Occupation code 23–1000) in the Motor Vehicle Manufacturing Industry is $95.85 [3] and the average hourly wage for Computer Support Specialists (BLS Occupation code 15–1230) in the Motor Vehicle Manufacturing Industry is $31.39.[4] The Bureau of Labor Statistics estimates that private industry workers, wages represent 70.2% of total labor compensation costs.[5] Therefore, NHTSA estimates the hourly labor costs to be $136.54 for Lawyers and $44.72 for Computer Support Specialists. NHTSA estimates the total labor cost associated with submitting one annual list to be $1,137.04 ($136.54 per hour × 8 attorney hours + $44.72 per hour × 1 IT hour) and $114,841.04 or $114,841 for all 101 annual lists NHTSA estimates will be submitted annually.

NHTSA estimates that submitting each foreign recall or safety campaign report involves 1 hour of clerical work and 2 hours of translation work. The Bureau of Labor Statistics (BLS) estimates that the average hourly wage for Office Clerks (BLS Occupation code 43–9061) in the Motor Vehicle Manufacturing Industry is $20.74 [6] and the average hourly wage for Interpreters and Translators (BLS Occupation code 27–3091) is $27.40.[7] The Bureau of Labor Statistics estimates that private industry workers' wages represent 70.2% of total labor compensation costs.[8] Therefore, NHTSA estimates the hourly labor costs to be $29.54 for Office Clerks and $39.03 for Interpreters and Translators. NHTSA estimates the total labor cost associated with submitting one foreign recall or safety campaign report to be $107.60 ($29.54 per hour × 1 Clerical hour + $39.03 per hour × 2 Translator hours) and $24,425.20 or $24,425 for all 227 foreign recall or safety campaign reports NHTSA estimates will be submitted annually.

Table 3 provides a summary of the labor costs associated with the foreign reporting requirements in part 579, Subpart B. NHTSA estimates that the total labor costs associated with the annual list requirement and the requirement to report foreign recalls and safety campaigns is $139,266 ($114,841 + $24,425).

TABLE 3—ANNUAL LABOR COST ESTIMATES FOR FOREIGN REPORTING

Submission type and labor category	Hours per submission	Hourly labor cost	Labor cost per submission	Number of submissions	Total labor cost
Annual List—Lawyer	8	$136.54	$1,092.32	101	$110,324.32.
Annual List—Computer Specialist	1	44.72	44.72	101	$4,516.72.
Totals for Annual List	9		1,137.04		$114,841.04 or $114,841.
Foreign Recall/Safety—Related Campaign Report—Clerical.	1	29.54	29.54	227	$6,705.58.
Foreign Recall/Safety—Related Campaign Report—Translator.	2	39.03	78.06	227	$17,719.62.
Totals for Foreign Recall/Safety Campaign Report.	3		107.60		$24,425.20 or $24,425.
Total Labor Costs for Part 579 Subpart B Requirements.					$139,266.24 or $139,266.

[3] May 2019 National Industry-Specific Occupational Employment and Wage Estimates NAICS 336100—Motor Vehicle Manufacturing, U.S. Bureau of Labor Statistics, *https://www.bls.gov/oes/current/naics4_336100.htm#23-0000.*

[4] *https://www.bls.gov/oes/current/naics4_336100.htm#15-0000.*

[5] Employer Costs for Employee Compensation, U.S. Bureau of Labor Statistics, *https://www.bls.gov/news.release/ecec.t01.htm.* Last Accessed July 31, 2020.

[6] May 2019 National Industry-Specific Occupational Employment and Wage Estimates NAICS 336100—Motor Vehicle Manufacturing, U.S. Bureau of Labor Statistics, *https://www.bls.gov/oes/current/naics4_336100.htm#43-0000.* Last Accessed June 17, 2020.

[7] May 2019 National Occupational Employment and Wage Estimates United States, U.S. Bureau of Labor Statistics, *https://www.bls.gov/oes/current/oes_nat.htm.* Last Accessed June 17, 2020.

[8] Employer Costs for Employee Compensation, U.S. Bureau of Labor Statistics, *https://www.bls.gov/news.release/ecec.t01.htm.* Last Accessed July 31, 2020.

Requirements Under Part 579, Subpart C (Reporting of Early Warning Information (EWR))

The third component of this information collection covers the requirements found in Part 579 Subpart C, ''Reporting of Early Warning Information.'' Besides production information, there are five major categories requiring reporting of incidents or claims in Subpart C, with the specific requirements and applicability of those categories varying by vehicle and equipment type and, in some circumstances, manufacturer volume. Sections 579.21–27 require manufacturers to submit the following: (1) Production information; (2) reports on incidents involving death or injury in the United States; (3) reports on incidents involving one or more deaths in a foreign country involving a vehicle or item of equipment that is identical or substantially similar to a vehicle or item of equipment that is offered for sale in the United States; (4) separate reports on the number of property damage claims, consumer complaints, warranty claims, and field reports that involve a specified system or event; (5) copies of field reports; and, for manufacturers of tires, (6) a list of common green tires (applicable to only tire manufacturers). Section 579.28(l) allows NHTSA to request additional related information to help identify a defect related to motor vehicle safety. The regulation specifies the time frame for reporting for each category. Foreign recalls of substantially similar vehicles and manufacturer communications are required to be submitted monthly, substantially similar vehicle listings are required annually, and all other report types are required to be submitted on a quarterly basis.

Production Information—Quarterly Reporting

Manufacturers are required to report production information to NHTSA on a quarterly basis (*e.g.,* 4 times per calendar year).[9] Estimates of the burden hours and reporting costs are based on:

- The number of manufacturers reporting;
- The frequency of required reports;
- The number of hours required per report; and
- The cost of personnel to report.

The number of hours for reporting ranges from 1 hour for trailer manufacturers to 8 hours for light vehicle manufacturers (Table 4). Quarterly reporting burden hours are calculated by multiplying hours used to report for a given category by the number of manufacturers for the category and by the four times per year quarterly reporting. Using these methods and the average number of manufacturers who report annually, we estimate the annual burden hours for quarterly reporting at 5,216 hours as detailed below in Table 4.

NHTSA assumes that 50 percent of the total burden hours are utilized by technical personnel while clerical staff consumes the remaining 50 percent. In other words, the hourly wage rate for each quarterly report is split evenly between technical and clerical personnel and a weighted hourly rate is developed from this assumption. Therefore, using the BLS total hourly compensation rates discussed above of $44.72 for a Computer Support Specialist and $29.54 for an Office Clerk, the weighted hourly rate is $37.13 (Technical Mean Hourly Wage of $44.72 × 0.5 + Clerical Mean Hourly Wage of $29.54 × 0.5). The estimated reporting costs are calculated as follows:

$$(M \times T_p \times \$37.13 = \text{quarterly cost of reporting}) \times 4 = \text{annual cost of reporting}\ *$$

* M = Manufacturers reporting data in the category; T_p = Reporting time for the category; $37.13 = Reporting labor cost compensation rate; 4 = Quarterly reports per year

For example, the estimated reporting cost for light vehicles is $42,773.76 (36 manufacturers × 8 hours × $37.13 compensation rate × 4 quarters), and the total annual labor costs associated with quarterly reporting are estimated to be $193,670. Table 4 includes the estimated burden hours and reporting costs for non-dealer field reports, aggregate submissions, and death and injury submissions, as well as the quarterly and annual labor costs associated with reporting.

TABLE 4—ESTIMATED MANUFACTURER ANNUAL BURDEN HOURS AND LABOR COSTS FOR QUARTERLY REPORTING

Vehicle/equipment category	Average number of manufacturers	Quarterly hours to report per manufacturer	Blended hourly comp. rate	Quarterly labor costs per manufacturer	Annual burden hours for reporting	Annual labor costs
Light Vehicles	36	8	$37.13	$297.04	1,152	$42,773.76.
Medium-Heavy Vehicles	39	5	37.13	185.65	780	28,961.40.
Trailers	96	1	37.13	37.13	384	14,257.92.
Motorcycles	15	2	37.13	74.26	120	4,455.60.
Emergency Vehicles	8	5	37.13	185.65	160	5,940.80.
Buses	33	5	37.13	185.65	660	24,505.80.
Tires	32	5	37.13	185.65	640	23,763.20.
Child Restraints	42	1	37.13	37.13	168	6,237.84.
Vehicle Equipment	36	8	37.13	297.04	1,152	42,773.76.
Totals		40			5,216	$193,670.08 or $193,670.

Early Warning Reporting (EWR) Submissions

Table 5 provides an average annual submission count for each category submitted per the requirements of 49 CFR part 579, subpart C: Reports on incidents involving death or injury in the United States; reports on incidents involving one or more deaths in a foreign country involving a vehicle or item of equipment that is identical or substantially similar to a vehicle or item of equipment that is offered for sale in the United States; separate reports on the number of property damage claims, consumer complaints, warranty claims, and field reports that involve a specified system or event; copies of field reports; and, for manufacturers of tires, a list of common green tires; and additional

[9] Low volume and equipment manufacturers are not required to submit production information.

follow-up information per § 579.28(l) related to injury and fatality claims or comprehensive inquiries. Each reporting category has specific requirements and types of reports that need to be submitted and we state ''N/A'' where there is no requirement for that reporting category.

TABLE 5—ANNUAL AVERAGE OF EWR SUBMISSIONS BY MANUFACTURERS
[2016–2018]

Category of claims	Light vehicles	Heavy, med vehicles	Trailers	Motor-cycles	Emer-gency vehicles	Buses	Tires	Child restraints	Equip-ment mfr.	Totals
Incidents Involving Injury or Fatality in U.S	11,124	39	30	133	8	33	58	453	9	11,887
Incidents Involving Fatality in Foreign Country	146	6	5	2	0	1	3	167	0	330
Reports on Number of Claims Involving Specific System or Event	10,261	666	91	40	0	0	1,154	NA	NA	12,212
Mfr. Field Reports	66,722	16,639	20	1,301	0	0	NA	3,727	NA	88,409
Common Green Tire Reporting	NA	NA	NA	NA	NA	NA	112	NA	NA	112
Average Number of Follow-Up Sequences per 579.28(l)	148	10	3	5	1	1	3	17	2	190
Totals:	88,401	17,360	149	1,481	9	35	1,330	4,364	11	113,140

The above updated submission totals represent an 12% increase from the previously approved information collection. Submission totals for each category have risen with an average of 11,887 injury and fatality claims in the United States (previously 9,804 claims), 330 foreign death claims (previously 101 claims), 12,212 claims involving specific system or event (previously 11,481 claims), 88,409 manufacturer field reports (previously 79,297 field reports), 112 common green tire reports, and 190 injury and fatality or comprehensive inquiry follow-up sequences per § 579.28(l), totaling 113,140 submissions on average (previously estimated at 100,683 submissions).

The agency estimates that an average of 5 minutes is required for a manufacturer to process each report, except for foreign death claims and follow-up responses. We estimate foreign death claims and follow-up responses per § 579.28(l) require an average of 15 minutes to process. Multiplying the total average number of minutes by the number of submissions NHTSA receives in each reporting category yields the burden hour estimates found below in Table 6. Our previous estimates of Early Warning associated burden hours totaled 8,407, and we now update that total to 9,515 burden hours, a 13.2% increase, associated with the above noted claim categories.

TABLE 6—ANNUAL MANUFACTURER BURDEN HOUR ESTIMATES FOR EWR SUBMISSIONS

Category of claims	Annual average of EWR submissions	Average time to process each report (min.)	Estimated annual burden hours
Incidents Involving Injury or Fatality in U.S	11,887	5	990.58
Incidents Involving Fatality in Foreign Country	330	15	82.50
Reports on Number of Claims Involving Specific System or Event	12,212	5	1,017.67
Mfr. Field Reports	88,409	5	7,367.42
Common Green Tire Reporting	112	5	9.33
Average Number of Follow-Up Sequences per 579.28(l)	190	15	47.5
Totals:	113,140	.....	9,515

Thus, the total estimated annual manufacturer burden hours for Sections 579.21–28 (EWR submissions and quarterly reporting) are 14,731 hours (5,216 (Table 4) + 9,515 (Table 6).

We have also constructed various estimates of the average five minutes of labor among the various occupations depending on the type of claim that was reviewed. Table 7 shows the estimated time allocations that it will take an individual to review each type of claim (in minutes) and the weighted hourly rate for individuals involved.

TABLE 7—ESTIMATED MANUFACTURER TIME ALLOCATION BY CLAIM TYPE AND WEIGHTED HOURLY RATE

Claim type	Estimated time (in minutes) to review a claim						
	Lawyer (rate: $136.54 [10])	Engineer (rate $63.03 [11])	IT (rate: $66.82 [12])	Technical (rate: $44.72 [13])	Clerical (rate: $29.54 [14])	Total time	Weighted hourly rate
Incidents Involving Injury or Fatality in U.S	3	0	0	0	2	5	$93.74
Incidents Involving Fatality in Foreign Country	3	10	0	0	2	15	73.27
Reports on Number of Claims Involving Specific System or Event	0	0	0	3	2	5	38.65
Mfr. Field Reports	0	0	0	3	2	5	38.65
Green Tire Events	0	0	0	0	5	5	29.54

TABLE 7—ESTIMATED MANUFACTURER TIME ALLOCATION BY CLAIM TYPE AND WEIGHTED HOURLY RATE—Continued

Claim type	Estimated time (in minutes) to review a claim						
	Lawyer (rate: $136.54 [10])	Engineer (rate $63.03 [11])	IT (rate: $66.82 [12])	Technical (rate: $44.72 [13])	Clerical (rate: $29.54 [14])	Total time	Weighted hourly rate
Average Number of Follow-Up Sequences per 579.28(l)	3	10	0	0	2	15	73.27

The total labor costs for claims documents were obtained using the following formula:

K × T × W = Costs for claim type *

* K = Claims submitted by industry; T = Estimated time spent on a claim; W = Weighted Hourly Rate.

Table 8 shows the annual labor costs of reporting EWR information to NHTSA.

TABLE 8—ESTIMATED EWR ANNUAL LABOR COSTS BY CATEGORY

Category of claims	Annual average of EWR submissions	Average time to process each report (min.)	Weighted hourly rate	Estimated labor cost per submission	Estimated annual labor cost
Incidents Involving Injury or Fatality in U.S	11,887	5	$93.74	$7.81	$92,857.28.
Incidents Involving Fatality in Foreign Country	330	15	73.27	18.32	6,044.78.
Reports on Number of Claims Involving Specific System or Event.	12,212	5	38.65	3.22	39,332.82.
Mfr. Field Reports	88,409	5	38.65	3.22	284,750.65.
Common Green Tire Reporting	112	5	29.54	2.46	275.71.
Average Number of Follow-Up Sequences per 579.28(l).	190	15	73.27	18.32	3,480.33.
Totals:	113,140	.....	.....	.....	426,741.56 or 426,742.

Computer Maintenance Burden

In addition to the burden associated with submitting documents under each subpart of part 579, NHTSA also estimates that manufacturers will incur computer maintenance burden hours associated with the information collection requirements. The estimated manufacturer burden hours associated with aggregate data submissions for consumer complaints, warranty claims, and dealer field reports are included in reporting and computer maintenance hours. The burden hours for computer maintenance are calculated by multiplying the hours of computer use (for a given category) by the number of manufacturers reporting in a category. NHTSA estimates that light vehicle manufacturers will spend approximately 347 hours per year on computer maintenance and that other vehicle manufacturers will spend about 25% as much time as light vehicle manufacturers on computer maintenance. Therefore, NHTSA estimates that medium-heavy truck, trailer, motorcycle manufacturers, emergency vehicle, and bus manufacturers will each spend approximately 86.5 hours on computer maintenance each year. NHTSA estimates that tire manufacturers and child restraint manufacturers will also spend 86.5 hours on computer maintenance per year. Therefore, NHTSA estimates the total burden for computer maintenance to be 35,415 hours per year (based on there being an estimated 36 light vehicle manufacturers, 39 medium-heavy vehicle manufacturers, 96 trailer manufacturers, 15 motorcycle manufacturers, 8 emergency vehicle manufacturers, 33 bus manufacturers, 32 tire manufacturers, and 42 child restraint manufactures).

To calculate the labor cost associated with computer maintenance hours, NHTSA looked at wage estimates for the type of personnel submitting the documents. The Bureau of Labor Statistics (BLS) estimates that the average hourly wage for Computer Support Specialists (BLS Occupation code 15–1230) in the Motor Vehicle Manufacturing Industry is $31.39.[15] The Bureau of Labor Statistics estimates that private industry workers' wages represent 70.2% of total labor compensation costs.[16] Therefore, NHTSA estimates the hourly labor costs to be $44.72 for Computer Support Specialists. For the estimated total of 35,415 annual computer maintenance burden hours, NHTSA estimates the associated labor costs will be approximately $1,583,736. Table 9

[10] May 2019 National Industry-Specific Wage Estimates—Motor Vehicle Manufacturing, U.S. Bureau of Labor Statistics, Lawyers (Code 23–1000), $95.85, *https://www.bls.gov/oes/current/naics4_336100.htm#23-0000,* divided by 70.2% for compensation rate, *https://www.bls.gov/news.release/ecec.t01.htm.*

[11] May 2019 National Industry-Specific Wage Estimates—Motor Vehicle Manufacturing, U.S. Bureau of Labor Statistics, Engineers (Code 17–2000), $44.25, *https://www.bls.gov/oes/current/naics4_336100.htm#17-0000,* divided by 70.2% for compensation rate, *https://www.bls.gov/news.release/ecec.t01.htm.*

[12] May 2019 National Occupational Employment and Wage Estimates, U.S. Bureau of Labor Statistics, Computer and Information Analysts (Code 15–1210), $46.91, *https://www.bls.gov/oes/current/oes_nat.htm#15-0000,* divided by 70.2% for compensation rate, *https://www.bls.gov/news.release/ecec.t01.htm.*

[13] May 2019 National Industry-Specific Wage Estimates—Motor Vehicle Manufacturing, U.S. Bureau of Labor Statistics, Computer Support Analyst (Code 15–1230), $31.39, *https://www.bls.gov/oes/current/naics4_336100.htm#15-0000,* divided by 70.2% for compensation rate, *https://www.bls.gov/news.release/ecec.t01.htm.*

[14] May 2019 National Industry-Specific Wage Estimates—Motor Vehicle Manufacturing, U.S. Bureau of Labor Statistics, Office Clerks (Code 43–9061), $20.74, *https://www.bls.gov/oes/current/naics4_336100.htm#43-0000,* divided by 70.2% for compensation rate, *https://www.bls.gov/news.release/ecec.t01.htm.*

[15] *https://www.bls.gov/oes/current/naics4_336100.htm#15-0000.*

[16] Employer Costs for Employee Compensation, U.S. Bureau of Labor Statistics, *https://www.bls.gov/news.release/ecec.t01.htm.* Last Accessed July 31, 2020.

shows the annual estimated burden hours for computer maintenance by vehicle/equipment category and the estimated labor costs associated with those burden hours.

TABLE 9—ESTIMATED MANUFACTURER ANNUAL BURDEN HOURS FOR COMPUTER MAINTENANCE FOR REPORTING

Vehicle/equipment category	Average number of manufacturers	Hours for computer maintenance per manufacturer	Average hourly labor cost	Annual burden hours for computer maintenance	Total labor costs
Light Vehicles	36	347	$44.72	12,492	$558,642.24.
Medium-Heavy Vehicles	39	86.5	44.72	3,373.5	150,862.92.
Trailers	96	86.5	44.72	8,304	371,352.88.
Motorcycles	15	86.5	44.72	1,297.5	58,024.20.
Emergency Vehicles	8	86.5	44.72	692	30,946.24.
Buses	33	86.5	44.72	2,854.5	127,653.24.
Tires	32	86.5	44.72	2,768	123,784.96.
Child Restraints	42	86.5	44.72	3,633	162,467.76.
Totals				35,414.5 or 35,415 hours	1,583,736.44 or 1,583,736.

Based on the foregoing, we estimate the burden hours for industry to comply with the current Part 579 reporting requirements (EWR requirements, foreign campaign requirements and Part 579.5 requirements) to be 53,810 hours per year. The total annual burden hours for this information collection consisting of manufacturer communications under Section 579.5 (Subpart A), foreign reporting (Subpart B), EWR submissions and reporting (Subpart C), and computer maintenance is outlined in Table 9 below.

TABLE 9—TOTAL MANUFACTURER BURDEN HOURS FOR THIS COLLECTION

Reporting type	Annual burden hours
Subpart A: Manufacturer Communications	
§ 579.5 (Table 1)	2,074
Subpart B: Foreign Reporting (Table 2)	1,590
Subpart C: EWR Submissions and Quarterly Reporting (Tables 4 & 6)	14,731
Computer Maintenance	35,415
Total	53,810

The burden estimates represent an overall increase in burden hours of 4,567 hours. The increase in burden hours is due to increases in the number of submissions and modifying this request to include reporting for common green tires and additional information requested by NHTSA per Section 579.28(l) that were left out of the previous information collection request. The wage estimates have been adjusted to reflect the latest available rates from the Bureau of Labor Statistics.

Estimated Total Annual Cost: NHTSA estimates the collection requires no additional costs to the respondents beyond the labor costs associated with the burden hours to collect and submit the reports to NHTSA and the labor hours and associated labor costs for computer maintenance.

Public Comments Invited: You are asked to comment on any aspects of this information collection, including (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; 49 CFR 1.49; and DOT Order 1351.29.

Jeffrey Mark Giuseppe,

Associate Administrator for Enforcement.

[FR Doc. 2020–28766 Filed 12–28–20; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund; Notice and Request for Public Comment

SUMMARY: The U.S. Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995 (PRA). Currently, the Community Development Financial Institutions Fund (CDFI Fund), U.S. Department of the Treasury, is soliciting comments concerning the New Markets Tax Credit Program (NMTC Program) Allocation Application, for the fiscal year (FY) 2021–FY 2024 funding rounds (hereafter, the Application or Applications). The CDFI Fund is required by law to make the Application publicly available for comment prior to submission for a new PRA number.

DATES: Written comments must be received on or before March 1, 2021 to be assured of consideration.

ADDRESSES: Direct all comments to Christopher Allison, NMTC Program Manager, CDFI Fund, at *nmtc@cdfi.treas.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Christopher Allison, NMTC Program Manager, CDFI Fund, U.S. Department of the Treasury, 1500 Pennsylvania Avenue NW, Washington, DC 20220, (202) 653–0421 (not a toll-free number), or by email to *nmtc@cdfi.treas.gov.* Other information regarding the CDFI Fund and its programs may be obtained on the CDFI Fund website at *https://www.cdfifund.gov.* The NMTC Allocation Application Template is provided online to aid the public in providing comments requested by this Notice, and presents the questions that will comprise the online Application, including substantive revisions relative to the existing Application. These proposed substantive revisions relative to the existing Application are highlighted in yellow in the NMTC Allocation Application Template. This document may be obtained from the NMTC page of the CDFI Fund's website at *https://www.cdfifund.gov/nmtc.*

SUPPLEMENTARY INFORMATION:

Title: NMTC Program Allocation Application.

OMB Number: 1559–0016.

Abstract: Title I, subtitle C, section 121 of the Community Renewal Tax Relief Act of 2000 (the Act) amended the Internal Revenue Code (IRC) by adding IRC § 45D and created the NMTC Program. The Department of the Treasury, through the CDFI Fund, Internal Revenue Service, and Office of Tax Policy, administers the NMTC Program. In order to claim the NMTC, taxpayers make Qualified Equity Investments (QEIs) in Community Development Entities (CDEs) and substantially all of the QEI proceeds must, in turn, be used by the CDE to provide investments in businesses and real estate developments in low-income communities and other purposes authorized under the statute.

The tax credit provided to the investor totals 39 percent of the amount of the investment and is claimed over a seven-year period. In each of the first three years, the investor receives a credit equal to five percent of the total amount paid for the stock or capital interest at the time of purchase. For the final four years, the value of the credit is six percent annually. Investors may not redeem their investments in CDEs prior to the conclusion of the seven-year period without forfeiting any credit amounts they have received.

The CDFI Fund is responsible for certifying organizations as CDEs, and administering the competitive allocation of tax credit authority to CDEs, which it does through annual allocation rounds. As part of the award selection process, CDEs will be required to prepare and submit an Application, which consists of five sections: Business Strategy; Community Outcomes; Organization Capacity; Capitalization Strategy; and Previous Allocations and Awards. Capitalized terms not defined in this Notice (other than titles) have the meaning set forth in the NMTC Allocation Application, Internal Revenue Code (IRC) § 45D or the IRS NMTC regulations.

Current Actions: Extension with significant changes from currently approved collection.

Type of Review: Regular.

Affected Public: CDEs applying for NMTC Allocations.

Estimated Number of Respondents: 222.

Estimated Annual Time per Respondent: 300.

Estimated Total Annual Burden Hours: 66,600 hours.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval. All comments will become a matter of public record and may be published on the Fund website at *http://www.cdfifund.gov.*

Comments concerning the Application are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services required to provide information.

Authority

26 U.S.C. 45D; 26 CFR 1.45D–1.

Jodie L. Harris,

Director, Community Development Financial Institutions Fund.

[FR Doc. 2020–28649 Filed 12–28–20; 8:45 am]

BILLING CODE 4810–70–P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network; Bank Secrecy Act Advisory Group; Solicitation of Application for Membership

AGENCY: Financial Crimes Enforcement Network (''FinCEN''), Treasury.

ACTION: Notice and request for nominations.

SUMMARY: FinCEN is inviting the public to nominate financial institutions, trade groups, and non-federal regulators or law enforcement agencies for membership on the Bank Secrecy Act Advisory Group. New members will be selected for three-year membership terms.

DATES: Nominations must be received by January 28, 2021.

ADDRESSES: Nominations must be emailed to *BSAAG@fincen.gov.*

FOR FURTHER INFORMATION CONTACT: FinCEN Resource Center at 800–767–2825.

SUPPLEMENTARY INFORMATION: Section 1654 of the Annunzio-Wylie Anti-Money Laundering Act of 1992 required the Secretary of the Treasury to establish a Bank Secrecy Act Advisory Group (BSAAG) consisting of representatives from federal agencies, and other interested persons and financial institutions subject to the regulatory requirements of the Bank Secrecy Act, found at 31 CFR 1010–1060. The BSAAG is the means by which the Treasury receives advice on the reporting requirements of the Bank Secrecy Act, and informs private sector representatives on how the information they provide is used. As chair of the BSAAG, the Director of FinCEN is responsible for ensuring that relevant issues are placed before the BSAAG for review, analysis, and discussion.

BSAAG membership is open to financial institutions, trade groups, and federal and non-federal regulators and law enforcement agencies that are located within the United States. Each member selected will serve a three-year term and must designate one individual to represent that member at plenary meetings. While BSAAG membership is granted to organizations, not to individuals, the designated representative for each selected organization should be knowledgeable about Bank Secrecy Act requirements and be willing and able to devote the necessary time and effort on behalf of the representative's organization. Members are expected to actively share anecdotal perspectives, and quantifiable insights on BSA requirements, and

industry trends in BSAAG discussions. The organization's representative must be able to attend biannual plenary meetings, generally held in Washington, DC over one or two days in May and October. Additional BSAAG meetings may be held by phone, videoconference, or in person. Members will not be paid for their time, services, or travel.

Nominations for individuals who are not representing an organization will not be considered, but organizations may nominate themselves. Please provide complete answers to the following items, as nominations will be evaluated based on the information provided in response to this notice and request for nominations. There is no required format; interested organizations may submit their nominations via email or email attachment. Nominations should consist of:

- Name of the organization requesting membership.
- Point of contact, title, address, email address, and phone number.
- Description of the financial institution or trade group and its involvement with the Bank Secrecy Act.
- Reasons why the organization's participation on the BSAAG will bring value to the group.
- Trade groups must submit a full list of their members along with their nomination. Trade groups must also confirm that, if selected, they will only share BSAAG information with their members that are located within the United States.

In making the selections, FinCEN will seek to complement current BSAAG members and obtain comprehensive representation in terms of affiliation, industry, and geographic representation. The Director of FinCEN retains full discretion on all membership decisions. The Director may consider prior years' applications when making selections and will not limit consideration to institutions nominated by the public when making selections.

Kenneth A. Blanco,

Director, Financial Crimes Enforcement Network.

[FR Doc. 2020–28674 Filed 12–28–20; 8:45 am]

BILLING CODE 4810–02–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 Specially Designated Nationals and Blocked Persons 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 applicable date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Andrea Gacki, Director, tel.: 202–622–2420; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*www.treas.gov/ofac*).

Notice of OFAC Actions

On December 22, 2020, 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.

Individuals

BILLING CODE 4810–AL–P

1. AL-KINAYEH, Lina Mohammed Nazir (Arabic: الكناية نـــذير محمد لينـــا) (a.k.a. AL-CANAIYA, Leena Muhammad Nathir; a.k.a. AL-KINAYA, Lina Muhammed Nazir; a.k.a. AL-KINAYEH, Leena; a.k.a. AL-KINAYEH, Lina (Arabic: كنايةال لينـــا); a.k.a. AL-KINAYEH, Lina Mohammad Natheer; a.k.a. KINAYEH, Lina (Arabic: كناية لينـــا); a.k.a. KNAYA, Lina; a.k.a. KNIYA, Lina), Al-Zahiriya, Northern Tripoli, Lebanon; DOB 20 Jan 1980; nationality Lebanon; alt. nationality Syria; Gender Female; National ID No. 000036055655 (Lebanon) (individual) [SYRIA].

   Designated pursuant to section 1(b)(i) of Executive Order 13573 of May 18, 2011, "Blocking Property of Senior Officials of the Government of Syria," 76 FR 29143, 3 CFR, 2011 Comp., p. 241, (E.O. 13573), for being a senior official of the Government of Syria.

2. MASOUTI, Mohammed Hammam Mohammed Adnan (Arabic: محمدهمام محمد مسوتي عـدنان) (a.k.a. HUMAM, Msuti; a.k.a. MASOUTI BIN MOHAMMED ADNAN, Mohammed Humam (Arabic: عدنان محمد بـــن مســـوتيهمام محمد); a.k.a. MASOUTI, Mohammad Humam; a.k.a. MASOUTI, Mohammad Hussam Mohammad Adnan; a.k.a. MASOUTI, Mohammed Hammam; a.k.a. MASOUTI, Mohammed Humam Mohammed Adnan; a.k.a. MSOUTI, Mohammad Humam Mohammad Adnan), Damascus, Syria; DOB 1976; POB Damascus, Syria; nationality Syria; Gender Male (individual) [SYRIA].

   Designated pursuant to section 1(b)(i) of E.O. 13573 for being a senior official of the Government of Syria.

Entities

1. AL-AMER DEVELOPMENT AND REAL ESTATE INVESTMENT (Arabic: العامر للتطوير والاستثمار العقاري) (a.k.a. AL-AMER DEVELOPMENT & REAL ESTATE INVESTMENT; a.k.a. AL-AMER DEVELOPMENT AND REAL ESTATE INVESTMENT COMPANY; a.k.a. AL-AMER REAL ESTATE DEVELOPMENT AND INVESTMENT LLC; a.k.a. "AL-AMER DEVELOPMENT"), Mezzeh Villas, Damascus, Syria; Organization Established Date 19 Dec 2019; Organization Type: Real estate activities with own or leased property; Registration Number 19096 (Syria) [SYRIA] (Linked To: KHITI, Amer Taysir).

   Identified as an entity in which AMER TAYSIR KHITI, a person whose property and interests are blocked pursuant to an Executve order or regulations administered by OFAC, owns, directly or indirectly, a 50 percent or greater interest as set forth in 31 CFR 542.411.

2. AL-AMER FOR MANUFACTURE OF CONCRETE AND FLAGSTONE (Arabic: العامر لصناعة المجبول البيتوني والبلاط والبلوك) (a.k.a. AL-AMER FOR CONCRETE, BLOCK AND TILE MANUFACTURING LLC; a.k.a. AL-AMER FOR MANUFACTURE OF CONCRETE, FLAGSTONE, LIMITED LIABILITY), Rural Damascus, Syria; Organization Established Date 04 Nov 2019; Organization Type: Manufacture of articles of concrete, cement and plaster; Registration Number 12428 (Syria) [SYRIA].

   Identified as an entity in which AMER TAYSIR KHITI and KHITI HOLDING GROUP, persons whose property and interests are blocked pursuant to an Executve order or regulations administered by OFAC, own, directly or indirectly, a 50 percent or greater interest as set forth in 31 CFR 542.411.

3. AL-AMER FOR MANUFACTURE OF PLASTIC (Arabic: العامر لصناعة البلاستيك) (a.k.a. ALAMER FOR MANUFACTURE OF PLASTIC LIMITED LIABILITY; a.k.a. AL-AMER PLASTIC INDUSTRY LLC), Rural Damascus, Syria; Organization Established Date 04 Nov 2019; Organization Type: Manufacture of plastics products; Registration Number 12427 (Syria) [SYRIA].

   Identified as an entity in which AMER TAYSIR KHITI and KHITI HOLDING GROUP, persons whose property and interests are blocked pursuant to an Executve order or regulations administered by OFAC, own, directly or indirectly, a 50 percent or greater interest as set forth in 31 CFR 542.411.

4. AL-LAYTH ALZAHABE TRANSPORTATION AND SHIPPING SERVICES (Arabic: الليث الذهبي لخدمات النقل والشحن) (a.k.a. ALLAYTH ALZAHABE (Arabic: الليث الذهبي); a.k.a. GOLDEN LAITH FREIGHT FORWARD SERVICES; a.k.a. GOLDEN LEIH TRANSPORTATION & SHIPMENT SERVICES L.L.C.; a.k.a. GOLDEN LEIH TRANSPORTATION AND SHIPMENT SERVICES L.L.C.; a.k.a. GOLDEN LEITH FOR TRANSPORTATION AND SHIPPING SERVICES), Damascus, Syria;

Organization Established Date 26 May 2019; Registration Number 12388 (Syria) [SYRIA] (Linked To: KHITI HOLDING GROUP).

Identified as an entity in which KHITI HOLDING GROUP, a person whose property and interests are blocked pursuant to an Executve order or regulations administered by OFAC, owns, directly or indirectly, a 50 percent or greater interest as set forth in 31 CFR 542.411.

5. GOOD LAND COMPANY (Arabic: ارض الخير شـركة) (a.k.a. ARD AL-KHAIR INTERNATIONAL COMPANY; a.k.a. ARD AL-KHER INTERNATIONAL COMPANY; a.k.a. GOOD LAND INTERNATIONAL COMPANY (Arabic: ارض شـركة الدولية الخـير); a.k.a. GOOD LAND INTERNATIONAL COMPANY FOR THE IMPORTING AND EXPORTING OF VEGETABLES AND FRUIT (Arabic: ارض شـركة الفواكة و الخضـار وتصـدير لاسـتيراد الدوليـة الخـير); a.k.a. GOOD LAND LIMITED LIABILITY COMPANY), Duma, Syria; Oman; Jordan; Egypt; Organization Established Date 1995; alt. Organization Established Date 2016; Organization Type: Wholesale of food, beverages and tobacco; Registration Number 10845 (Syria) [SYRIA] (Linked To: KHITI, Amer Taysir).

   Identified as an entity in which AMER TAYSIR KHITI, a person whose property and interests are blocked pursuant to an Executve order or regulations administered by OFAC, owns, directly or indirectly, a 50 percent or greater interest as set forth in 31 CFR 542.411.

6. LETIA COMPANY (Arabic: ليتيا شـركة) (a.k.a. LETIA JOINT-STOCK COMPANY L.L.C.; a.k.a. LETIA LIMITED LIABILITY COMPANY; a.k.a. LITIA COMPANY), Damascus, Syria; Organization Established Date 10 Jan 2019; Organization Type: Manufacture of medical and dental instruments and supplies [SYRIA].

   Identified as an entity in which LINA MOHAMMED NAZIR AL-KINAYEH and MOHAMMED HAMMAM MOHAMMED ADNAN MASOUTI, persons whose property and interests in property are blocked pursuant to an Executive order or regulations administered by OFAC, own, directly or indirectly, a 50 percent or greater interest, as set forth in 31 CFR 542.411.

7. LIA COMPANY (Arabic: ليا شـركة) (a.k.a. LIA CO L.L.C.; a.k.a. "LEAH COMPANY"), Damascus, Syria; Organization Established Date 30 Jan 2011 [SYRIA] (Linked To: MASOUTI, Mohammed Hammam Mohammed Adnan).

Designated pursuant to section 1(b)(iv) of E.O. 13573 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, MOHAMMED HAMMAM MOHAMMED ADNAN MASOUTI, a person whose property and interests in property are blocked pursuant to E.O. 13573.

8. POLYMEDICS LLC (Arabic: المتعددة اتىالطـب شــركة) (a.k.a. "POLYMEDICS COMPANY"), Damascus, Syria; Organization Established Date 19 Oct 2011; Organization Type: Wholesale of other machinery and equipment [SYRIA] (Linked To: MASOUTI, Mohammed Hammam Mohammed Adnan).

Designated pursuant to section 1(b)(iv) of E.O. 13573 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, MOHAMMED HAMMAM MOHAMMED ADNAN MASOUTI, a person whose property and interests in property are blocked pursuant to E.O. 13573.

9. SOURAN COMPANY (Arabic: سوران شــركة) (a.k.a. SORAN COMPANY), Damascus, Syria; Organization Established Date 03 Sep 2018; Organization Type: Other telecommunications activities; alt. Organization Type: Wholesale of electronic and telecommunications equipment and parts [SYRIA] (Linked To: MASOUTI, Mohammed Hammam Mohammed Adnan).

Designated pursuant to section 1(b)(iv) of E.O. 13573 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, MOHAMMED HAMMAM MOHAMMED ADNAN MASOUTI, a person whose property and interests in property are blocked pursuant to E.O. 13573.

On December 22, 2020, OFAC added the below identifying information to the Specially Designated Nationals and Blocked Persons List for the CENTRAL BANK OF SYRIA, an entity that falls within the definition of the GOVERNMENT OF SYRIA, whose property and interests in property subject to U.S. jurisdiction are blocked pursuant to Executive Order 13582 of August 17, 2011, "Blocking Property of the Government of Syria and Prohibiting Certain Transactions with Respect to Syria" (76 FR 52209) 3 CFR, 2011 Comp., p. 264.

1. CENTRAL BANK OF SYRIA (Arabic: المركزي اىســور مصــرف) (a.k.a. BANQUE CENTRALE DE SYRIE; a.k.a. MASRIF SOURIYA AL-MARKAZI), P.O. Box 2254, Altajrida Al Mughrabia Square, Damascus, Syria; Sabaa Bahrat Square, Damascus, Syria; SWIFT/BIC CBSYSYDA; Organization Established Date 28 Mar 1953; alt. Organization Established Date 01 Aug 1956; Organization Type: Central banking [SYRIA].

Dated: December 22, 2020.

Andrea M. Gacki,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2020–28737 Filed 12–28–20; 8:45 am]

BILLING CODE 4810–AL–C

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 Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more entities and individuals that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List). OFAC has determined that one or more applicable legal criteria were satisfied to place the entities and individuals on the SDN List. All property and interests in property subject to U.S. jurisdiction of these entities and individuals are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT:

OFAC: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480; or Assistant Director for Regulatory Affairs, tel.: 202–622–4855.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*www.treasury.gov/ofac*).

Notice of OFAC Action

On December 18, 2020, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following entity and individuals are blocked under the relevant sanctions authority listed below.

Entity

1. EX–CLE SOLUCIONES BIOMETRICAS C.A. (a.k.a. EX–CLE C.A.; a.k.a. ''EX–CLE''), Municipio Libertador, Parroquia Catedral, Urbanizacion Catedral, Avenida Sur, Esquina Sociedad a Gradillas, Edificio Bompland, Caracas, Venezuela; 2da Transversal entre 2da y 3er Avenida de Santa Eduvigis, Municipio Sucre, Caracas, Estado Miranda, Venezuela; RIF # J407882333 (Venezuela) [VENEZUELA] (Linked To: MADURO MOROS, Nicolas).

Designated pursuant to section 1(a)(ii)(D)(1) of Executive Order 13692 of March 8, 2015, ''Blocking Property and Suspending Entry of Certain Persons Contributing to the Situation in Venezuela,'' 80 FR 12747, 3 CFR, 2015 Comp., p. 276 (E.O. 13692), as amended by Executive Order 13857 of January 25, 2019, ''Taking Additional Steps To Address the National Emergency With Respect to Venezuela,'' 84 FR 509 (E.O. 13857), for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, Nicolas Maduro Moros, a person whose property and interests in property are blocked pursuant to E.O. 13692.

Individuals

1. SAN AGUSTIN, Guillermo Carlos, Buenos Aires, Argentina; Caracas, Venezuela; DOB 28 Apr 1975; POB Argentina; nationality Argentina; alt. nationality Italy; Gender Male; Cedula No. E–84424403 (Venezuela); alt. Cedula No. 24498939 (Argentina); Passport AA2196839 (Italy) expires 26 Jun 2018; C.U.I.T. 20–24498939–0 (Argentina) (individual) [VENEZUELA] (Linked To: EX–CLE SOLUCIONES BIOMETRICAS C.A.).

Designated pursuant to section 1(a)(ii)(E) of E.O. 13692, as amended by E.O. 13857, for having acted or purported to act for or on behalf of, directly or indirectly, EX–CLE SOLUCIONES BIOMETRICAS C.A., an entity whose property and interests in property are blocked pursuant to E.O. 13692.

2. MACHADO REQUENA, Marcos Javier, Caracas, Venezuela; DOB 18 Jun 1981; POB Venezuela; nationality Venezuela; Gender Male; Cedula No. V–15334084 (Venezuela); Passport 093061892 (Venezuela) expires 15 Feb 2021 (individual) [VENEZUELA] (Linked To: EX–CLE SOLUCIONES BIOMETRICAS C.A.).

Designated pursuant to section 1(a)(ii)(E) of E.O. 13692, as amended by E.O. 13857, for having acted or purported to act for or on behalf of, directly or indirectly, EX–CLE SOLUCIONES BIOMETRICAS C.A., an entity whose property and interests in property are blocked pursuant to E.O. 13692.

Dated: December 18, 2020.

Andrea Gacki,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2020–28699 Filed 12–28–20; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on the Readjustment of Veterans; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2, that the Advisory Committee on the Readjustment of Veterans will hold two meetings virtually. The meetings will begin and end as follows:

Date	Time (EST)	Open session
January 26, 2021	1 p.m. to 5 p.m ...	Yes.
January 27, 2021	1 p.m. to 5 p.m ...	Yes.

The meetings are open to the public.

The purpose of the Committee is to advise the Department of Veterans Affairs (VA) regarding the provision by VA of benefits and services to assist Veterans in the readjustment to civilian life. In carrying out this duty, the Committee shall take into account the needs of Veterans who served in combat theaters of operation. The Committee assembles, reviews, and assesses information relating to the needs of Veterans readjusting to civilian life and the effectiveness of VA services in assisting Veterans in that readjustment.

The Committee, comprised of 12 subject matter experts, advises the Secretary, through the VA Readjustment Counseling Service, on the provision by VA of benefits and services to assist Veterans in the readjustment to civilian life. In carrying out this duty, the Committee assembles, reviews, and assesses information relating to the needs of Veterans readjusting to civilian life and the effectiveness of VA services in assisting Veterans in that readjustment, specifically taking into account the needs of Veterans who served in combat theaters of operation.

On January 26, 2021, the agenda will include presentations from the VA Office of Tribal Government Relations, Veteran Legal Services Organization, the Travis Manion Foundation and a presentation from a Vet Center and Medical Center, from 1 p.m.–5 p.m. For public members wishing to join the meeting, please use the following Webex link: *https://veteransaffairs.webex.com/veteransaffairs/j.php?MTID=m0b8f4c3969ff82506a309ed36cb53069.*

On January 27, 2021, the agenda will include committee discussion of the annual report, from 1 p.m.–5 p.m. For public members wishing to join the meeting, please use the following Webex link: *https://veteransaffairs.webex.com/veteransaffairs/j.php?MTID=m6aa9a858c5eec9ec6a1b8619fdeb7a2a.*

No time will be allotted for receiving oral comments from the public; however, the Committee will accept written comments from interested parties on issues outlined in the meeting agenda or other issues regarding the readjustment of Veterans. Parties should

contact Mr. Richard Barbato via email at *VHA10RCSAction@va.gov,* or by mail at Department of Veterans Affairs, Readjustment Counseling Service (10RCS), 810 Vermont Avenue, Washington, DC 20420. Any member of the public seeking additional information should contact Mr. Barbato at the phone number or email addressed noted above.

Dated: December 22, 2020.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2020–28751 Filed 12–28–20; 8:45 am]

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FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 411, 412, et al.

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; Physician-Owned Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots, Radiation Oncology Model; and Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) To Report COVID-19 Therapeutic Inventory and Usage and To Report Acute Respiratory Illness During the Public Health Emergency (PHE) for Coronavirus Disease 2019 (COVID–19); Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 411, 412, 414, 416, 419, 482, 485, 512

[CMS–1736–FC, 1736–IFC]

RIN 0938–AU12

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; Physician-Owned Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots, Radiation Oncology Model; and Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) To Report COVID–19 Therapeutic Inventory and Usage and To Report Acute Respiratory Illness During the Public Health Emergency (PHE) for Coronavirus Disease 2019 (COVID–19)

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

ACTION: Final rule with comment period and interim final rule with comment period.

SUMMARY: This final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for Calendar Year (CY) 2021 based on our continuing experience with these systems. In this final rule with comment period, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. Also, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program. In addition, this final rule with comment period establishes and updates the Overall Hospital Quality Star Rating beginning with the CY 2021; removes certain restrictions on the expansion of physician-owned hospitals that qualify as ''high Medicaid facilities,'' and clarifies that certain beds are counted toward a hospital's baseline number of operating rooms, procedure rooms, and beds; adds two new service categories to the Hospital Outpatient Department (OPD) Prior Authorization Process; provides notice of the closure of two teaching hospitals and the opportunity to apply for available slots for purposes of indirect medical education (IME) and direct graduate medical education (DGME) payments; and revises the Clinical Laboratory Date of Service (DOS) policy. This interim final rule with comment period modifies the Radiation Oncology Model (RO Model) Model performance period for CY 2021, and establishes new requirements in the hospital and critical access hospital (CAH) Conditions of Participation (CoPs) for tracking of COVID–19 therapeutic inventory and usage and for tracking of the incidence and impact of Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection) during the ongoing COVID–19 public health emergency (PHE).

DATES:

Effective date: This rule is effective January 1, 2021, with the exceptions of amendatory instructions 21 and 23 (amending 42 CFR 482.42 and 485.640) and 25 through 31 (amending 42 CFR 512.205, 512.210, 512.217, 512.220, 512.245, 512.255, and 512.285), which are effective on December 4, 2021.

Comment period: To be assured consideration, comments on the payment classifications assigned to the interim APC assignments and/or status indicators of new or replacement Level II HCPCS codes in this final rule with comment period (CMS–1736–FC) must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on January 4, 2021.

To be assured consideration, comments on the Reporting Requirements for Hospitals and CAHs to Report Acute Respiratory Illness During the PHE for COVID–19, instructions 21 and 23 amending §§ 482.42 and 485.640, and the Radiation Oncology (RO) Model, instructions 25 through 31 amending 42 CFR 512.205, 512.210, 512.217, 512.220, 512.245, 512.255, and 512.285 in this interim final rule with comment period (CMS–1736–IFC) must be received at one of the addresses provided below, no later than 5 p.m. on February 2, 2021.

Applicability dates: The provisions related to the Radiation Oncology (RO) Model contained in section XXI of this interim final rule with comment period are applicable beginning July 1, 2021.

ADDRESSES: In commenting, please refer to file code CMS–1736–FC or CMS–1736–IFC as appropriate, when commenting on the issues in this final rule with comment period and interim final rule with comment period. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may (and we encourage you to) submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the instructions under the ''submit a comment'' tab.

2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1736–FC or CMS–1736–IFC, P.O. Box 8010, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1736–FC or CMS–1736–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact the HOP Panel mailbox at *APCPanel@cms.hhs.gov*.

Ambulatory Surgical Center (ASC) Payment System, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or Mitali Dayal via email *Mitali.Dayal2@cms.hhs.gov*.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email at *Anita.Bhatia@cms.hhs.gov*.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Measures, contact Cyra Duncan via email *Cyra.Duncan@cms.hhs.gov*.

Blood and Blood Products, contact Josh McFeeters via email *Joshua.McFeeters@cms.hhs.gov*. Cancer

Hospital Payments, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov*.

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver via email *Chuck.Braver@cms.hhs.gov*.

Composite APCs (Low Dose Brachytherapy and Multiple Imaging), contact Au'Sha Washington via email *AuSha.Washington@cms.hhs.gov.*

Comprehensive APCs (C–APCs), contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov*, or Mitali Dayal via email *Mitali.Dayal2@cms.hhs.gov*.

Hospital Outpatient Quality Reporting (OQR) Program Administration, Validation, and Reconsideration Issues, contact Shaili Patel via email *Shaili.Patel@cms.hhs.gov*.

Hospital Outpatient Quality Reporting (OQR) Program Measures, contact Nicole P. Crenshaw via email *PNicole.Crenshaw@cms.hhs.gov*.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Elise Barringer via email *Elise.Barringer@cms.hhs.gov*.

Hospital Quality Star Rating Methodology, contact Annese Abdullah-Mclaughlin via email *Annese.Abdullah-Mclaughlin@cms.hhs.gov*.

Inpatient Only (IPO) Procedures List, contact Au'Sha Washington via email *Ausha.Washington@cms.hhs.gov*, or Allison Bramlett via email *Allison.Bramlett@cms.hhs.gov*, or Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov*.

Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2021 and Subsequent Years (2-Midnight Rule), contact Elise Barringer via email *Elise.Barringer@cms.hhs.gov*.

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov*.

No Cost/Full Credit and Partial Credit Devices, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov*.

OPPS Brachytherapy, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov*.

OPPS Data (APC Weights, Conversion Factor, Copayments, Cost-to-Charge Ratios (CCRs), Data Claims, Geometric Mean Calculation, Outlier Payments, and Wage Index), contact Erick Chuang via email *Erick.Chuang@cms.hhs.gov*, or Scott Talaga via email *Scott.Talaga@cms.hhs.gov*, or Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*.

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*, or Gil Ngan via email at *Gil.Ngan@cms.hhs.gov* or, or Cory Duke via email at *Cory.Duke@cms.hhs.gov*.

OPPS New Technology Procedures/Services, contact the New Technology APC mailbox at *NewTechAPCapplications@cms.hhs.gov*.

OPPS Packaged Items/Services, contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov*, or Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov*.

OPPS Pass-Through Devices, contact the Device Pass-Through mailbox at *DevicePTapplications@cms.hhs.gov*.

OPPS Status Indicators (SI) and Comment Indicators (CI), contact Marina Kushnirova via email *Marina.Kushnirova@cms.hhs.gov*.

Partial Hospitalization Program (PHP) and Community Mental Health Center (CMHC) Issues, contact the PHP Payment Policy Mailbox at *PHPPaymentPolicy@cms.hhs.gov*.

Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services, contact Thomas Kessler via email at *Thomas.Kessler@cms.hhs.gov*.

Rural Hospital Payments, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*.

Skin Substitutes, contact Josh McFeeters via email *Joshua.McFeeters@cms.hhs.gov*.

Supervision of Outpatient Therapeutic Services in Hospitals and CAHs, contact Josh McFeeters via email *Joshua.McFeeters@cms.hhs.gov*.

All Other Issues Related to Hospital Outpatient and Ambulatory Surgical Center Payments Not Previously Identified, contact Elise Barringer via email *Elise.Barringer@cms.hhs.gov* or at 410–786–9222.

RO Model, contact *RadiationTherapy@cms.hhs.gov* or at 844–711–2664, Option 5.

CAPT Scott Cooper, USPHS, (410) 786–9465, for the hospital and CAH COVID–19 Therapeutic Inventory and Usage reporting requirements and for the Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection) reporting requirements.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov/*. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Addenda Available Only Through the Internet on the CMS Website

In the past, a majority of the Addenda referred to in our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the CY 2012 OPPS/ASC proposed rule, all of the Addenda no longer appear in the **Federal Register** as part of the annual OPPS/ASC proposed and final rules to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these Addenda are published and available only on the CMS website. The Addenda relating to the OPPS are available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*.

The Addenda relating to the ASC payment system are available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices*.

Current Procedural Terminology (CPT) Copyright Notice

Throughout this final rule with comment period, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2019 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR and Defense Federal Acquisition Regulations (DFAR) apply.

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I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this final rule with comment period and interim final rule with comment period, we are updating the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs), beginning January 1, 2021. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). Specifically, section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS not less often than annually, and to revise the groups, the relative payment weights, and the wage and other adjustments that take into account changes in medical practices, changes in technology, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i)(D)(v) of the Act, we annually review and update the ASC payment rates. This final rule with comment period also includes additional policy changes made in accordance with our experience with the OPPS and the ASC payment system and recent changes in our statutory authority. We describe these and various other statutory authorities in the relevant sections of this final rule with comment period. In addition, this final rule with comment period updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

2. Summary of the Major Provisions

- *OPPS Update:* For CY 2021, we are increasing the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 2.4 percent. This increase factor is based on the final hospital inpatient market basket percentage increase of 2.4 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS). Based on this update, we estimate that total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for calendar year (CY) 2021 would be approximately $83.888 billion, an increase of approximately $7.541 billion compared to estimated CY 2020 OPPS payments.

We are continuing to implement the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements by applying a reporting factor of 0.9805 to the OPPS payments and copayments for all applicable services.

- *Partial Hospitalization Update:* For CY 2021 OPPS/ASC final rule with comment period, CMS is maintaining the unified rate structure established in CY 2017, with a single PHP APC for each provider type for days with 3 or more services per day. We are using the CMHC and hospital-based PHP (HB PHP) geometric mean per diem costs, consistent with existing policy, using updated data for each provider type. Accordingly, we are calculating the CY 2021 PHP APC per diem rates for HB PHPs and CMHC PHPs based on updated cost and claims data. Given that the final calculated geometric mean per diem costs are much higher than the proposed cost floors, we are not extending the cost floors to CY 2021 and subsequent years.
- *Changes to the Inpatient Only (IPO) List:* For CY 2021, we are eliminating the IPO list over the course of 3 calendar years beginning with the removal of 266 musculoskeletal-related services. We are also removing 32 additional HCPCS codes from the IPO list for CY 2021 based on public comments.
- *Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2021 and Subsequent Years (2-Midnight Rule):* For CY 2021, we are finalizing a policy to exempt procedures that are removed from the inpatient only (IPO) list under the OPPS beginning on January 1, 2021 from site-of-service claim denials, Beneficiary and Family-Centered Care Quality Improvement Organization (BFCC–QIO) referrals to Recovery Audit Contractor (RAC) for persistent noncompliance with the 2-midnight rule, and RAC reviews for ''patient status'' (that is, site-of-service) until such procedures are more commonly billed in the outpatient setting.
- 340B—*Acquired Drugs:* We are continuing our current policy of paying an adjusted amount of ASP minus 22.5 percent for drugs and biologicals acquired under the 340B program. We are continuing to exempt Rural SCHs, PPS-exempt cancer hospitals and children's hospitals from our 340B payment policy.
- *Comprehensive APCs:* For CY 2021, we are creating two new comprehensive APCs (C–APCs): C–APC 5378 (Level 8 Urology and Related Services) and C–APC 5465 (Level 5 Neurostimulator and Related Procedures). Adding these C–APCs increases the total number of C–APCs to 69.
- *Device Pass-Through Payment Applications:* For CY 2021, we evaluated five applications for device pass-through payments. Two of these applications (CUSTOMFLEX® ARTIFICIALIRIS and EXALT™ Model D Single-Use Duodenoscope) received preliminary approval for pass-through payment status through our quarterly review process. Based on our review and public comments received, we are continuing the pass-through payment status for CUSTOMFLEX® ARTIFICIALIRIS and EXALT™ Model D Single-Use Duodenoscope and approving the remaining three applications for device pass-through payment status.
- *Changes to the Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals:* For CY 2021 and subsequent years, we are changing the minimum default level of supervision for non-surgical extended duration therapeutic services (NSEDTS) to general supervision for the entire service, including the initiation portion of the service, for which we had previously required direct supervision. This is consistent with the minimum required level of general supervision that currently applies for most outpatient hospital therapeutic services. We are finalizing our proposed policy to permit direct supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services using virtual presence of the physician through audio/video real-time communications technology subject to the clinical judgment of the supervising physician until the later of the end of the calendar year in which the PHE ends or December 31, 2021.
- *Cancer Hospital Payment Adjustment:* For CY 2021, we are continuing to provide additional payments to cancer hospitals so that a cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. However, section 16002(b) of the 21st Century Cures Act requires that this weighted average PCR be reduced by 1.0 percentage point. Based on the data and the required 1.0 percentage point reduction, a target PCR of 0.89 will be used to determine the CY 2021 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments will be the additional payments needed to result in

a PCR equal to 0.89 for each cancer hospital.

• *ASC Payment Update:* For CYs 2019 through 2023, we adopted a policy to update the ASC payment system using the hospital market basket update. Using the hospital market basket methodology, for CY 2021, we are increasing payment rates under the ASC payment system by 2.4 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This increase is based on a hospital market basket percentage increase of 2.4 percent minus a multifactor productivity adjustment of 0.0 percentage point. Based on this update, we estimate that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2021 would be approximately 5.42 billion, an increase of approximately 120 million compared to estimated CY 2020 Medicare payments.

• *Changes to the List of ASC Covered Surgical Procedures:* For CY 2021, we are adding eleven procedures to the ASC covered procedures list (CPL), including total hip arthroplasty (CPT 27130). Additionally, we are revising the criteria we use to add covered surgical procedures to the ASC CPL, providing that certain criteria we used to add covered surgical procedures to the ASC CPL in the past will now be factors for physicians to consider in deciding whether a specific beneficiary should receive a covered surgical procedure in an ASC, and adopting a notification process for surgical procedures the public believes can be added to the ASC CPL under the criteria we are retaining. Using our revised criteria, we are adding an additional 267 surgical procedures to the ASC CPL beginning in CY 2021.

• *Hospital Outpatient Quality Reporting (OQR) and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs:* For the Hospital OQR and ASCQR Programs, we are updating and refining requirements to further meaningful measurement and reporting for quality of care provided in these outpatient settings while limiting compliance burden. We are revising and codifying previously finalized administrative procedures and are codifying an expanded review and corrections process to further the programs' alignment while clarifying program requirements. We are not making any measure additions or removals for either program.

• *Overall Hospital Quality Star Ratings:* We are establishing and updating the methodology that will be used to calculate the Overall Hospital Quality Star Ratings beginning with 2021 and for subsequent years. We are updating and simplifying how the ratings are calculated, with policies such as adopting a simple average of measure scores instead of the latent variable model and reducing the total number of measure groups from seven to five measure groups due to the removal of measures through the Meaningful Measure Initiative. Additionally, we are increasing the comparability of star ratings by peer grouping hospitals by the number of measure groups. These changes will simplify the methodology, and therefore, reduce provider burden, improve the predictability of the star ratings, and increase the comparability between hospital star ratings. We did not finalize our proposals related to stratification of the Readmissions group by dual-eligible patients.

• *Addition of New Service Categories for Hospital Outpatient Department Prior Authorization Process:* We are adding the following two categories of services to the prior authorization process for hospital outpatient departments beginning for dates of service on or after July 1, 2021: (1) Cervical fusion with disc removal and (2) implanted spinal neurostimulators.

• *Clinical Laboratory Date of Service (DOS) Policy:* We are excluding certain protein-based Multianalyte Assays with Algorithmic Analyses (MAAAs), which are not generally performed in the HOPD setting, from the OPPS packaging policy and adding them to the laboratory DOS exception at 42 CFR 414.510(b)(5).

• *Physician-Owned Hospitals:* We are removing unnecessary regulatory restrictions on high Medicaid facilities and including beds in a physician-owned hospital's baseline consistent with state law.

• *Radiation Oncology Model (RO Model):* On September 29, 2020, we published a final rule in the **Federal Register** (85 FR 61114) entitled ''Specialty Care Models to Improve Quality of Care and Reduce Expenditures'' that finalized the Radiation Oncology Model (RO Model). To ensure that participation in the RO Model during the public health emergency (PHE) for the Coronavirus disease 2019 (COVID–19) pandemic does not further strain RO participants' capacity, we are revising the RO Model's Model performance period to begin on July 1, 2021 and end December 31, 2025 in this interim final rule with comment period. We are requesting comments on this change.

• *Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) to Report COVID–19 Therapeutic Inventory and Usage and to Report Acute Respiratory Illness During the Public Health Emergency (PHE) for Coronavirus Disease 2019 (COVID–19):* This interim final rule with comment period establishes new requirements in the hospital and critical access hospital (CAH) Conditions of Participation (CoPs) for tracking COVID–19 therapeutic inventory and usage and for tracking the incidence and impact of Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection) during the ongoing COVID–19 PHE; and for providing this information and data to the Secretary of Health and Human Services (Secretary) in such form and manner, and at such timing and frequency, as the Secretary may prescribe during the Public Health Emergency (PHE).

3. Summary of Costs and Benefit

In section XXVII and XXVIII of this final rule with comment period and interim final rule with comment period, we set forth a detailed analysis of the regulatory and federalism impacts that the changes will have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of All OPPS Changes

Table 79 in section XXVII.C of the CY 2021 OPPS/ASC final rule with comment period displays the distributional impact of all the OPPS changes on various groups of hospitals and CMHCs for CY 2021 compared to all estimated OPPS payments in CY 2020. We estimate that the policies in the CY 2021 OPPS/ASC final rule with comment period will result in a 2.4 percent overall increase in OPPS payments to providers. We estimate that total OPPS payments for CY 2021, including beneficiary cost-sharing, to the approximately 3,665 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) will increase by approximately $1.61 billion compared to CY 2020 payments, excluding our estimated changes in enrollment, utilization, and case-mix.

We estimated the isolated impact of our OPPS policies on CMHCs because CMHCs are only paid for partial hospitalization services under the OPPS. Continuing the provider-specific structure we adopted beginning in CY 2011, and basing payment fully on the type of provider furnishing the service, we estimate an 11.9 percent increase in CY 2021 payments to CMHCs relative to their CY 2020 payments.

b. Impacts of the Updated Wage Indexes

We estimate that our update of the wage indexes based on the FY 2021 IPPS final rule wage indexes will result in an estimated increase in payments of 0.2 percent for urban hospitals under the OPPS and an estimated increase in payments of 0.4 percent for rural hospitals. These wage indexes include the continued implementation of the OMB labor market area delineations based on 2010 Decennial Census data, with updates, as discussed in section II.C. of this final rule with comment period.

c. Impacts of the Rural Adjustment and the Cancer Hospital Payment Adjustment

There are no significant impacts of our CY 2021 payment policies for hospitals that are eligible for the rural adjustment or for the cancer hospital payment adjustment. We are not making any change in policies for determining the rural hospital payment adjustments. While we are implementing the reduction to the cancer hospital payment adjustment for CY 2021 required by section 1833(t)(18)(C) of the Act, as added by section 16002(b) of the 21st Century Cures Act, the target payment-to-cost ratio (PCR) for CY 2021 is 0.89, equivalent to the 0.89 target PCR for CY 2020, and therefore has no budget neutrality adjustment.

d. Impacts of the OPD Fee Schedule Increase Factor

For the CY 2021 OPPS/ASC, we are establishing an OPD fee schedule increase factor of 2.4 percent and applying that increase factor to the conversion factor for CY 2021. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that urban hospitals will experience an increase in payments of approximately 2.6 percent and that rural hospitals would experience an increase in payments of 2.9 percent. Classifying hospitals by teaching status, we estimate nonteaching hospitals will experience an increase in payments of 2.9 percent, minor teaching hospitals will experience an increase in payments of 3.0 percent, and major teaching hospitals will experience an increase in payments of 2.0 percent. We also classified hospitals by the type of ownership. We estimate that hospitals with voluntary ownership will experience an increase of 2.6 percent in payments, while hospitals with government ownership will experience an increase of 2.2 percent in payments. We estimate that hospitals with proprietary ownership will experience an increase of 3.5 percent in payments.

e. Impacts of the ASC Payment Update

For impact purposes, the surgical procedures on the ASC covered surgical procedure list are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The percentage change in estimated total payments by specialty groups under the CY 2021 payment rates, compared to estimated CY 2020 payment rates, generally ranges between an increase of 2 and 5 percent, depending on the service, with some exceptions. We estimate the impact of applying the hospital market basket update to ASC payment rates will be an increase in payments of $120 million under the ASC payment system in CY 2021.

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the Act was enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the reasonable cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added section 1833(t) to the Act, authorizing implementation of a PPS for hospital outpatient services. The OPPS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPPS are located at 42 CFR parts 410 and 419.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) made major changes in the hospital OPPS. The following Acts made additional changes to the OPPS: The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554); The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) (Pub. L. 109–432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), enacted on July 15, 2008; the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010 (these two public laws are collectively known as the Affordable Care Act); the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111–309); the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA, Pub. L. 112–78), enacted on December 23, 2011; the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA, Pub. L. 112–96), enacted on February 22, 2012; the American Taxpayer Relief Act of 2012 (Pub. L. 112–240), enacted January 2, 2013; the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) enacted on December 26, 2013; the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113–93), enacted on March 27, 2014; the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 114–10), enacted April 16, 2015; the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted November 2, 2015; the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), enacted on December 18, 2015, the 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016; the Consolidated Appropriations Act, 2018 (Pub. L. 115–141), enacted on March 23, 2018; and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115–271), enacted on October 24, 2018.

Under the OPPS, we generally pay for hospital Part B services on a rate-per-service basis that varies according to the APC group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C. of the CY 2021 OPPS/ASC final rule. Section 1833(t)(1)(B) of the Act provides for payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services that are paid under Medicare Part B.

The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage

differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and with respect to resource use, as required by section 1833(t)(2)(B) of the Act. In accordance with section 1833(t)(2)(B) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group (referred to as the ''2 times rule''). In implementing this provision, we generally use the cost of the item or service assigned to an APC group.

For new technology items and services, special payments under the OPPS may be made in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as ''transitional pass-through payments,'' for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not eligible for transitional pass-through payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

C. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercises the authority granted under the statute to also exclude from the OPPS certain services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); certain laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. In addition, section 1833(t)(1)(B)(v) of the Act does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017 by an off-campus outpatient department of a provider (as defined in subparagraph (B) of paragraph (21)). We set forth the services that are excluded from payment under the OPPS in regulations at 42 CFR 419.22.

Under § 419.20(b) of the regulations, we specify the types of hospitals that are excluded from payment under the OPPS. These excluded hospitals are:

- Critical access hospitals (CAHs);
- Hospitals located in Maryland and paid under Maryland's All-Payer or Total Cost of Care Model;
- Hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico; and
- Indian Health Service (IHS) hospitals.

D. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for hospital outpatient services. The hospital OPPS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS, not less often than annually, and to revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practices, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*.

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)

1. Authority of the Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Public Law 106–113, and redesignated by section 202(a)(2) of Public Law 106–113, requires that we consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to annually review (and advise the Secretary concerning) the clinical integrity of the payment groups and their weights under the OPPS. In CY 2000, based on section 1833(t)(9)(A) of the Act, the Secretary established the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to fulfill this requirement. In CY 2011, based on section 222 of the Public Health Service Act, which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary expanded the panel's scope to include the supervision of hospital outpatient therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel). The HOP Panel is not restricted to using data compiled by CMS, and in conducting its review, it may use data collected or developed by organizations outside the Department.

2. Establishment of the Panel

On November 21, 2000, the Secretary signed the initial charter establishing the Panel, and, at that time, named the APC Panel. This expert panel is composed of appropriate representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise) who review clinical data and advise CMS about the clinical integrity of the APC groups and their payment weights. Since CY 2012, the Panel also is charged with advising the Secretary on the appropriate level of supervision for individual hospital outpatient therapeutic services. The Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). The

current charter specifies, among other requirements, that the Panel—

- May advise on the clinical integrity of Ambulatory Payment Classification (APC) groups and their associated weights;
- May advise on the appropriate supervision level for hospital outpatient services;
- May advise on OPPS APC rates for ASC covered surgical procedures;
- Continues to be technical in nature;
- Is governed by the provisions of the FACA;
- Has a Designated Federal Official (DFO); and
- Is chaired by a Federal Official designated by the Secretary.

The Panel's charter was amended on November 15, 2011, renaming the Panel and expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and to add critical access hospital (CAH) representation to its membership. The Panel's charter was also amended on November 6, 2014 (80 FR 23009), and the number of members was revised from up to 19 to up to 15 members. The Panel's current charter was approved on November 20, 2020, for a 2-year period.

The current Panel membership and other information pertaining to the Panel, including its charter, **Federal Register** notices, membership, meeting dates, agenda topics, and meeting reports, can be viewed on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html*.

3. Panel Meetings and Organizational Structure

The Panel has held many meetings, with the last meeting taking place on August 31, 2020. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting, new members, and any other changes of which the public should be aware. Beginning in CY 2017, we have transitioned to one meeting per year (81 FR 31941). In CY 2018, we published a **Federal Register** notice requesting nominations to fill vacancies on the Panel (83 FR 3715). As published in this notice, CMS is accepting nominations on a continuous basis.

In addition, the Panel has established an administrative structure that, in part, currently includes the use of three subcommittee workgroups to provide preparatory meeting and subject support to the larger panel. The three current subcommittees include the following:

- APC Groups and Status Indicator Assignments Subcommittee, which advises and provides recommendations to the Panel on the appropriate status indicators to be assigned to HCPCS codes, including but not limited to whether a HCPCS code or a category of codes should be packaged or separately paid, as well as the appropriate APC assignment of HCPCS codes regarding services for which separate payment is made;
- Data Subcommittee, which is responsible for studying the data issues confronting the Panel and for recommending options for resolving them; and
- Visits and Observation Subcommittee, which reviews and makes recommendations to the Panel on all technical issues pertaining to observation services and hospital outpatient visits paid under the OPPS.

Each of these workgroup subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended at the August 31, 2020, meeting that the subcommittees continue. We accepted this recommendation.

For discussions of earlier Panel meetings and recommendations, we refer readers to previously published OPPS/ASC proposed and final rules, the CMS website mentioned earlier in this section, and the FACA database at *http://facadatabase.gov*.

F. Public Comments Received in Response to the CY 2021 OPPS/ASC Proposed Rule

We received approximately 1,350 timely pieces of correspondence on the CY 2021 OPPS/ASC proposed rule that appeared in the **Federal Register** on August 12, 2020 (85 FR 48772). We note that we received some public comments that were outside the scope of the CY 2021 OPPS/ASC proposed rule. Out-of-scope-public comments are not addressed in this CY 2021 OPPS/ASC final rule with comment period. Summaries of those public comments that are within the scope of the proposed rule and our responses are set forth in the various sections of this final rule with comment period under the appropriate headings.

G. Public Comments Received on the CY 2020 OPPS/ASC Final Rule With Comment Period

We received approximately 22 timely pieces of correspondence on the CY 2020 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 12, 2019 (84 FR 61142), most of which were outside of the scope of the final rule. In-scope comments related to the interim APC assignments and/or status indicators of new or replacement Level II HCPCS codes (identified with comment indicator ''NI'' in OPPS Addendum B, ASC Addendum AA, and ASC Addendum BB to that final rule). Summaries of the public comments on topics that were open to comment and our responses to them are set forth in various sections of this final rule with comment period under the appropriate subject-matter headings. Summaries of the public comments on new or replacement Level II HCPCS codes are set forth in the CY 2021 OPPS/ASC proposed rule and this final rule with comment period under the appropriate subject matter headings.

II. Updates Affecting OPPS Payments

A. Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the relative payment weights for APCs. In the April 7, 2000 OPPS final rule with comment period (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000 for each APC group.

For the CY 2021 OPPS/ASC proposed rule (85 FR 48779), we proposed to recalibrate the APC relative payment weights for services furnished on or after January 1, 2021, and before January 1, 2022 (CY 2021), using the same basic methodology that we described in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61149), using updated CY 2019 claims data. That is, as we proposed, we recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services, using the most recent available data to construct a database for calculating APC group weights.

For the purpose of recalibrating the proposed APC relative payment weights for CY 2021, we began with approximately 167 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for HOPD services furnished on or after January 1, 2019, and before January 1, 2020, before applying our exclusionary criteria and other methodological adjustments. After the application of those data processing changes, we used approximately 87 million final action claims to develop the proposed CY 2021 OPPS payment weights. For exact numbers of claims used and additional details on the

claims accounting process, we refer readers to the claims accounting narrative under supporting documentation for the CY 2021 OPPS/ASC proposed rule on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

Addendum N to the CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website) included the proposed list of bypass codes for CY 2021. The proposed list of bypass codes contained codes that were reported on claims for services in CY 2019 and, therefore, included codes that were in effect in CY 2019 and used for billing, but were deleted for CY 2020. We retained these deleted bypass codes on the proposed CY 2021 bypass list because these codes existed in CY 2019 and were covered OPD services in that period, and CY 2019 claims data were used to calculate proposed CY 2021 payment rates. Keeping these deleted bypass codes on the bypass list potentially allows us to create more ''pseudo'' single procedure claims for ratesetting purposes. ''Overlap bypass codes'' that are members of the proposed multiple imaging composite APCs were identified by asterisks (*) in the third column of Addendum N to the proposed rule. HCPCS codes that we proposed to add for CY 2021 were identified by asterisks (*) in the fourth column of Addendum N.

b. Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2021, in the CY 2020 OPPS/ASC proposed rule (85 FR 48779), we proposed to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC costs on which the CY 2021 APC payment rates are based, we calculated hospital-specific overall ancillary CCRs and hospital-specific departmental CCRs for each hospital for which we had CY 2019 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, are from CY 2018. For the proposed CY 2021 OPPS payment rates, we used the set of claims processed during CY 2019. We applied the hospital-specific CCR to the hospital's charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a hierarchy of CCRs used to estimate costs from charges for each revenue code. To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2019 (the year of claims data we used to calculate the proposed CY 2021 OPPS payment rates) and updates to the NUBC 2019 Data Specifications Manual. That crosswalk is available for review and continuous comment on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

In accordance with our longstanding policy, we calculate CCRs for the standard and nonstandard cost centers accepted by the electronic cost report database. In general, the most detailed level at which we calculate CCRs is the hospital-specific departmental level. For a discussion of the hospital-specific overall ancillary CCR calculation, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 67983 through 67985). The calculation of blood costs is a longstanding exception (since the CY 2005 OPPS) to this general methodology for calculation of CCRs used for converting charges to costs on each claim. This exception is discussed in detail in the CY 2007 OPPS/ASC final rule with comment period and discussed further in section II.A.2.a.(1) of the proposed rule and this final rule with comment period.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74840 through 74847), we finalized our policy of creating new cost centers and distinct CCRs for implantable devices, magnetic resonance imaging (MRIs), computed tomography (CT) scans, and cardiac catheterization. However, in response to the CY 2014 OPPS/ASC proposed rule, commenters reported that some hospitals used a less precise ''square feet'' allocation methodology for the costs of large moveable equipment like CT scan and MRI machines. They indicated that while we recommended using two alternative allocation methods, ''direct assignment'' or ''dollar value,'' as a more accurate methodology for directly assigning equipment costs, industry analysis suggested that approximately only half of the reported cost centers for CT scans and MRIs rely on these preferred methodologies. In response to concerns from commenters, we finalized a policy for the CY 2014 OPPS/ASC final rule with comment period (78 FR 74847) to remove claims from providers that use a cost allocation method of ''square feet'' to calculate CCRs used to estimate costs associated with the APCs for CT and MRI. Further, we finalized a transitional policy to estimate the imaging APC relative payment weights using only CT and MRI cost data from providers that do not use ''square feet'' as the cost allocation statistic. We provided that this finalized policy would sunset in 4 years to provide sufficient time for hospitals to transition to a more accurate cost allocation method and for the related data to be available for ratesetting purposes (78 FR 74847). Therefore, beginning in CY 2018 with the sunset of the transition policy, we would estimate the imaging APC relative payment weights using cost data from all providers, regardless of the cost allocation statistic employed. However, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59228 and 59229) and in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58831), we finalized a policy to extend the transition policy for 1 additional year and we continued to remove claims from providers that use a cost allocation method of ''square feet'' to calculate CT and MRI CCRs for the CY 2018 OPPS and the CY 2019 OPPS.

As we discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59228), some stakeholders have raised concerns regarding using claims from all providers to calculate CT and MRI CCRs, regardless of the cost allocations statistic employed (78 FR 74840 through 74847). Stakeholders noted that providers continue to use the ''square feet'' cost allocation method and that including claims from such providers would cause significant reductions in the imaging APC payment rates.

Table 1 demonstrates the relative effect on imaging APC payments after removing cost data for providers that report CT and MRI standard cost centers using ''square feet'' as the cost allocation method by extracting HCRIS data on Worksheet B–1. Table 2 provides statistical values based on the CT and MRI standard cost center CCRs using the different cost allocation methods.

TABLE 1: PERCENTAGE CHANGE IN ESTIMATED COST FOR CT AND MRI APCS WHEN EXCLUDING CLAIMS FROM PROVIDERS USING "SQUARE FEET" AS THE COST ALLOCATION METHOD

APC	APC Descriptor	Percentage Change
5521	Level 1 Imaging without Contrast	-2.8%
5522	Level 2 Imaging without Contrast	5.5%
5523	Level 3 Imaging without Contrast	4.3%
5524	Level 4 Imaging without Contrast	5.3%
5571	Level 1 Imaging with Contrast	6.8%
5572	Level 2 Imaging with Contrast	8.2%
5573	Level 3 Imaging with Contrast	2.3%
8005	CT and CTA without Contrast Composite	13.9%
8006	CT and CTA with Contrast Composite	10.8%
8007	MRI and MRA without Contrast Composite	7.6%
8008	MRI and MRA with Contrast Composite	7.2%

TABLE 2: CCR STATISTICAL VALUES BASED ON USE OF DIFFERENT COST ALLOCATION METHODS

Cost Allocation Method	CT		MRI	
	Median CCR	Mean CCR	Median CCR	Mean CCR
All Providers	0.0342	0.0483	0.0752	0.1008
Square Feet Only	0.0285	0.0435	0.0660	0.0919
Direct Assign	0.0459	0.0557	0.0910	0.1151
Dollar Value	0.0405	0.0546	0.0858	0.1126
Direct Assign and Dollar Value	0.0406	0.0548	0.0862	0.1128

Our analysis shows that since the CY 2014 OPPS in which we established the transition policy, the number of valid MRI CCRs has increased by 18.7 percent to 2,199 providers and the number of valid CT CCRs has increased by 16.5 percent to 2,280 providers. Table 1 displays the impact on OPPS payment rates for CY 2021 if claims from providers that report using the ''square feet'' cost allocation method were removed. This can be attributed to the generally lower CCR values from providers that use a ''square feet'' cost allocation method as shown in Table 1.

We note that the CT and MRI cost center CCRs have been available for ratesetting since the CY 2014 OPPS in which we established the transition policy. Since the initial 4-year transition, we had extended the transition an additional 2 years to offer providers flexibility in applying cost allocation methodologies for CT and MRI cost centers other than ''square feet.'' In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61152), we finalized a 2-year phased-in approach, as suggested by some commenters, that applied 50 percent of the payment impact from ending the transition in CY 2020 and 100 percent of the payment impact from ending the transition in CY 2021.

We believe we have provided sufficient time for providers to adopt an alternative cost allocation methodology for CT and MRI cost centers if they intended to do so and many providers continue to use the ''square feet'' cost allocation methodology, which we believe indicates that these providers believe this methodology is a sufficient method for attributing costs to this cost center. Additionally, we generally believe that increasing the amount of claims data available for use in ratesetting improves our ratesetting process. Therefore, as finalized in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61152), in the CY 2021 OPPS we are using all claims with valid CT and MRI cost center CCRs, including those that use a ''square feet'' cost allocation method, to estimate costs for the APCs for CT and MRI identified in Table 1.

The Deficit Reduction Act (DRA) of 2005 requires Medicare to limit Medicare payment for certain imaging services covered by the Physician Fee Schedule (PFS) to not exceed what Medicare pays for these services under the OPPS. As required by law, for certain imaging services paid for under the PFS, we cap the technical component of the PFS payment amount for the applicable year at the OPPS payment amount (71 FR 69659 through

69661). As we stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74845), we have noted the potential impact the CT and MRI CCRs may have on other payment systems. We understand that payment reductions for imaging services under the OPPS could have significant payment impacts under the PFS where the technical component payment for many imaging services is capped at the OPPS amount. We will continue to monitor OPPS imaging payments in the future and consider potential impacts of payment changes on the PFS and the ASC payment system.

Comment: Several commenters requested that CMS not use the CT and MRI-specific cost centers and instead estimate cost using the single diagnostic radiology cost center, believing that this will solve the inaccurate reporting of costs for CT and MR services. Commenters stated that many hospitals have ''near zero'' CT and MRI CCRs and the existing cost centers are inaccurate, too low, and depressing the valuation of APCs that include CT and MRI services. One commenter recommended that CMS establish detailed instructions for nonstandard cost centers to improve the accuracy of the cost center data used to calculate CT and MRI CCRs. Commenters also noted that the impact of our proposal may diminish beneficiary access to medical imaging services for beneficiaries, specifically noting low OPPS payments for cardiac computed tomography angiography (CCTA). Several commenters noted that the use of separate CT and MRI CCRs creates unintended consequences on the technical component of CT and MRI codes in the Medicare Physician Fee Schedule and on the payment rate under the ASC payment system for these codes.

Response: We appreciate the thoughtful comments and analysis regarding the use of the CT and MRI cost center CCRs. However, as discussed in the CY 2020 OPPS/ASC final rule (84 FR 61152), we finalized a policy to end the transition policy and use all data submitted (including all providers, regardless of cost allocation method) in the CY 2021 OPPS. We did not propose to make any changes in the CY 2021 OPPS and are not modifying the policy at this time.

2. Final Data Development and Calculation of Costs Used for Ratesetting

In this section of this final rule with comment period, we discuss the use of claims to calculate the OPPS payment rates for CY 2021. The Hospital OPPS page on the CMS website on which this final rule with comment period is posted (*http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*) provides an accounting of claims used in the development of the final payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, later in this section we discuss the file of claims that comprises the data set that is available upon payment of an administrative fee under a CMS data use agreement. The CMS website, *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*, includes information about obtaining the ''OPPS Limited Data Set,'' which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including ICD–10–CM diagnosis codes and revenue code payment amounts. This file is derived from the CY 2019 claims that were used to calculate the final payment rates for this CY 2021 OPPS/ASC final rule with comment period.

Previously, the OPPS established the scaled relative weights, on which payments are based using APC median costs, a process described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f. of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271), we finalized the use of geometric mean costs to calculate the relative weights on which the CY 2013 OPPS payment rates were based. While this policy changed the cost metric on which the relative payments are based, the data process in general remained the same, under the methodologies that we used to obtain appropriate claims data and accurate cost information in determining estimated service cost. For CY 2021, we are finalizing our proposal to continue to use geometric mean costs to calculate the relative weights on which the final CY 2021 OPPS payment rates are based.

We used the methodology described in sections II.A.2.a. through II.A.2.c. of the CY 2021 OPPS/ASC final rule with comment period to calculate the costs we used to establish the relative payment weights used in calculating the OPPS payment rates for CY 2021 shown in Addenda A and B to the CY 2021 OPPS/ASC final rule with comment period (which are available via the internet on the CMS website). We referred readers to section II.A.4. of the CY 2021 OPPS/ASC final rule with comment period for a discussion of the conversion of APC costs to scaled payment weights.

We note that under the OPPS, CY 2019 was the first year in which the claims data used for setting payment rates (CY 2017 data) contained lines with the modifier ''PN'', which indicates nonexcepted items and services furnished and billed by off-campus provider-based departments (PBDs) of hospitals. Because nonexcepted services are not paid under the OPPS, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58832), we finalized a policy to remove those claim lines reported with modifier ''PN'' from the claims data used in ratesetting for the CY 2019 OPPS and subsequent years. For the CY 2021 OPPS, we will continue to remove these claim lines with modifier ''PN'' from the ratesetting process.

For details of the claims accounting process used in the CY 2021 OPPS/ASC final rule with comment period, we refer readers to the claims accounting narrative under supporting documentation for this CY 2021 OPPS/ASC final rule with comment period on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

a. Calculation of Single Procedure APC Criteria-Based Costs

(1) Blood and Blood Products

(a) Methodology

Since the implementation of the OPPS in August 2000, we have made separate payments for blood and blood products through APCs rather than packaging payment for them into payments for the procedures with which they are administered. Hospital payments for the costs of blood and blood products, as well as for the costs of collecting, processing, and storing blood and blood products, are made through the OPPS payments for specific blood product APCs.

We proposed to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers, and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-

specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products. Specifically, to address the differences in CCRs and to better reflect hospitals' costs, we proposed to continue to simulate blood CCRs for each hospital that does not report a blood cost center by calculating the ratio of the blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers. We also proposed to apply this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports to simulate blood-specific CCRs for those hospitals. We proposed to calculate the costs upon which the proposed CY 2021 payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific, simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

We continue to believe that the hospital-specific, simulated blood-specific, CCR methodology better responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. Because this methodology takes into account the unique charging and cost accounting structure of each hospital, we believe that it yields more accurate estimated costs for these products. We continue to believe that this methodology in CY 2021 will result in costs for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and, therefore, for these blood products in general.

We note that we defined a comprehensive APC (C–APC) as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Under this policy, we include the costs of blood and blood products when calculating the overall costs of these C–APCs. We proposed to continue to apply the blood-specific CCR methodology described in this section when calculating the costs of the blood and blood products that appear on claims with services assigned to the C–APCs. Because the costs of blood and blood products will be reflected in the overall costs of the C–APCs (and, as a result, in the proposed payment rates of the C–APCs), we proposed not to make separate payments for blood and blood products when they appear on the same claims as services assigned to the C–APCs (we refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66796)). We refer readers to Addendum B the CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website) for the proposed CY 2021 payment rates for blood and blood products (which are generally identified with status indicator ''R''). For a more detailed discussion of the blood-specific CCR methodology, we refer readers to the CY 2005 OPPS proposed rule (69 FR 50524 through 50525). For a full history of OPPS payment for blood and blood products, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810).

For CY 2021, we proposed to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology. We did not receive any comments on our proposal to establish payment rates for blood and blood products using our blood-specific CCR methodology and we are finalizing this policy as proposed.

(b) Payment for Blood Not Otherwise Classified (NOC) Code

Recently, providers and stakeholders in the blood products field have reported that product development for new blood products has accelerated. There may be several additional new blood products entering the market by the end of CY 2021, compared to only one or two new products entering the market over the previous 15 to 20 years. To encourage providers to use these new products, providers and stakeholders requested that we establish a new HCPCS code to allow for payment for unclassified blood products prior to these products receiving their own HCPCS code. Under the OPPS, unclassified procedures are generally assigned to the lowest APC payment level of an APC family. However, since blood products are each assigned to their own unique APC, the concept of a lowest APC payment level does not apply in this context.

Starting January 1, 2020, we established a new HCPCS code, P9099 (Blood component or product not otherwise classified) which allows providers to report unclassified blood products. We assigned HCPCS code P9099 to status indicator ''E2'' (Not payable by Medicare when submitted on an outpatient claim) for CY 2020. We took this action because HCPCS code P9099 potentially could be reported for multiple products with different costs during the same period of time. Therefore, we could not identify an individual blood product HCPCS code that would have a similar cost to HCPCS code P9099, and were not able to crosswalk a payment rate from an established blood product HCPCS code to HCPCS code P9099. Some stakeholders expressed concerns that assigning HCPCS code P9099 to a non-payable status in the OPPS meant that hospitals would receive no payment when they used unclassified blood products. Also, claim lines billed with P9099 are rejected by Medicare, which prevents providers from tracking the utilization of unclassified blood products.

Because of the challenges of determining an appropriate payment rate for unclassified blood products, we stated in the CY 2021 OPPS/ASC proposed rule that we were considering packaging the cost of unclassified blood products into their affiliated primary medical procedure. Although we typically do not package blood products under the OPPS, for unclassified blood products, we stated that we do not believe it is possible to accurately determine an appropriate rate that would apply for all of the products (potentially several, with varying costs) that may be reported using HCPCS code P9099. Packaging the cost of unclassified blood products into the payment for the primary medical service by assigning HCPCS code P9099 a status indicator of ''N'' would allow providers to report the cost of unclassified blood products to Medicare. Over time, the costs of unspecified blood products would be reflected in the payment rate for the primary medical service if the blood product remains unclassified. However, we stated that we expect that most blood products would seek and be granted more specific coding such that the unclassified HCPCS code P9099 would no longer be applicable. We also explained that we believe that packaging the costs of unclassified blood products would be an improvement over the current non-payable status for HCPCS code P9099 as it would allow for tracking of the costs and utilization of unclassified blood products.

Another option we considered for the CY 2021 OPPS/ASC proposed rule, but ultimately rejected was similar to our policy under the OPPS to assign NOC codes to the lowest APC within the appropriate clinical family. We stated that we could have cross-walked and assigned the same payment rate for HCPCS code P9099 as HCPCS code P9043 (Infusion, plasma protein fraction (human), 5 percent, 50 ml), which is the lowest cost blood product with a

proposed CY 2021 payment rate of $8.02 per unit. This option would have provided a small, separate payment for each unclassified blood product service, and, similar to our proposal to package the costs of HCPCS code P9099 into their primary procedure, would have allowed for tracking of the cost and utilization for unclassified blood products. However, given that the cross-walked payment rate is potentially significantly lower than the cost of the product, we concluded that providers may find that packaging the cost of unclassified blood products into another medical service may generate more payment for the products over time.

Thus, for CY 2021, we proposed to package the cost of unclassified blood products reported by HCPCS code P9099 into the cost of the associated primary procedure. We proposed to change the status indicator for HCPCS code P9099 from ''E2'' (not payable by Medicare in the OPPS) to ''N'' (payment is packaged into other services in the OPPS). In addition, we also sought comment on the alternative proposal to make HCPCS code P9099 separately payable with a payment rate equivalent to the payment rate for the lowest cost blood product, HCPCS code P9043 (Infusion, plasma protein fraction (human), 5 percent, 50 ml), with a proposed CY 2021 payment rate of $8.02 per unit. We stated that if we were to adopt this option as our final policy, we would also change the status indicator for HCPCS code P9099 from ''E2'' (not payable by Medicare in the OPPS) to ''R'' (blood and blood products, paid under OPPS).

Comment: Multiple commenters opposed our proposal to reassign HCPCS code P9099 to status indicator ''N'' and package the payment for unclassified blood products into the associated primary procedure. Commenters were concerned that because blood products are usually separately paid in the OPPS, APC payment rates for the associated procedures would not reflect the cost of the unclassified blood products, and that it would take a long time before providers would see any changes in payments that would include the cost of unclassified blood products. One commenter was also concerned that packaging the cost of unclassified blood products would make providers less likely to report HCPCS code P9099, making it harder to track the utilization of unclassified blood products, and reluctant to use blood products that would not receive separate payment.

Response: We agree with the concerns expressed by the commenters, and we have considered these concerns in determining the payment policy for the blood NOC code.

Comment: One commenter supported our proposal to reassign HCPCS code P9099 to status indicator ''N'' and package the payment for unclassified blood products into the associated primary procedure. The commenter also encouraged us to work with manufacturers and blood product stakeholders to move quickly to establish individual HCPCS codes for these new blood products.

Response: We appreciate the commenter's support for our proposal and we also support the request that codes be established in a timely manner for unclassified blood products.

Comment: Multiple commenters opposed our alternative proposal to pay services billed with HCPCS code P9099 at the lowest payment rate for a blood product in the OPPS, which is $7.79 per unit. The commenters believe the payment rate will be too low for new, unclassified blood products and may discourage manufacturers from pursuing new innovations in the blood products field.

Response: We understand the concerns of the commenters who believe paying for unclassified blood products at the lowest payment rate for a separately payable blood product in the OPPS does not provide adequate payment for new, unclassified blood products. However, our goal is to limit the time it is necessary for providers to report HCPCS code P9099 until a new blood product has an individual HCPCS code established for the product. Once a new blood product has an individual HCPCS code, it will allow for a payment for the new service that is better aligned with its costs and make it easier to track utilization for the service. Establishing a payment rate for the blood NOC code that is equal to the payment rate for the lowest payment rate for a separately payable blood product is consistent with OPPS policy for other major categories of medical care where the payment rate for the unclassified service is equal to the lowest-paying APC in an APC series for that category of service.

Comment: The CMS HOP Panel and multiple commenters requested that unclassified blood products be separately paid using a weighted average of the payment rates of all separately payable blood products in the OPPS. The average payment rate would be weighted by the number of units billed for each service in the OPPS. Commenters believe a weighted average would be consistent with OPPS policy to provide separate payment for all blood products and would encourage the use of HCPCS code P9099 to track the utilization of unclassified blood products until the new products could receive individual HCPCS codes. The weighted average also would provide a higher payment for services billed with HCPCS code P9099 than the alternative proposal of assigning the lowest payment rate for a separately payable blood product as payment for unclassified blood products. Other commenters suggested that unclassified blood products be paid either at charges reduced to cost or at reasonable cost to appropriately compensate providers billing unclassified blood products.

Response: Providing payment for HCPCS code P9099 through a weighted average payment, charges reduced to cost, or reasonable cost could provide incentives to discourage manufacturers of new blood products from seeking individual HCPCS codes for their products. A weighted average payment would encourage manufacturers of relatively inexpensive unclassified blood products not to seek a HCPCS code for their products because the payment using P9099 for the products would be substantially higher than payment the products would receive once an individual code is established for the blood products. In addition, the level of payment from a weighted average payment may reduce the urgency of manufacturers to seek an individual HCPCS cost even for higher-cost products, which would delay our ability to track payment for individual blood products. We have similar concerns about paying unclassified blood products using either charges reduced to cost or reasonable cost. Although these payment methods would accurately reflect the cost of unclassified blood products to providers, there would be no incentive for providers to manage their costs when using unclassified blood products, and no incentives for the manufacturers to seek individual HCPCS codes for the unclassified blood products. The OPPS is a prospective payment system, and we want to limit rather than expand the types of services within the OPPS that do not receive prospective payment.

After reviewing the public comments, we are not finalizing our original proposal to package HCPCS code P9099 into the associated primary procedure. Instead, we are finalizing our alternative proposal to make HCPCS code P9099 separately payable, assign it a status indicator of ''R'', and pay the code at a rate equal to the lowest paid separately payable blood product in the OPPS, which is P9043 (Infusion, plasma protein fraction (human), 5 percent, 50 ml) with a payment rate of $7.79 per unit. Our alternative proposal aligns

with our general policy in the OPPS to pay NOC codes at the lowest available APC rate for a service category, while providing a payment for unclassified blood products when a service is reported on the claim. We believe our alternative proposal is superior to our original proposal, which would not have provided any separate payment for blood products reported using HCPCS code P9099. Our alternative proposal also provides incentives for manufacturers to seek individual HCPCS codes for new blood products, which helps us to track the utilization of these new blood products and establish a payment rate for these new products that better reflects their cost.

We decided to finalize our alternative proposal, as it gives providers some payment for unclassified blood products, is consistent with OPPS policy for other major categories of medical care where the payment rate for the unclassified service is based on the lowest-paying APC in an APC series for that category of service, while maintaining incentives for manufacturers to establish individual HCPCS codes for their new blood products in a timely manner.

(2) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act mandates the creation of additional groups of covered OPD services that classify devices of brachytherapy consisting of a seed or seeds (or radioactive source) (''brachytherapy sources'') separately from other services or groups of services. The statute provides certain criteria for the additional groups. For the history of OPPS payment for brachytherapy sources, we refer readers to prior OPPS final rules, such as the CY 2012 OPPS/ASC final rule with comment period (77 FR 68240 through 68241). As we have stated in prior OPPS updates, we believe that adopting the general OPPS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons (77 FR 68240). The general OPPS methodology uses costs based on claims data to set the relative payment weights for hospital outpatient services. This payment methodology results in more consistent, predictable, and equitable payment amounts per source across hospitals by averaging the extremely high and low values, in contrast to payment based on hospitals' charges adjusted to costs. We believe that the OPPS methodology, as opposed to payment based on hospitals' charges adjusted to cost, also would provide hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology for the vast majority of items and services paid under the OPPS. We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70323 through 70325) for further discussion of the history of OPPS payment for brachytherapy sources.

For CY 2021, except where otherwise indicated, we proposed to use the costs derived from CY 2019 claims data to set the proposed CY 2021 payment rates for brachytherapy sources because CY 2019 is the year of data we proposed to use to set the proposed payment rates for most other items and services that would be paid under the CY 2021 OPPS. With the exception of the proposed payment rate for brachytherapy source C2645 (Brachytherapy planar source, palladium-103, per square millimeter), we proposed to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we proposed for other items and services paid under the OPPS, as discussed in section II.A.2. of the CY 2021 OPPS/ASC proposed rule. We also proposed to continue the other payment policies for brachytherapy sources that we finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). We proposed to pay for the stranded and nonstranded not otherwise specified (NOS) codes, HCPCS codes C2698 (Brachytherapy source, stranded, not otherwise specified, per source) and C2699 (Brachytherapy source, non-stranded, not otherwise specified, per source), at a rate equal to the lowest stranded or nonstranded prospective payment rate for such sources, respectively, on a per source basis (as opposed to, for example, a per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). We also proposed to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims data, based on the same reasons we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was delayed until January 1, 2010 by section 142 of Pub. L. 110–275). Specifically, this policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals. The proposed CY 2021 payment rates for brachytherapy sources are included in Addendum B to the CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website) and identified with status indicator ''U''.

For CY 2018, we assigned status indicator ''U'' (Brachytherapy Sources, Paid under OPPS; separate APC payment) to HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) in the absence of claims data and established a payment rate using external data (invoice price) at $4.69 per mm^2. For CY 2019, in the absence of sufficient claims data, we continued to establish a payment rate for C2645 at $4.69 per mm^2. Our CY 2018 claims data available for the final CY 2020 OPPS/ASC final rule with comment period, included two claims with a geometric mean cost for HCPCS code C2645 of $1.02 per mm^2. In response to comments from stakeholders, we agreed with commenters that given the limited claims data available and a new outpatient indication for C2645, a payment rate for HCPCS code C2645 based on the geometric mean cost of 1.02 per mm^2 may not adequately reflect the cost of HCPCS code C2645. In the CY 2020 OPPS/ASC final rule with comment period, we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CY 2020.

For CY 2021, we proposed to continue to assign status indicator ''U'' to HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter). For CY 2020, in the absence of sufficient claims data, we continued to establish a payment rate for C2645 at $4.69 per mm^2. Our CY 2019 claims data available for the proposed CY 2021 rule included one claim with over 4,000 units of HCPCS code C2645. The geometric mean cost of HCPCS code C2645 from this one claim is $1.07 per mm^2 for CY 2019. We do not believe that this one claim is adequate to establish an APC payment rate for HCPCS code C2645 and to discontinue our use of external data for this brachytherapy source. Therefore, for CY 2021, we proposed to continue assigning the brachytherapy source described by HCPCS code C2645 a payment rate of $4.69 mm^2 for CY 2021

through use of our equitable adjustment authority.

Comment: One commenter recommended that we should review outpatient claims data for low-volume brachytherapy sources and consider removing outliers to ensure appropriate and stable brachytherapy source reimbursement in future years. The commenter contends that brachytherapy source payments have fluctuated significantly since 2013 and may create barriers to access for individual cancer patients.

Response: We thank the commenter for their recommendation. As we have stated in past rulemaking, the OPPS relies on the concept of averaging, where the payment may be more or less than the estimated cost of providing a service for a particular patient; however, with the exception of outlier cases, we believe that such a prospective payment is adequate to ensure access to appropriate care. We acknowledge that payment for brachytherapy sources based on geometric mean costs from a small set of claims may be more variable on a year-to-year basis when compared to the geometric mean costs for brachytherapy sources from a larger claims set. We will take the commenter's recommendation into consideration in future rulemaking.

Comment: One commenter recommended that we exclude erroneous claims data for C2642 (Brachytherapy source, stranded, cesium-131, per source) from a particular hospital. The commenter stated the hospital reported costs per source of $42.59 for C2642. Further, the commenter argued the proposed payment rate for C2642 as a result of including the hospital's claims information would threaten access to cancer therapy and would be less than the actual amount paid by any hospital for this source over the past decade.

Response: In our review of CY 2019 brachytherapy claims used for CY 2021 OPPS ratesetting, we did not find any erroneous billing of C2642 with respect to the particular hospital mentioned by the commenter. OPPS relative payment weights based on geometric mean costs capture the range of costs associated with services that are introduced slowly into the system on a case-by-case or hospital-by-hospital basis. For these reasons we believe it would be inappropriate to remove any outliers when determining brachytherapy geometric mean costs and payment rates for C2642.

After consideration of the public comments we received, we are finalizing our proposal to assign the brachytherapy source described by HCPCS code C2645 a payment rate of $4.69 per mm^2 for CY 2021 through use of our equitable adjustment authority.

We continue to invite hospitals and other parties to submit recommendations to us for new codes to describe new brachytherapy sources. Such recommendations should be direction via email to *outpatientpps@cms.hhs.gov* or by mail to the Division of Outpatient Care, Mail Stop C4–01–26, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. We will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

b. Comprehensive APCs (C–APCs) for CY 2021

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910), we finalized a comprehensive payment policy that packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. The policy was finalized in CY 2014, but the effective date was delayed until January 1, 2015, to allow additional time for further analysis, opportunity for public comment, and systems preparation. The comprehensive APC (C–APC) policy was implemented effective January 1, 2015, with modifications and clarifications in response to public comments received regarding specific provisions of the C–APC policy (79 FR 66798 through 66810).

A C–APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We established C–APCs as a category broadly for OPPS payment and implemented 25 C–APCs beginning in CY 2015 (79 FR 66809 through 66810). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70332), we finalized 10 additional C–APCs to be paid under the existing C–APC payment policy and added 1 additional level to both the Orthopedic Surgery and Vascular Procedures clinical families, which increased the total number of C–APCs to 37 for CY 2016. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79584 through 79585), we finalized another 25 C–APCs for a total of 62 C–APCs. In the CY 2018 OPPS/ASC final rule with comment period, we did not change the total number of C–APCs from 62. In the CY 2019 OPPS/ASC final rule with comment period, we created 3 new C–APCs, increasing the total number to 65 (83 FR 58844 through 58846). Most recently in the CY 2020 OPPS/ASC final rule with comment period, we created two new C–APCs, increasing the total number to 67 C–APCs (84 FR 61158 through 61166).

Under our C–APC policy, we designate a service described by a HCPCS code assigned to a C–APC as the primary service when the service is identified by OPPS status indicator ''J1''. When such a primary service is reported on a hospital outpatient claim, taking into consideration the few exceptions that are discussed below, we make payment for all other items and services reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service (hereinafter collectively referred to as ''adjunctive services'') and representing components of a complete comprehensive service (78 FR 74865 and 79 FR 66799). Payments for adjunctive services are packaged into the payments for the primary services. This results in a single prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level.

Services excluded from the C–APC policy under the OPPS include services that are not covered OPD services, services that cannot by statute be paid for under the OPPS, and services that are required by statute to be separately paid. This includes certain mammography and ambulance services that are not covered OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act; brachytherapy seeds, which also are required by statute to receive separate payment under section 1833(t)(2)(H) of the Act; pass-through payment drugs and devices, which also require separate payment under section 1833(t)(6) of the Act; self-administered drugs (SADs) that are not otherwise packaged as supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act; and certain preventive services (78 FR 74865 and 79 FR 66800 through 66801). A list of services excluded from the C–APC policy is included in Addendum J to the CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

In the interim final with request for comments (IFC) entitled, ''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'', published on November 6, 2020, we stated that effective for services furnished on or

after the effective date of the IFC and until the end of the PHE for COVID–19, there is an exception to the OPPS C–APC policy to ensure separate payment for new COVID–19 treatments that meet certain criteria (85 FR 71158 through 71160). Under this exception, any new COVID–19 treatment that meets the two following criteria will, for the remainder of the PHE for COVID–19, always be separately paid and will not be packaged into a C–APC when it is provided on the same claim as the primary C–APC service. First, the treatment must be a drug or biological product (which could include a blood product) authorized to treat COVID–19, as indicated in section ''I. Criteria for Issuance of Authorization'' of the letter of authorization for the drug or biological product, or the drug or biological product must be approved by the FDA for treating COVID–19. Second, the emergency use authorization (EUA) for the drug or biological product (which could include a blood product) must authorize the use of the product in the outpatient setting or not limit its use to the inpatient setting, or the product must be approved by the FDA to treat COVID–19 disease and not limit its use to the inpatient setting. For further information regarding the exception to the C–APC policy for COVID–19 treatments, please refer to the IFC (85 FR 71158 through 71160).

The C–APC policy payment methodology set forth in the CY 2014 OPPS/ASC final rule with comment period for the C–APCs and modified and implemented beginning in CY 2015 is summarized as follows (78 FR 74887 and 79 FR 66800):

Basic Methodology. As stated in the CY 2015 OPPS/ASC final rule with comment period, we define the C–APC payment policy as including all covered OPD services on a hospital outpatient claim reporting a primary service that is assigned to status indicator ''J1'', excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS. Services and procedures described by HCPCS codes assigned to status indicator ''J1'' are assigned to C–APCs based on our usual APC assignment methodology by evaluating the geometric mean costs of the primary service claims to establish resource similarity and the clinical characteristics of each procedure to establish clinical similarity within each APC.

In the CY 2016 OPPS/ASC final rule with comment period, we expanded the C–APC payment methodology to qualifying extended assessment and management encounters through the ''Comprehensive Observation Services'' C–APC (C–APC 8011). Services within this APC are assigned status indicator ''J2''. Specifically, we make a payment through C–APC 8011 for a claim that:

- Does not contain a procedure described by a HCPCS code to which we have assigned status indicator ''T;''
- Contains 8 or more units of services described by HCPCS code G0378 (Hospital observation services, per hour);
- Contains services provided on the same date of service or 1 day before the date of service for HCPCS code G0378 that are described by one of the following codes: HCPCS code G0379 (Direct admission of patient for hospital observation care) on the same date of service as HCPCS code G0378; CPT code 99281 (Emergency department visit for the evaluation and management of a patient (Level 1)); CPT code 99282 (Emergency department visit for the evaluation and management of a patient (Level 2)); CPT code 99283 (Emergency department visit for the evaluation and management of a patient (Level 3)); CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)) or HCPCS code G0380 (Type B emergency department visit (Level 1)); HCPCS code G0381 (Type B emergency department visit (Level 2)); HCPCS code G0382 (Type B emergency department visit (Level 3)); HCPCS code G0383 (Type B emergency department visit (Level 4)); HCPCS code G0384 (Type B emergency department visit (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); or HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient); and
- Does not contain services described by a HCPCS code to which we have assigned status indicator ''J1''.

The assignment of status indicator ''J2'' to a specific combination of services performed in combination with each other allows for all other OPPS payable services and items reported on the claim (excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS) to be deemed adjunctive services representing components of a comprehensive service and resulting in a single prospective payment for the comprehensive service based on the costs of all reported services on the claim (80 FR 70333 through 70336).

Services included under the C–APC payment packaging policy, that is, services that are typically adjunctive to the primary service and provided during the delivery of the comprehensive service, include diagnostic procedures, laboratory tests, and other diagnostic tests and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; uncoded services and supplies used during the service; durable medical equipment as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other components reported by HCPCS codes that represent services that are provided during the complete comprehensive service (78 FR 74865 and 79 FR 66800).

In addition, payment for hospital outpatient department services that are similar to therapy services and delivered either by therapists or nontherapists is included as part of the payment for the packaged complete comprehensive service. These services that are provided during the perioperative period are adjunctive services and are deemed not to be therapy services as described in section 1834(k) of the Act, regardless of whether the services are delivered by therapists or other nontherapist health care workers. We have previously noted that therapy services are those provided by therapists under a plan of care in accordance with section 1835(a)(2)(C) and section 1835(a)(2)(D) of the Act and are paid for under section 1834(k) of the Act, subject to annual therapy caps as applicable (78 FR 74867 and 79 FR 66800). However, certain other services similar to therapy services are considered and paid for as hospital outpatient department services. Payment for these nontherapy outpatient department services that are reported with therapy codes and provided with a comprehensive service is included in the payment for the packaged complete comprehensive service. We note that these services, even though they are reported with therapy codes, are hospital outpatient department services and not therapy services. We refer readers to the July 2016 OPPS Change Request 9658 (Transmittal 3523) for further instructions on reporting these services in the context of a C–APC service.

Items included in the packaged payment provided in conjunction with the primary service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and SADs, unless they function as packaged supplies (78 FR 74868 through 74869 and 74909 and 79 FR 66800). We refer readers to Section

50.2M, Chapter 15, of the Medicare Benefit Policy Manual for a description of our policy on SADs treated as hospital outpatient supplies, including lists of SADs that function as supplies and those that do not function as supplies.

We define each hospital outpatient claim reporting a single unit of a single primary service assigned to status indicator ''J1'' as a single ''J1'' unit procedure claim (78 FR 74871 and 79 FR 66801). Line item charges for services included on the C–APC claim are converted to line item costs, which are then summed to develop the estimated APC costs. These claims are then assigned one unit of the service with status indicator ''J1'' and later used to develop the geometric mean costs for the C–APC relative payment weights. (We note that we use the term ''comprehensive'' to describe the geometric mean cost of a claim reporting ''J1'' service(s) or the geometric mean cost of a C–APC, inclusive of all of the items and services included in the C–APC service payment bundle.) Charges for services that would otherwise be separately payable are added to the charges for the primary service. This process differs from our traditional cost accounting methodology only in that all such services on the claim are packaged (except certain services as described above). We apply our standard data trims, which exclude claims with extremely high primary units or extreme costs.

The comprehensive geometric mean costs are used to establish resource similarity and, along with clinical similarity, dictate the assignment of the primary services to the C–APCs. We establish a ranking of each primary service (single unit only) to be assigned to status indicator ''J1'' according to its comprehensive geometric mean costs. For the minority of claims reporting more than one primary service assigned to status indicator ''J1'' or units thereof, we identify one ''J1'' service as the primary service for the claim based on our cost-based ranking of primary services. We then assign these multiple ''J1'' procedure claims to the C–APC to which the service designated as the primary service is assigned. If the reported ''J1'' services on a claim map to different C–APCs, we designate the ''J1'' service assigned to the C–APC with the highest comprehensive geometric mean cost as the primary service for that claim. If the reported multiple ''J1'' services on a claim map to the same C–APC, we designate the most costly service (at the HCPCS code level) as the primary service for that claim. This process results in initial assignments of claims for the primary services assigned to status indicator ''J1'' to the most appropriate C–APCs based on both single and multiple procedure claims reporting these services and clinical and resource homogeneity.

Complexity Adjustments. We use complexity adjustments to provide increased payment for certain comprehensive services. We apply a complexity adjustment by promoting qualifying paired ''J1'' service code combinations or paired code combinations of ''J1'' services and certain add-on codes (as described further below) from the originating C–APC (the C–APC to which the designated primary service is first assigned) to the next higher paying C–APC in the same clinical family of C–APCs. We apply this type of complexity adjustment when the paired code combination represents a complex, costly form or version of the primary service according to the following criteria:

- Frequency of 25 or more claims reporting the code combination (frequency threshold); and
- Violation of the 2 times rule, as stated in section 1833(t)(2) of the Act and section III.B.2. of the CY 2021 OPPS/ASC proposed rule, in the originating C–APC (cost threshold).

These criteria identify paired code combinations that occur commonly and exhibit materially greater resource requirements than the primary service. The CY 2017 OPPS/ASC final rule with comment period (81 FR 79582) included a revision to the complexity adjustment eligibility criteria. Specifically, we finalized a policy to discontinue the requirement that a code combination (that qualifies for a complexity adjustment by satisfying the frequency and cost criteria thresholds described above) also not create a 2 times rule violation in the higher level or receiving APC.

After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim assigned to status indicator ''J1'' (or certain add-on codes) to determine if there are paired code combinations that meet the complexity adjustment criteria. For a new HCPCS code, we determine initial C–APC assignment and qualification for a complexity adjustment using the best available information, crosswalking the new HCPCS code to a predecessor code(s) when appropriate.

Once we have determined that a particular code combination of ''J1'' services (or combinations of ''J1'' services reported in conjunction with certain add-on codes) represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described above, we promote the claim including the complex version of the primary service as described by the code combination to the next higher cost C–APC within the clinical family, unless the primary service is already assigned to the highest cost APC within the C–APC clinical family or assigned to the only C–APC in a clinical family. We do not create new APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C–APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any claim including a code combination for services assigned to a C–APC would be the highest paying C–APC in the clinical family (79 FR 66802).

We package payment for all add-on codes into the payment for the C–APC. However, certain primary service add-on combinations may qualify for a complexity adjustment. As noted in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70331), all add-on codes that can be appropriately reported in combination with a base code that describes a primary ''J1'' service are evaluated for a complexity adjustment.

To determine which combinations of primary service codes reported in conjunction with an add-on code may qualify for a complexity adjustment for CY 2021, we proposed to apply the frequency and cost criteria thresholds discussed above, testing claims reporting one unit of a single primary service assigned to status indicator ''J1'' and any number of units of a single add-on code for the primary ''J1'' service. If the frequency and cost criteria thresholds for a complexity adjustment are met and reassignment to the next higher cost APC in the clinical family is appropriate (based on meeting the criteria outlined above), we make a complexity adjustment for the code combination; that is, we reassign the primary service code reported in conjunction with the add-on code to the next higher cost C–APC within the same clinical family of C–APCs. As previously stated, we package payment for add-on codes into the C–APC payment rate. If any add-on code reported in conjunction with the ''J1'' primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the

primary service and is not reassigned to the next higher cost C–APC. We listed the complexity adjustments for ''J1'' and add-on code combinations for CY 2021, along with all of the other proposed complexity adjustments, in Addendum J to the CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

Addendum J to the CY 2021 OPPS/ASC proposed rule includes the cost statistics for each code combination that would qualify for a complexity adjustment (including primary code and add-on code combinations). Addendum J to the CY 2021 OPPS/ASC proposed rule also contains summary cost statistics for each of the paired code combinations that describe a complex code combination that would qualify for a complexity adjustment and are proposed to be reassigned to the next higher cost C–APC within the clinical family. The combined statistics for all proposed reassigned complex code combinations are represented by an alphanumeric code with the first 4 digits of the designated primary service followed by a letter. For example, the proposed geometric mean cost listed in Addendum J for the code combination described by complexity adjustment assignment 3320R, which is assigned to C–APC 5224 (Level 4 Pacemaker and Similar Procedures), includes all paired code combinations that are proposed to be reassigned to C–APC 5224 when CPT code 33208 is the primary code. Providing the information contained in Addendum J to the CY 2021 OPPS/ASC proposed rule allows stakeholders the opportunity to better assess the impact associated with the proposed reassignment of claims with each of the paired code combinations eligible for a complexity adjustment.

Comment: A commenter stated that CMS should not use claims data from complexity adjustment code pairs in calculating the geometric mean cost for the next higher paying APC to which the complexity adjusted code pair is assigned and that doing so can decrease the geometric mean cost of APCs with a low number of claims, specifically C–APC 5493—Level 3 Intraocular Procedures. The commenter stated that CMS did not intend to include the costs of complexity-adjusted code pairs in calculating the geometric mean cost for the higher-paying APCs to which the complexity-adjustment code pair is assigned when the C–APC complexity adjustment policy was initially established and that complexity adjustments were intended as payment adjustments for complex versions of the comprehensive service only. To further support their claim that CMS intended for complexity adjustments to only provide higher payment for claims including complex comprehensive services, the commenter noted that, unlike other HCPCS codes with a significant number of claims assigned to an APC, complexity adjusted code pairs are not evaluated for a 2 times rule violation in the higher-paying APC to which they are promoted.

Response: We disagree with the commenter's assertion regarding the policy of including the costs of a complexity adjusted code pair in the calculation of the geometric mean costs of the next higher paying C–APC to which the code pair is assigned. The current C–APC complexity adjustment policy, including the calculation of the geometric mean cost of APCs that include complexity-adjusted code pairs, was initially described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74887). In that rule, we stated the following: ''We then considered reassigning complex subsets of claims for each primary service HCPCS code. All claims reporting more than one procedure described by HCPCS codes assigned to status indicator ''J1'' are evaluated for the existence of commonly occurring combinations of procedure codes reported on claims that exhibit a materially greater comprehensive geometric mean cost relative to the geometric mean cost of the claims reporting that primary HCPCS code. This indicates that the subset of procedures identified by the secondary HCPCS code has increased resource requirements relative to less complex subsets of that procedure. If a combination of procedure codes reported on claims is identified that meets these requirements, that is, commonly occurring and exhibiting materially greater resource requirements, it is further evaluated to confirm clinical validity as a complex subset of the primary procedure and the combination of procedure codes is then identified as complex, and primary service claims with that combination of procedure codes are subsequently reassigned as appropriate. If a combination of procedure codes does not meet the requirement for a materially different cost or does not occur commonly, it is not considered to be a complex, and primary service claims with that combination of procedure codes are not reassigned. All combinations of procedures described by HCPCS codes assigned to status indicator ''J1'' for each primary HCPCS code are similarly evaluated.

Once all combinations of procedures described by HCPCS codes assigned to status indicator ''J1'' have been evaluated, all claims identified for reassignment for each primary service are combined and the group is assigned to a higher level comprehensive APC within a clinical family of comprehensive APCs, that is, an APC with greater estimated resource requirements than the initially assigned comprehensive APC and with appropriate clinical homogeneity. We assessed resource variation for reassigned claims within the receiving APC using the geometric mean cost for all reassigned claims for the primary service relative to other services assigned to that APC using the 2 times rule criteria. For new HCPCS codes and codes without data, we will use the best data available to us to identify combinations of procedures that represent a more complex form of the primary procedure and warrant reassignment to a higher level APC. We will reevaluate our APC assignments, and identification and APC placement of complex claims once claims data become available. *We then recalculate all APC comprehensive geometric mean costs and ensure clinical and resource homogeneity.*''

We believe that the final statement clearly communicates our policy of including the costs of the complexity-adjusted codes pairs in calculating the geometric mean cost for the higher-paying APCs to which the complexity-adjustment code pairs are assigned. While the commenter is correct that we no longer require that a code combination (that qualifies for a complexity adjustment by satisfying the frequency and cost criteria thresholds described above) not create a 2 times rule violation in the higher level or receiving APC, this change was based on our belief that the requirement was not useful because most code combinations fall below our established frequency threshold for considering 2 times rule violations (81 FR 79582). In summary, we do not believe it is necessary to change the current policy that includes the costs of the paired code combinations in the next higher-paying APC at this time.

Comment: Several commenters requested that CMS alter the established C–APC complexity adjustment eligibility criteria to allow additional code combinations to qualify for complexity adjustments. We also received several comments requesting that CMS modify its complexity adjustment criteria by eliminating the claims frequency requirement to determine eligibility for the complexity adjustment and expanding the eligibility for a complexity adjustment to other APCs besides C–APCs to apply the

complexity adjustment to all blue light cystoscopy with Cysview procedures in the HOPD, even those assigned to clinical APCs.

Response: We appreciate these comments. However, at this time, we do not believe changes to the C–APC complexity adjustment criteria are necessary or that we should make exceptions to the criteria to allow claims with the code combinations suggested by the commenters to receive complexity adjustments. As stated previously (81 FR 79582), we continue to believe that the complexity adjustment criteria, which require a frequency of 25 or more claims reporting a code combination and a violation of the 2 times rule in the originating C–APC in order to receive payment in the next higher cost C–APC within the clinical family, are adequate to determine if a combination of procedures represents a complex, costly subset of the primary service. If a code combination meets these criteria, the combination receives payment at the next higher cost C–APC. Code combinations that do not meet these criteria receive the C–APC payment rate associated with the primary ''J1'' service. A minimum of 25 claims is already a very low threshold for a national payment system. Lowering the minimum of 25 claims further could lead to unnecessary complexity adjustments for service combinations that are rarely performed.

With regard to the requests for complexity adjustments for blue light cystoscopy procedures involving the use of Cysview, in CY 2018 we created a HCPCS C-code (C9738—Adjunctive blue light cystoscopy with fluorescent imaging agent (list separately in addition to code for primary procedure)) to describe blue light cystoscopy with fluorescent imaging agent and allowed this code to be eligible for complexity adjustments when billed with procedure codes used to describe white light cystoscopy of the bladder, although this code is not a ''J1'' service or an add-on code for the primary ''J1'' service. For CY 2021, there is one code combination, of the six total available combinations involving C9738 and procedure codes used to describe white light cystoscopy, that qualifies for a complexity adjustment (HCPCS code 52204 Cystourethroscopy, with biopsy(s) + C9738 Adjunctive blue light cystoscopy with fluorescent imaging agent (list separately in addition to code for primary procedure)). The remaining five code combinations do not meet the cost and frequency criteria to qualify for a complexity adjustment. At this time, we do not believe that further modifications to the C–APC complexity adjustment policy, including allowing services assigned to clinical APCs to qualify for complexity adjustments, are necessary to allow for complexity adjustments for these procedures.

After consideration of the public comments we received on the proposed complexity adjustment policy, we are finalizing the C–APC complexity adjustment policy for CY 2021, as proposed, without modification.

(2) Exclusion of Procedures Assigned to New Technology APCs From the C–APC Policy

Services that are assigned to New Technology APCs are typically new procedures that do not have sufficient claims history to establish an accurate payment for the procedures. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected (82 FR 59277).

The C–APC payment policy packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. Prior to CY 2019, when a procedure assigned to a New Technology APC was included on the claim with a primary procedure, identified by OPPS status indicator ''J1'', payment for the new technology service was typically packaged into the payment for the primary procedure. Because the new technology service was not separately paid in this scenario, the overall number of single claims available to determine an appropriate clinical APC for the new service was reduced. This was contrary to the objective of the New Technology APC payment policy, which is to gather sufficient claims data to enable us to assign the service to an appropriate clinical APC.

To address this issue and ensure that there is sufficient claims data for services assigned to New Technology APCs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58847), we finalized excluding payment for any procedure that is assigned to a New Technology APC (APCs 1491 through 1599 and APCs 1901 through 1908) from being packaged when included on a claim with a ''J1'' service assigned to a C–APC. In the CY 2020 OPPS/ASC final rule with comment period, we finalized that payment for services assigned to a New Technology APC would be excluded from being packaged into the payment for comprehensive observation services assigned status indicator ''J2'' when they are included on a claim with a ''J2'' service starting in CY 2020 (84 FR 61167).

(3) Additional C–APCs for CY 2021

For CY 2021 and subsequent years, we proposed to continue to apply the C–APC payment policy methodology. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79583) for a discussion of the C–APC payment policy methodology and revisions.

Each year, in accordance with section 1833(t)(9)(A) of the Act, we review and revise the services within each APC group and the APC assignments under the OPPS. As a result of our annual review of the services and the APC assignments under the OPPS, we did not propose to convert any conventional APCs to C–APCs in CY 2021. However, as discussed in section III.D.7, we proposed to create an additional level in the ''Urology and Related Services'' APC series and, as discussed in section III.D.1, we proposed to create an additional level in the ''Neurostimulator and Related Procedures'' APC series. Table 3 lists the proposed C–APCs for CY 2021, all of which were established in past rules.

Comment: Commenters supported the creation of the two new proposed C–APCs, based on resource cost and clinical characteristics.

Response: We appreciate the commenters' support.

Comment: Several commenters expressed concern that the C–APC payment rates may not adequately reflect the costs associated with services. These comments stated that the C–APC methodology does not account for the complexity of certain care processes, fails to capture the necessary claims, and the resulting data may lead to inaccurate payment rates that will negatively impact access to services.

Commenters also had concerns around the claims data used for ratesetting, due to variations in clinical practice and billing patterns across the hospitals that submit these claims, and urged CMS to consider alternatives to the current methodology. Some commenters were concerned that hospitals are not correctly charging for procedures assigned to C–APCs and urged CMS to invest in policies and education for hospitals regarding correct

billing patterns. These commenters also requested that CMS provide an analysis of the impact of the C–APC policy on affected procedures and patient access to services. One commenter requested that CMS review and use Part B claims data in order to estimate costs for the appropriate C–APCs for CY 2021 ratesetting.

Response: We appreciate the comments. We continue to believe that the current C–APC methodology is appropriate. We also note that, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59246), we conducted an analysis of the effects of the C–APC policy. The analysis used claims data for the CY 2016 OPPS/ASC final rule with comment period, the CY 2017 OPPS/ASC final rule with comment period, and the CY 2018 OPPS/ASC proposed rule, which were for the period from CY 2014 (before C–APCs became effective) to CY 2016. We looked at separately payable codes that were then assigned to C–APCs and, overall, we observed an increase in claim line frequency, units billed, and Medicare payment for those procedures, which suggest that the C–APC payment policy did not adversely affect access to care or reduce payments to hospitals and is working as intended.

Comment: Several commenters requested that CMS discontinue the C–APC payment policy for all surgical insertion codes required for brachytherapy treatment. The commenters stated concerns about how the C–APC methodology impacts radiation oncology, particularly the delivery of brachytherapy for the treatment of cervical cancer. They also stated that they oppose C–APC payment for cancer care given the complexity of coding, serial billing for cancer care, and potentially different sites of service for the initial surgical device insertion and subsequent treatment delivery or other supportive services. These commenters suggested that CMS allow brachytherapy to be reported through the traditional APC methodology, move procedures to a higher C–APC, or separately pay for preparation and planning services to fully account for accurate reflection of the costs associated with these procedures.

Response: While we continue to believe that the C–APC policy is appropriately applied to these surgical procedures, we will continue to examine these concerns and will determine if any modifications to this policy are warranted in future rulemaking.

Comment: One commenter urged CMS to eliminate the C–APC policy for single-session stereotactic radiosurgery codes (77371 and 77372). The commenter requested that CMS continue to make separate payments for the 10 planning and preparation codes related to SRS and include the HCPCS code for IMRT planning (77301) on the list of planning and preparation codes, stating that the service has become more common in single fraction radiosurgery treatment planning.

Response: At this time, we do not believe that it is necessary to discontinue the C–APCs that include single session SRS procedures. We continue to believe that the C–APC policy is appropriately applied to these surgical procedures for the reasons cited when this policy was first adopted and note that the commenters did not provide any empirical evidence to support their claims that the existing C–APC policy does not adequately pay for these procedures. Also, we will continue in CY 2021 to pay separately for the 10 planning and preparation services (HCPCS codes 70551, 70552, 70553, 77011, 77014, 77280, 77285, 77290, 77295, and 77336) adjunctive to the delivery of the SRS treatment using either the Cobalt-60-based or LINAC-based technology when furnished to a beneficiary within 1 month of the SRS treatment for CY 2021.

Comment: We received one comment requesting that CMS carefully consider the proper location of care before establishing a C–APC for autologous hematopoietic stem cell transplant.

Response: We thank the commenter for this comment. This comment relates to a recommendation from last year's Advisory Panel on Hospital Outpatient Payment (HOP Panel), which recommended that CMS consider creating a C–APC for autologous stem cell transplantation and that CMS provide a rationale if it decides not to create such an APC. In the CY 2020 OPPS/ASC final rule with comment period, we evaluated the possibility of creating this C–APC and found that it was not appropriate to create a C–APC for autologous hematopoietic stem cell transplant at that time for the reasons discussed in that rule (84 FR 61162).

After consideration of the public comments we received, we are finalizing the proposed C–APCs for CY 2021. Table 3 below lists the final C–APCs for CY 2021. All C–APCs are displayed in Addendum J to this final rule with comment period (which is available via the internet on the CMS website). Addendum J to this final rule with comment period also contains all of the data related to the C–APC payment policy methodology, including the list of complexity adjustments and other information for CY 2021.

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TABLE 3: CY 2021 C-APCs

C-APC	CY 2021 APC Group Title	Clinical Family	New C-APC
5072	Level 2 Excision/Biopsy/Incision and Drainage	EBIDX	
5073	Level 3 Excision/Biopsy/Incision and Drainage	EBIDX	
5091	Level 1 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5092	Level 2 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5093	Level 3 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5094	Level 4 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5112	Level 2 Musculoskeletal Procedures	ORTHO	
5113	Level 3 Musculoskeletal Procedures	ORTHO	
5114	Level 4 Musculoskeletal Procedures	ORTHO	
5115	Level 5 Musculoskeletal Procedures	ORTHO	
5116	Level 6 Musculoskeletal Procedures	ORTHO	
5153	Level 3 Airway Endoscopy	AENDO	
5154	Level 4 Airway Endoscopy	AENDO	
5155	Level 5 Airway Endoscopy	AENDO	
5163	Level 3 ENT Procedures	ENTXX	
5164	Level 4 ENT Procedures	ENTXX	
5165	Level 5 ENT Procedures	ENTXX	
5166	Cochlear Implant Procedure	COCHL	
5182	Level 2 Vascular Procedures	VASCX	
5183	Level 3 Vascular Procedures	VASCX	
5184	Level 4 Vascular Procedures	VASCX	
5191	Level 1 Endovascular Procedures	EVASC	
5192	Level 2 Endovascular Procedures	EVASC	
5193	Level 3 Endovascular Procedures	EVASC	
5194	Level 4 Endovascular Procedures	EVASC	
5200	Implantation Wireless PA Pressure Monitor	WPMXX	
5211	Level 1 Electrophysiologic Procedures	EPHYS	
5212	Level 2 Electrophysiologic Procedures	EPHYS	
5213	Level 3 Electrophysiologic Procedures	EPHYS	
5222	Level 2 Pacemaker and Similar Procedures	AICDP	
5223	Level 3 Pacemaker and Similar Procedures	AICDP	
5224	Level 4 Pacemaker and Similar Procedures	AICDP	
5231	Level 1 ICD and Similar Procedures	AICDP	
5232	Level 2 ICD and Similar Procedures	AICDP	
5244	Level 4 Blood Product Exchange and Related Services	SCTXX	
5302	Level 2 Upper GI Procedures	GIXXX	
5303	Level 3 Upper GI Procedures	GIXXX	
5313	Level 3 Lower GI Procedures	GIXXX	
5331	Complex GI Procedures	GIXXX	
5341	Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX	
5361	Level 1 Laparoscopy and Related Services	LAPXX	
5362	Level 2 Laparoscopy and Related Services	LAPXX	
5373	Level 3 Urology and Related Services	UROXX	
5374	Level 4 Urology and Related Services	UROXX	
5375	Level 5 Urology and Related Services	UROXX	
5376	Level 6 Urology and Related Services	UROXX	

C-APC	CY 2021 APC Group Title	Clinical Family	New C-APC
5377	Level 7 Urology and Related Services	UROXX	
5378	Level 8 Urology and Related Services	UROXX	*
5414	Level 4 Gynecologic Procedures	GYNXX	
5415	Level 5 Gynecologic Procedures	GYNXX	
5416	Level 6 Gynecologic Procedures	GYNXX	
5431	Level 1 Nerve Procedures	NERVE	
5432	Level 2 Nerve Procedures	NERVE	
5461	Level 1 Neurostimulator and Related Procedures	NSTIM	
5462	Level 2 Neurostimulator and Related Procedures	NSTIM	
5463	Level 3 Neurostimulator and Related Procedures	NSTIM	
5464	Level 4 Neurostimulator and Related Procedures	NSTIM	
5465	Level 5 Neurostimulator and Related Procedures	NSTIM	*
5471	Implantation of Drug Infusion Device	PUMPS	
5491	Level 1 Intraocular Procedures	INEYE	
5492	Level 2 Intraocular Procedures	INEYE	
5493	Level 3 Intraocular Procedures	INEYE	
5494	Level 4 Intraocular Procedures	INEYE	
5495	Level 5 Intraocular Procedures	INEYE	
5503	Level 3 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	
5504	Level 4 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	
5627	Level 7 Radiation Therapy	RADTX	
5881	Ancillary Outpatient Services When Patient Dies	N/A	
8011	Comprehensive Observation Services	N/A	

C-APC Clinical Family Descriptor Key:

AENDO = Airway Endoscopy
AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices.
BREAS = Breast Surgery
COCHL = Cochlear Implant
EBIDX = Excision/ Biopsy/Incision and Drainage
ENTXX = ENT Procedures
EPHYS = Cardiac Electrophysiology
EVASC = Endovascular Procedures
EXEYE = Extraocular Ophthalmic Surgery
GIXXX = Gastrointestinal Procedures
GYNXX = Gynecologic Procedures
INEYE = Intraocular Surgery
LAPXX = Laparoscopic Procedures
NERVE = Nerve Procedures
NSTIM = Neurostimulators
ORTHO = Orthopedic Surgery
PUMPS = Implantable Drug Delivery Systems
RADTX = Radiation Oncology
SCTXX = Stem Cell Transplant
UROXX = Urologic Procedures
VASCX = Vascular Procedures
WPMXX = Wireless PA Pressure Monitor

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c. Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide necessary, high quality care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service.

Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite policies for mental health services and multiple imaging services. (We note that, in the CY 2018 OPPS/ASC final rule with comment period, we finalized a policy to delete the composite APC 8001 (LDR Prostate Brachytherapy Composite) for CY 2018 and subsequent years.) We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66611 through 66614 and 66650 through 66652) for a full discussion of the development of the composite APC methodology, and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163) and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59241 through 59242 and 59246 through 52950) for more recent background.

(1) Mental Health Services Composite APC

We proposed to continue our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment for a day of partial hospitalization services provided by a hospital, which we consider to be the most resource-intensive of all outpatient mental health services. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74168) for more recent background.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79588 through 79589), we finalized a policy to combine the existing Level 1 and Level 2 hospital-based PHP APCs into a single hospital-based PHP APC, and thereby discontinue APCs 5861 (Level 1—Partial Hospitalization (3 services) for Hospital-Based PHPs) and 5862 (Level—2 Partial Hospitalization (4 or more services) for Hospital-Based PHPs) and replace them with APC 5863 (Partial Hospitalization (3 or more services per day)).

In the CY 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33580 through 33581 and 59246 through 59247, respectively), we proposed and finalized the policy for CY 2018 and subsequent years that, when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services will be paid through composite APC 8010 (Mental Health Services Composite). In addition, we set the payment rate for composite APC 8010 for CY 2018 at the same payment rate that will be paid for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital, and finalized a policy that the hospital will continue to be paid the payment rate for composite APC 8010. Under this policy, the I/OCE will continue to determine whether to pay for these specified mental health services individually, or to make a single payment at the same payment rate established for APC 5863 for all of the specified mental health services furnished by the hospital on that single date of service. We continue to believe that the costs associated with administering a partial hospitalization program at a hospital represent the most resource intensive of all outpatient mental health services. Therefore, we do not believe that we should pay more for mental health services under the OPPS than the highest partial hospitalization per diem payment rate for hospitals.

We proposed that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services would be paid through composite APC 8010 for CY 2021. In addition, we proposed to set the proposed payment rate for composite APC 8010 at the same payment rate that we proposed for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital, and that the hospital continue to be paid the proposed payment rate for composite APC 8010.

We did not receive any public comment on these proposals. Therefore, we are finalizing our proposal, without modification, that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services would be paid through composite APC 8010 for CY 2021. In addition, we are finalizing our proposal to set the payment rate for composite APC 8010 for CY 2021 at the same payment rate that we set for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital.

(2) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

Effective January 1, 2009, we provide a single payment each time a hospital submits a claim for more than one imaging procedure within an imaging family on the same date of service, to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session (73 FR 41448 through 41450). We utilize three imaging families based on imaging modality for purposes of this methodology: (1) Ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 12 of the CY 2014 OPPS/ASC final rule with comment period (78 FR 74920 through 74924).

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast. While the ultrasound procedures included under the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

We define the single imaging session for the ''with contrast'' composite APCs

as having at least one or more imaging procedures from the same family performed with contrast on the same date of service. For example, if the hospital performs an MRI without contrast during the same session as at least one other MRI with contrast, the hospital will receive payment based on the payment rate for APC 8008, the ''with contrast'' composite APC.

We make a single payment for those imaging procedures that qualify for payment based on the composite APC payment rate, which includes any packaged services furnished on the same date of service. The standard (noncomposite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. For a full discussion of the development of the multiple imaging composite APC methodology, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569).

For CY 2021, we proposed to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. We continue to believe that this policy would reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session.

The proposed CY 2021 payment rates for the five multiple imaging composite APCs (APCs 8004, 8005, 8006, 8007, and 8008) were based on proposed geometric mean costs calculated from CY 2019 claims available for the CY 2021 OPPS/ASC proposed rule that qualified for composite payment under the current policy (that is, those claims reporting more than one procedure within the same family on a single date of service). To calculate the proposed geometric mean costs, we used the same methodology that we have used to calculate the geometric mean costs for these composite APCs since CY 2014, as described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918). The imaging HCPCS codes referred to as ''overlap bypass codes'' that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC geometric mean costs, in accordance with our established methodology as stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918), are identified by asterisks in Addendum N to this CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website) and are discussed in more detail in section II.A.1.b. of this CY 2021 OPPS/ASC proposed rule.

For the CY 2021 OPPS/ASC proposed rule, we were able to identify approximately 964,000 ''single session'' claims out of an estimated 4.9 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 14 percent of all eligible claims, to calculate the proposed CY 2021 geometric mean costs for the multiple imaging composite APCs. Table 4 of the CY 2021 OPPS/ASC proposed rule lists the proposed HCPCS codes that would be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC proposed geometric mean costs for CY 2021.

We did not receive any public comments on this proposal. Therefore, we are finalizing our proposal to continue the use of multiple imaging composite APCs to pay for services providing more than one imaging procedure from the same family on the same date, without modification. Table 4 lists the HCPCS codes that will be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC final geometric mean costs for CY 2021.

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TABLE 4: OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1 – Ultrasound	
CY 2021 APC 8004 (Ultrasound Composite)	**CY 2021 Approximate APC Geometric Mean Cost = $290.63**
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76776	Us exam k transpl w/Doppler
76831	Echo exam, uterus
76856	Us exam, pelvic, complete
76857	Us exam, pelvic, limited
76981	Us parenchyma
76982	Us 1st target lesion
Family 2 - CT and CTA with and without Contrast	
CY 2021 APC 8005 (CT and CTA without Contrast Composite)*	**CY 2021 Approximate APC Geometric Mean Cost = $218.53**
0633T	Ct breast w/3d uni c-
0636T	Ct breast w/3d bi c-

70450	Ct head/brain w/o dye
70480	Ct orbit/ear/fossa w/o dye
70486	Ct maxillofacial w/o dye
70490	Ct soft tissue neck w/o dye
71250	Ct thorax w/o dye
72125	Ct neck spine w/o dye
72128	Ct chest spine w/o dye
72131	Ct lumbar spine w/o dye
72192	Ct pelvis w/o dye
73200	Ct upper extremity w/o dye
73700	Ct lower extremity w/o dye
74150	Ct abdomen w/o dye
74176	Ct angio abd & pelvis
74261	Ct colonography, w/o dye
CY 2021 APC 8006 (CT and CTA with Contrast Composite)	**CY 2021 Approximate APC Geometric Mean Cost = $423.88**
0634T	Ct breast w/3d uni c+
0635T	Ct breast w/3d uni c-/c+
0637T	Ct breast w/3d bi c+
0638T	Ct breast w/3d bi c-/c+
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye
70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o & w/dye
70487	Ct maxillofacial w/dye
70488	Ct maxillofacial w/o & w/dye
70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye
70496	Ct angiography, head
70498	Ct angiography, neck
71260	Ct thorax w/dye
71270	Ct thorax w/o & w/dye
71275	Ct angiography, chest
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72191	Ct angiograph pelv w/o & w/dye
72193	Ct pelvis w/dye
72194	Ct pelvis w/o & w/dye
73201	Ct upper extremity w/dye

73202	Ct uppr extremity w/o & w/dye
73206	Ct angio upr extrm w/o & w/dye
73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o & w/dye
73706	Ct angio lwr extr w/o & w/dye
74160	Ct abdomen w/dye
74170	Ct abdomen w/o & w/dye
74175	Ct angio abdom w/o & w/dye
74177	Ct angio abd & pelv w/contrast
74178	Ct angio abd & pelv 1+ regns
74262	Ct colonography, w/dye
75635	Ct angio abdominal arteries
* If a "without contrast" CT or CTA procedure is performed during the same session as a "with contrast" CT or CTA procedure, the I/OCE assigns the procedure to APC 8006 rather than APC 8005.	
Family 3 - MRI and MRA with and without Contrast	
CY 2021 APC 8007 (MRI and MRA without Contrast Composite)*	**CY 2021 Approximate APC Geometric Mean Cost = $509.27**
0609T	Mrs disc pain acquisj data
70336	Magnetic image, jaw joint
70540	Mri orbit/face/neck w/o dye
70544	Mr angiography head w/o dye
70547	Mr angiography neck w/o dye
70551	Mri brain w/o dye
70554	Fmri brain by tech
71550	Mri chest w/o dye
72141	Mri neck spine w/o dye
72146	Mri chest spine w/o dye
72148	Mri lumbar spine w/o dye
72195	Mri pelvis w/o dye
73218	Mri upper extremity w/o dye
73221	Mri joint upr extrem w/o dye
73718	Mri lower extremity w/o dye
73721	Mri jnt of lwr extre w/o dye
74181	Mri abdomen w/o dye
75557	Cardiac mri for morph
75559	Cardiac mri w/stress img
76391	Mr elastography
77046	Mri breast c- unilateral
77047	Mri breast c- bilateral
C8901	MRA w/o cont, abd
C8910	MRA w/o cont, chest
C8913	MRA w/o cont, lwr ext
C8919	MRA w/o cont, pelvis

C8932	MRA, w/o dye, spinal canal
C8935	MRA, w/o dye, upper extr
C9762	Cardiac MRI seg dys strain
C9763	Cardiac MRI seg dys stress
CY 2021 APC 8008 (MRI and MRA with Contrast Composite)	**CY 2021 Approximate APC Geometric Mean Cost = $821.40**
70542	Mri orbit/face/neck w/dye
70543	Mri orbt/fac/nck w/o & w/dye
70545	Mr angiography head w/dye
70546	Mr angiograph head w/o & w/dye
70547	Mr angiography neck w/o dye
70548	Mr angiography neck w/dye
70549	Mr angiograph neck w/o & w/dye
70552	Mri brain w/dye
70553	Mri brain w/o & w/dye
71551	Mri chest w/dye
71552	Mri chest w/o & w/dye
72142	Mri neck spine w/dye
72147	Mri chest spine w/dye
72149	Mri lumbar spine w/dye
72156	Mri neck spine w/o & w/dye
72157	Mri chest spine w/o & w/dye
72158	Mri lumbar spine w/o & w/dye
72196	Mri pelvis w/dye
72197	Mri pelvis w/o & w/dye
73219	Mri upper extremity w/dye
73220	Mri uppr extremity w/o & w/dye
73222	Mri joint upr extrem w/dye
73223	Mri joint upr extr w/o & w/dye
73719	Mri lower extremity w/dye
73720	Mri lwr extremity w/o & w/dye
73722	Mri joint of lwr extr w/dye
73723	Mri joint lwr extr w/o & w/dye
74182	Mri abdomen w/dye
74183	Mri abdomen w/o & w/dye
75561	Cardiac mri for morph w/dye
75563	Card mri w/stress img & dye
C8900	MRA w/cont, abd
C8902	MRA w/o fol w/cont, abd
C8903	MRI w/cont, breast, uni
C8905	MRI w/o fol w/cont, brst, un
C8906	MRI w/cont, breast, bi
C8908	MRI w/o fol w/cont, breast,

C8909	MRA w/cont, chest
C8911	MRA w/o fol w/cont, chest
C8912	MRA w/cont, lwr ext
C8914	MRA w/o fol w/cont, lwr ext
C8918	MRA w/cont, pelvis
C8920	MRA w/o fol w/cont, pelvis
C8931	MRA, w/dye, spinal canal
C8933	MRA, w/o&w/dye, spinal canal
C8934	MRA, w/dye, upper extremity
C8936	MRA, w/o&w/dye, upper extr
* If a "without contrast" MRI or MRA procedure is performed during the same session as a "with contrast" MRI or MRA procedure, the I/OCE assigns the procedure to APC 8008 rather than APC 8007.	

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3. Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular beneficiary. The OPPS packages payments for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more costly than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which may occur if separate payment is provided for the item.

Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging may reduce the importance of refining service-specific payment because packaged payments include costs associated with higher cost cases requiring many ancillary items and services and lower cost cases requiring fewer ancillary items and services. Because packaging encourages efficiency and is an essential component of a prospective payment system, packaging payments for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000. For an extensive discussion of the history and background of the OPPS packaging policy, we refer readers to the CY 2000 OPPS final rule (65 FR 18434), the CY 2008 OPPS/ASC final rule with comment period (72 FR 66580), the CY 2014 OPPS/ASC final rule with comment period (78 FR 74925), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66817), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70343), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79592), the CY 2018 OPPS/ASC final rule with comment period (82 FR 59250), the CY 2019 OPPS/ASC final rule with comment period (83 FR 58854), and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61173). As we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care, we have expanded the OPPS packaging policies. Most, but not necessarily all, categories of items and services currently packaged in the OPPS are listed in 42 CFR 419.2(b). Our overarching goal is to make payments for all services under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided under the OPPS to determine which OPPS services can be packaged to further achieve the objective of advancing the OPPS toward a more prospective payment system.

For CY 2021, we examined the items and services currently provided under the OPPS, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment for the primary service that they support. Specifically, we examined the HCPCS code definitions (including CPT code descriptors) and outpatient hospital billing patterns to determine whether there were categories of codes for which packaging would be appropriate according to existing OPPS packaging policies or a logical expansion of those existing OPPS packaging policies. In CY 2021, we proposed no changes to this policy. We will continue to conditionally package the costs of selected newly identified ancillary services into payment for a primary service where we believe that the packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code. Below we discuss the proposed changes to the packaging policies in CY 2021.

Comment: We received one comment asking CMS for an update regarding a comment solicitation from the CY 2018 OPPS/ASC Proposed Rule regarding the ''Comment Solicitation on Packaging of

Items and Services Under the OPPS'' (82 FR 33588).

Response: We thank the commenter for their inquiry. As noted in our response in the CY 2018 OPPS/ASC final rule with comment period, we appreciated the comments we received in response to this comment solicitation and will take them into consideration as we continue to explore and evaluate packaging policies that apply under the OPPS (82 FR 59254).

Comment: We received a comment on balancing packaging policy with market access concerns after pass-through status expires. The commenter noted that some packaging policies create incentives that could limit patient access to certain items, services, and care. They requested that CMS reconsider packaging policies, especially in the ASC and HOPD setting, and review packaging decisions on a case-by-case basis upon pass-through status expiration and not via the ''integral to'' policy, applying a holistic separate payment policy for innovations. Specifically, this commenter asked CMS to evaluate drugs and devices on a case-by-case basis in order to determine the item's packaging status after pass-through expires. This commenter also stated CMS should take into consideration the drug or device's clinical value when determining packaging status.

Response: We thank the commenter for their input. We continue to believe our packaging policies support our strategic goal of using larger payment bundles to maximize incentives to provide care in the most efficient manner. However, we will take this comment into consideration for future rulemaking.

Comment: We received several comments from patient advocates, physicians, drug manufacturers, and professional medical societies regarding payment for blue light cystoscopy procedures involving Cysview® (hexaminolevulinate HCl) (described by HCPCS code C9275). Cysview® is a drug that functions as a supply in a diagnostic test or procedure and therefore payment for this product is packaged with payment for the primary procedure in the OPPS and ASC settings. Commenters stated that utilization of Cysview® is low in the HOPD and ASC settings, which they attributed to the fact that Cysview is packaged as a drug that functions as a supply in a diagnostic test or procedure. Commenters indicated that packaged payment does not adequately pay for the blue light cystoscopy procedures, particularly in the ASC setting where payment is generally approximately 55 percent of the HOPD payment. Commenters believe that providers have been deterred from the use of this technology, especially in the ASC setting, and as a result, a significant percentage of beneficiaries are not able to access the procedure.

Commenters also stated that there has been literature published showing that Blue Light Cystoscopy with Cysview® is more effective than white light cystoscopy alone at detecting and eliminating nonmuscle invasive bladder cancer tumors, leading to a reduction in bladder cancer recurrence.

Commenters made various recommendations for payment for blue light cystoscopy procedures involving Cysview®, including to pay separately for Cysview® when it is used with blue light cystoscopy in the HOPD and ASC settings, similar to the policy finalized for Exparel® in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58860), or to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to provide an ''add-on'' or ''drug intensive'' payment to ASCs when using Cysview® in blue light cystoscopy procedures. Other commenters requested separate payment for all diagnostic imaging drugs (radiopharmaceuticals and contrast agents).

Response: We acknowledge the concerns of the numerous stakeholders who commented on this issue and understand the importance of blue light cystoscopy procedures involving Cysview®. Cysview has been packaged as a drug, biological, or radiopharmaceutical that functions as a supply in a diagnostic test or procedure since CY 2014 (78 FR 74930). As we stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59244), we recognize that blue light cystoscopy represents an additional elective but distinguishable service as compared to white light cystoscopy that, in some cases, may allow greater detection of bladder tumors in beneficiaries relative to white light cystoscopy alone. Given the additional equipment, supplies, operating room time, and other resources required to perform blue light cystoscopy in addition to white light cystoscopy, in CY 2018, we created a new HCPCS C–code to describe blue light cystoscopy and since CY 2018 have allowed for complexity adjustments to higher paying C–APCs for qualifying white light and blue light cystoscopy code combinations. At this time, we continue to believe that Cysview® is a drug that functions as a supply in a diagnostic test or procedure, and therefore, payment for this drug should be packaged with payment for the diagnostic procedure. Therefore, we do not believe it is necessary to pay separately for Cysview® when it is used with blue light cystoscopy in either the HOPD or ASC setting. We also do not believe that it would be appropriate to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to provide an ''add-on'' or ''drug intensive'' payment to ASCs when using Cysview® in blue light cystoscopy procedures, as our equitable adjustment authority at section (t)(2)(E) only authorizes adjustments under the OPPS, not the ASC payment system. We do not have any evidence to show that separate payment for blue light cystoscopy procedures involving Cysview is required, based on commenter concerns regarding utilization and access issues for Cysview. However, we will continue to examine payment for blue light cystoscopy procedures involving Cysview to determine if any changes to this policy would be appropriate in future rulemaking.

Comment: Some commenters requested that we eliminate the packaging policy for drugs that function as a supply when used in a diagnostic test or procedure.

Response: In the CY 2014 OPPS/ASC final rule with comment period, we established a policy to package drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure. In particular, we referred to drugs, biologicals, and radiopharmaceuticals that function as supplies as a part of a larger, more encompassing service or procedure, namely, the diagnostic test or procedure in which the drug, biological, or radiopharmaceutical is employed (78 FR 74927). At this time, we do not believe it is necessary to eliminate this policy. As previously noted, the OPPS packages payments for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner.

Comment: One commenter requested separate payment for add-on codes for Fractional Flow Reserve Studies (FFR/iFR) and Intravascular Ultrasound (IVUS). The commenter stated that they believe the packaging of these codes will disincentivize physicians to perform these adjunct procedures because of cost. The codes are:

• 93571—Intravascular doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; initial vessel (list separately in addition to code for primary procedure);

• 93572—Intravascular doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; each additional vessel (list separately in addition to code for primary procedure));

• 92978—Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (ivus) or optical coherence tomography (oct) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; initial vessel (list separately in addition to code for primary procedure); and

• 92979—Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (ivus) or optical coherence tomography (oct) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel (list separately in addition to code for primary procedure)).

Response: As stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66630), we continue to believe that IVUS and FFR are dependent services that are always provided in association with a primary service. Add-on codes represent services that are integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment is appropriately packaged into payment for the primary service that they support. As we have noted in past rules, add-on codes do not represent standalone procedures and are inclusive to other procedures performed at the same time (79 FR 66818). We continue to believe it is unnecessary to provide separate payment for the previously mentioned add-on codes at this time.

b. Packaging Policy for Non-Opioid Pain Management Therapies

(1) Background on OPPS/ASC Non-Opioid Pain Management Packaging Policies

In the CY 2018 OPPS/ASC proposed rule (82 FR 33588), within the framework of existing packaging categories, such as drugs that function as supplies in a surgical procedure or diagnostic test or procedure, we requested stakeholder feedback on common clinical scenarios involving currently packaged items and services described by HCPCS codes that stakeholders believe should not be packaged under the OPPS. We also expressed interest in stakeholder feedback on common clinical scenarios involving separately payable HCPCS codes for which payment would be most appropriately packaged under the OPPS. Commenters who responded to the CY 2018 OPPS/ASC proposed rule expressed a variety of views on packaging under the OPPS. The public comments ranged from requests to unpackage most items and services that are unconditionally packaged under the OPPS, including drugs and devices, to specific requests for separate payment for a specific drug or device.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 52485), we reiterated our position with regard to payment for Exparel®, a non-opioid analgesic that functions as a surgical supply, stating that we believed that payment for this drug is appropriately packaged with the primary surgical procedure. We also stated in the CY 2018 OPPS/ASC final rule with comment period that we would continue to explore and evaluate packaging policies under the OPPS and consider these policies in future rulemaking.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58855 through 58860), we finalized a policy to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2019, due to decreased utilization in the ASC setting.

For the CY 2020 OPPS/ASC proposed rule (84 FR 39423 through 39427), as required by section 1833(t)(22)(A)(i) of the Act, as added by section 6082(a) of the SUPPORT Act, we reviewed payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. We used currently available data to analyze the payment and utilization patterns associated with specific non-opioid alternatives, including drugs that function as a supply, nerve blocks, and neuromodulation products, to determine whether our packaging policies have reduced the use of non-opioid alternatives. For the CY 2020 OPPS/ASC proposed rule (84 FR 39423 through 39427), we proposed to continue our policy to pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2020. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61173 through 61180), after reviewing data from stakeholders and Medicare claims data, we did not find compelling evidence to suggest that revisions to our OPPS payment policies for non-opioid pain management alternatives were necessary for CY 2020. We finalized our proposal to continue to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2020. Under this policy, the only drug that met these criteria in CY 2020 was Exparel.

(2) Evaluation and CY 2021 Payment for Non-Opioid Alternatives

Section 1833(t)(22)(A)(i) of the Act, as added by section 6082(a) of the SUPPORT Act, states that the Secretary must review payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. As part of this review, under section 1833(t)(22)(A)(iii) of the Act, the Secretary must consider the extent to which revisions to such payments (such as the creation of additional groups of covered OPD services to separately classify those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce the payment incentives for using opioids instead of non-opioid alternatives for pain management. In conducting this review and considering any revisions, the Secretary must focus on covered OPD services (or groups of services) assigned to C–APCs, APCs that include surgical services, or services determined by the Secretary that generally involve treatment for pain management. If the Secretary identifies revisions to payments pursuant to section 1833(t)(22)(A)(iii) of the Act, section

1833(t)(22)(C) of the Act requires the Secretary to, as determined appropriate, begin making revisions for services furnished on or after January 1, 2020. Any revisions under this paragraph are required to be treated as adjustments for purposes of paragraph (9)(B), which requires any adjustments to be made in a budget neutral manner.

As noted in the background section above, we conducted an evaluation to determine whether there are payment incentives for using opioids instead of non-opioid alternatives in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61176 through 61180). The results of our review and evaluation of our claims data did not provide evidence to indicate that the OPPS packaging policy had the unintended consequence of discouraging the use of non-opioid treatments for postsurgical pain management in the hospital outpatient department. Higher utilization may be a potential indicator that the packaged payment is not causing an access to care issue and that the payment rate for the primary procedure adequately reflects the cost of the drug. Our updated review of claims data showed a continued decline in the utilization of Exparel® in the ASC setting, which supported our proposal to continue paying separately for Exparel® in the ASC setting. Decreased utilization could potentially indicate that the packaging policy is discouraging use of that treatment and that providers are choosing less expensive treatments. However, it is difficult to attribute causality of changes in utilization to Medicare packaging payment policy only. We believe that unpackaging and paying separately for Exparel addresses decreased utilization because it eliminates any potential Medicare payment disincentive for the use of this non-opioid alternative, rather than prescription opioids.

We believe we fulfilled the statutory requirement to review payments for opioids and evidence-based non-opioid alternatives to ensure that there are not financial incentives to use opioids instead of non-opioid alternatives in CY 2020 OPPS/ASC rulemaking. We are committed to evaluating our current policies to adjust payment methodologies, if necessary, in order to ensure appropriate access for beneficiaries amid the current opioid epidemic. However, we did not believe conducting a similar CY 2021 review would yield significantly different outcomes or new evidence that would prompt us to change our payment policies under the OPPS or ASC payment system.

Therefore, for CY 2021, we proposed to continue our policy to pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2021.

Comment: Multiple commenters, including medical specialty societies and drug manufacturers, requested that we pay separately for Exparel and other drugs that may function as surgical supplies in the hospital outpatient setting. Some of these commenters noted that Exparel is more frequently used in this setting and the use of non-opioid pain management treatments should also be encouraged in the hospital outpatient department. Commenters believed that separate payment in the hospital outpatient department would significantly increase utilization, which would be beneficial in reducing opioid use.

Response: As we stated in the CY 2019 and CY 2020 OPPS/ASC final rules with comment period (83 FR 58856 and 84 FR 61177, respectively), we do not believe that there is sufficient evidence that non-opioid pain management drugs should be paid separately in the hospital outpatient setting at this time. The commenters did not provide convincing evidence that the OPPS packaging policy for Exparel (or other non-opioid drugs) creates a barrier to use of Exparel in the hospital setting. Further, while we received some public comments suggesting that, as a result of using Exparel in the OPPS setting, providers may prescribe fewer opioids for Medicare beneficiaries, we do not believe that the OPPS payment policy presents a barrier to use of Exparel or affects the likelihood that providers will prescribe fewer opioids in the HOPD setting. Several drugs are packaged under the OPPS and payment for such drugs is included in the payment for the associated primary procedure. We were not persuaded by the information supplied by commenters suggesting that some providers avoid use of non-opioid alternatives in the outpatient hospital setting (including Exparel) solely because of the OPPS packaged payment policy, as there was no evidence in our review and evaluation of claims data in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61176 through 61180) to indicate that the OPPS packaging policy had the unintended consequence of discouraging the use of non-opioid treatments for postsurgical pain management in the hospital outpatient department. As noted above, we do not believe conducting a similar CY 2021 review would yield significantly different outcomes or new evidence that would prompt us to change our payment policy. Based on previously conducted analysis, we observed increasing Exparel utilization in the HOPD setting with the total units increasing from 14.8 million in 2018 to 19.5 million in 2019, despite the drug payment being packaged into the procedure payment in the OPPS setting. This upward trend has been consistent since 2015, as the data shows approximately 6.5 million total units in 2015 and 8.1 million total units in 2016. Therefore, we do not believe that the current OPPS payment methodology for Exparel or other non-opioid pain management drugs presents a widespread barrier to their use.

In addition, increased use in the hospital outpatient setting not only supports the notion that the packaged payment for Exparel is not causing an access to care issue, but also that the payment rate for primary procedures in the HOPD using Exparel adequately reflects the cost of the drug. That is, because Exparel is commonly used and billed under the OPPS, the APC rates for the primary procedures reflect such utilization. Therefore, the increased utilization in the OPPS setting seems to indicate that the payment amount is sufficient for hospitals to furnish the drug. We remind readers that the OPPS is a prospective payment system, not a cost-based system and, by design, is based on a system of averages under which payment for certain cases may exceed the costs incurred, while for others, it may not. The OPPS packages payments for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. We continue to invite stakeholders to share evidence, such as published peer-reviewed literature, on these non-opioid alternatives. We also intend to continue to analyze the evidence and monitor utilization of non-opioid alternatives in the HOPD setting for potential future rulemaking.

Comment: Some commenters encouraged CMS to establish permanent separate payment for drugs that are currently on drug pass-through status in

the OPPS and ASC settings, such as Dexycu (HCPCS code J1095). Regarding Dexycu specifically, the commenters stated they were conducting a new, comprehensive study of a longitudinal claim dataset that will provide deeper insights into the association between cataract surgery and opioid utilization, as well as the role of Dexycu in reducing the prescribing of opioids.

Response: We refer readers to section V.A., ''OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals'' of this final rule with comment period regarding pass-through payments under the OPPS. Dexycu will receive separate payment due to its drug pass-through status through CY 2021. We will determine whether separate payment for this drug should be applied under the policy to pay separately for non-opioid pain management drugs that function as a surgical supply when furnished in the ASC setting when Dexycu's pass-through status expires. We thank commenters for conducting studies regarding their specific products and look forward to reviewing the results.

Comment: Several commenters requested that the drug Omidria, CPT J1097, (*phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*), be excluded from the OPPS policy to package drugs that function as surgical supplies once its pass-through status expires on September 30, 2020. Omidria is indicated for maintaining pupil size by preventing intraoperative miosis and reducing postoperative ocular pain in cataract or intraocular surgeries. The commenters stated that there is extensive clinical evidence and medical literature which supports their claims that Omidria reduces dependence on opioids for patients undergoing cataract surgery and postoperative prescription opioids. The commenters asserted that Omidria meets all of the requirements in regulation to qualify for separate payment in the ASC setting, as Omidria is FDA-approved for intraocular use in cataract procedures, a pain management drug, a non-opioid, and functions as a surgical supply during cataract surgery according to CMS' definition of a surgical supply. Commenters asserted that the use of Omidria decreases patients' need for fentanyl during surgeries and provided a manuscript stating that Omidria reduces opioid use based on pill counts after surgery.

Response: We thank commenters for their feedback on Omidria. Omidria received pass-through status for a 3-year period from 2015 to 2017. After expiration of its pass-through status, payment for Omidria was packaged under both the OPPS and the ASC payment system. Subsequently, Omidria's pass-through status under the OPPS was reinstated beginning on October 1, 2018 through September 30, 2020, as required by section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018 (Pub. L. 115–141), which means that Omidria continued to be paid separately under the ASC payment system through September 30, 2020.

Our previous review of the clinical evidence submitted indicated that the studies the commenter supplied were not sufficient to demonstrate that Omidria reduces opioid use. Moreover, the results of a CMS analysis of cataract procedures performed on Medicare beneficiaries in HOPDs and ASCs between January 2015 and July 2019, which compared procedures performed with Omidria to procedures performed without Omidria, did not demonstrate a significant decrease in fentanyl utilization during the cataract surgeries in the HOPDs and ASCs when Omidria was used. Our findings also did not suggest any decrease in opioid utilization post-surgery for procedures involving Omidria.

However, we will continue to apply separate payment for non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2021, as discussed in section XIII.D.3, and as we have described in regulation at 42 CFR 416.164 and 416.171(b)(1). After careful consideration of the commenters' assertion that Omidria meets this definition, we believe that Omidria does qualify as a non-opioid pain management drug that functions as a surgical supply and are excluding Omidria from packaging under the ASC payment system beginning October 1, 2020 and in CY 2021, in accordance with this policy.

Comment: Two commenters briefly mentioned the drug IV acetaminophen (CPT code J0131), which they believe may reduce opioid usage if CMS paid separately for the drug. These commenters believed IV acetaminophen decreases use of post-operative opioids.

Response: We thank commenters for their comments. We do not find it appropriate to pay separately for IV acetaminophen as suggested by the commenters due to our drug packaging threshold policies. We remind stakeholders of our drug packaging threshold policies, as described in section V.B.1.a to this final rule with comment period. In accordance with section 1833(t)(16)(B) of the Act, we finalized our proposal to set the drug packaging threshold for CY 2021 to $130. To the extent that the items and services mentioned by the commenters are effective alternatives to opioid prescriptions, we encourage providers to use them when medically necessary. Additionally, please see section XIII.D.3 for a full discussion on our policies in the ASC setting.

Comment: Commenters suggested modified payment for ''pain block'' CPT codes 64415, 64416, 64417, 64445, 64446, 64447, 64448, and 64450. Two commenters stated that providers use these pain blocks to mitigate the post-operative pain that is otherwise typically addressed with short-term opioid use. Additionally, a few commenters stated that CPT code J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0.1 mg*) used for treatment of ocular inflammation and pain following ophthalmic surgery is administered through CPT code 0356T (*Insertion of drug-eluting implant (including punctal dilation and implant removal when performed) into lacrimal canaliculus, each*). These commenters felt CPT code 0356T, which describes the administration of the drug, should also receive separate or additional payment due to the purported clinical benefits of the drug, including treatment of pain.

Response: We thank the commenters for their suggestions. At this time, we have not found compelling evidence for the non-opioid pain management alternatives described above to warrant separate or modified payment under the OPPS or ASC payment systems for CY 2021. Additionally, we do not believe that the ''pain blocks'' described by stakeholders qualify as non-opioid pain management drugs that function as a surgical supply as the codes provided by stakeholders are used to describe procedures under the OPPS and not drugs. To the extent that the items and services mentioned by the commenters are effective alternatives to opioid prescriptions, we encourage providers to use them when medically necessary. For a greater discussion of CPT code 0356T, please see section III. D. (Administration of Lacrimal Ophthalmic Insert Into Lacrimal Canaliculus (APC 5692)) of this final rule with comment period.

Comment: Commenters also requested separate payments for various non-opioid pain management treatments, such as ERAS® protocols or spinal cord stimulators (SCS), that they believe decrease the number of opioid prescriptions beneficiaries receive during and following an outpatient visit or procedure. For SCS, several commenters noted that this therapy may lead to a reduction in the use of opioids

for chronic pain patients. They noted that neurostimulation is a key alternative to opioid prescription for pain management and recommended that CMS increase access to SCS.

Response: We appreciate the commenters' information on this topic. At this time, we have not found compelling evidence for the non-opioid pain management alternatives described above to warrant separate payment under the OPPS or ASC payment systems for CY 2021. However, we plan to take these comments and suggestions into consideration for future rulemaking. We agree that providing incentives to avoid or reduce opioid prescriptions may be one of several strategies for addressing the opioid epidemic. To the extent that the items and services mentioned by the commenters are effective alternatives to opioid drugs, we encourage providers to use them when medically appropriate.

We look forward to working with stakeholders as we further consider suggested refinements to the OPPS and the ASC payment system that will encourage use of medically necessary items and services that have demonstrated efficacy in decreasing opioid prescriptions and/or opioid abuse or misuse during or after an outpatient visit or procedure.

After consideration of the public comments we received, we are finalizing the proposed policy, without modification, to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2021. We will continue to analyze the issue of access to non-opioid pain management alternatives in the OPPS and the ASC settings as part of any subsequent reviews we conduct under section 1833(t)(22)(A)(ii). We are continuing to examine whether there are other non-opioid pain management alternatives for which our payment policy should be revised to allow separate payment. We will be reviewing evidence-based support, such as published peer-reviewed literature, that we could use to determine whether these products help to deter or avoid prescription opioid use and addiction as well as evidence that the current packaged payment for such non-opioid alternatives presents a barrier to access to care and therefore warrants revised, including possibly separate, payment under the OPPS. This policy is also discussed in section XIII.D.3 of this final rule with comment period.

c. Clinical Diagnostic Laboratory Tests Packaging Policy

(1) Background

Prior to CY 2014, clinical diagnostic laboratory tests were excluded from payment under the hospital OPPS because they were paid separately under the Clinical Laboratory Fee Schedule (CLFS). Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. Under this authority, the Secretary excluded from the OPPS those services that are paid under fee schedules or other payment systems. Because laboratory services are paid separately under the CLFS, laboratory tests were excluded from separate payment under the OPPS. We codified this policy at 42 CFR 419.22(l).

However, in CY 2014, we revised the categories of packaged items and services under the OPPS to include certain laboratory tests. We stated that certain laboratory tests, similar to other covered outpatient services that are packaged under the OPPS, are typically integral, ancillary, supportive, dependent, or adjunctive to a primary hospital outpatient service and should be packaged under the hospital OPPS. We stated that laboratory tests and their results support clinical decision making for a broad spectrum of primary services provided in the hospital outpatient setting, including surgery and diagnostic evaluations (78 FR 74939). Consequently, we finalized the policy to package payment for most laboratory tests in the OPPS when they are integral, ancillary, supportive, dependent, or adjunctive to a primary service or services provided in the hospital outpatient setting (78 FR 74939 through 74942 and 42 CFR 419.2(b)(17)). In the same final rule, we clarified that certain laboratory tests would be excluded from packaging. Specifically, we stated that laboratory tests would be paid separately under the CLFS when the laboratory test is the only service provided to a beneficiary or when a laboratory test is conducted on the same date of service (DOS) as the primary service but is ordered for a different purpose than the primary service by a practitioner different than the practitioner who ordered the primary service or when the laboratory test is a molecular pathology test (78 FR 74942). As explained in the CY 2014 OPPS/ASC final rule, we excluded molecular pathology tests from packaging because we believe these tests are relatively new and may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that we package (78 FR 74939). Based on these changes, we revised the regulation text at §§ 419.2(b) and 419.22(l) to reflect this laboratory test packaging policy.

In CY 2016, we made some modifications to this policy (80 FR 70348 through 70350). First, we clarified that all molecular pathology tests would be excluded from our packaging policy, including any new codes that also describe molecular pathology tests. In the CY 2014 OPPS/ASC final rule, we stated that only those molecular pathology codes described by CPT codes in the ranges of 81200 through 81383, 81400 through 81408, and 81479 were excluded from OPPS packaging (78 FR 74939 through 74942). However, in 2016, we expanded this policy to include not only the original code range but also all new molecular pathology test codes (80 FR 70348). Secondly, we excluded preventive laboratory tests from OPPS packaging and provided that they would be paid separately under the CLFS. Laboratory tests that are considered preventive are listed in Section 1.2, Chapter 18 of the Medicare Claims Processing Manual (Pub. L. 100–04). As stated in the CY 2016 OPPS/ASC final rule, we make an exception to conditional packaging of ancillary services for ancillary services that are also preventive services (80 FR 70348). For consistency, we excluded from OPPS packaging those laboratory tests that are classified as preventive services. In addition, we modified our conditional packaging policy so that laboratory tests provided during the same outpatient stay (rather than specifically provided on the same DOS as the primary service) are considered as integral, ancillary, supportive, dependent, or adjunctive to a primary service or services, except when a laboratory test is ordered for a different diagnosis and by a different practitioner than the practitioner who ordered the other hospital outpatient services. We explained in the CY 2016 OPPS/ASC final rule that this modification did not affect our policy to provide separate payment for laboratory tests: (1) If they are the only services furnished to an outpatient and are the only services on a claim and have a payment rate on the CLFS; or (2) if they are ordered for a different diagnosis than another hospital outpatient service by a practitioner different than the practitioner who ordered the other hospital outpatient service (80 FR 70349 through 70350).

In CY 2017, we modified the policy to remove the ''unrelated'' laboratory test exclusion and to expand the laboratory

test packaging exclusion to apply to laboratory tests designated as advanced diagnostic laboratory tests (ADLTs) under the CLFS. We clarified that the exception would only apply to those ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act, which are defined as tests that provide an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result (81 FR 79592 through 79594).

(2) Current Categories of Clinical Diagnostic Laboratory Tests Excluded From OPPS Packaging

As we discussed in the CY 2021 OPPS/ASC proposed rule (85 FR 48798), under our current policy, certain clinical diagnostic laboratory tests (CDLTs) that are listed on the CLFS are packaged as integral, ancillary, supportive, dependent, or adjunctive to the primary service or services provided in the hospital outpatient setting during the same outpatient encounter and billed on the same claim. While we package most CDLTs under the OPPS, when a CDLT is listed on the CLFS and meets one of the following four criteria, we do not pay for the test under the OPPS, but rather, we pay for it under the CLFS when it is: (1) The only service provided to a beneficiary on a claim; (2) considered a preventive service; (3) a molecular pathology test; or (4) an ADLT that meets the criteria of section 1834A(d)(5)(A) of the Act. Generally, when laboratory tests are not packaged under the OPPS and are listed on the CLFS, they are paid under the CLFS instead of the OPPS.

(3) New Category of Laboratory Tests Excluded From OPPS Packaging

(a) Background on Protein-Based MAAAs

As part of recent rulemaking cycles, stakeholders have suggested that some protein-based Multianalyte Assays with Algorithmic Analyses tests (MAAAs) may have a pattern of clinical use that makes them relatively unconnected to the primary hospital outpatient service (84 FR 61439). In the CY 2018 OPPS/ASC final rule (82 FR 59299), we stated that stakeholders indicated that certain protein-based MAAAs, specifically those described by CPT codes 81490, 81503, 81535, 81536, 81538, and 81539, are generally not performed in the HOPD setting and have similar clinical patterns of use as the DNA and RNA-based MAAA tests that are assigned to status indicator ''A'' under the OPPS and are paid separately under the CLFS. Notably, all of the tests described by these CPT codes (with the exception of CPT code 81490, which we discuss below) are cancer-related protein-based MAAAs. In the same final rule, stakeholders suggested that, based on the June 23, 2016 CLFS final rule entitled ''Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System,'' in which CMS defined an ADLT under section 1834A(d)(5)(A) of the Act to include DNA, RNA, and protein-based tests, they believe that the reference to ''protein-based tests'' in the definition applies equally to the tests they identified, that is, protein-based MAAAs. Consequently, the stakeholders believed that protein-based MAAAs should be excluded from OPPS packaging and paid separately under the CLFS. As we noted in the CY 2021 OPPS/ASC proposed rule, one of the protein-based MAAAs previously requested by stakeholders to be excluded from OPPS packaging policy is CPT code 81538 (Oncology (lung), mass spectrometric 8-protein signature, including amyloid a, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival), which has been designated as an ADLT under section 1834A(d)(5)(A) of the Act as of December 21, 2018. Therefore, CPT code 81538 is currently excluded from the OPPS packaging policy and paid under the CLFS instead of the OPPS when it also meets the laboratory DOS requirements.

(b) CY 2021 Cancer-Related Protein-Based MAAAs

As discussed in the CY 2021 OPPS/ASC proposed rule (85 FR 49032), we have continued to consider previous stakeholder requests to exclude some protein-based MAAAs from the OPPS packaging policy. We stated that, after further review of this issue, we believe that cancer-related protein-based MAAAs, in particular, may be relatively unconnected to the primary hospital outpatient service during which the specimen was collected from the patient. Similar to molecular pathology tests, which are currently excluded from the OPPS packaging policy, cancer-related protein-based MAAAs appear to have a different pattern of clinical use, which may make them generally less tied to the primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged.

As we noted previously in the CY 2021 OPPS/ASC proposed rule and in this section of the final rule, commenters to the CY 2018 OPPS/ASC final rule identified specific cancer-related protein-based MAAAs as tests that are generally not performed in the HOPD setting (82 FR 59299). In fact, those tests identified by commenters are used to guide future surgical procedures and chemotherapeutic interventions. Treatments that are based on the results of cancer-related protein-based MAAAs are typically furnished after the patient is no longer in the hospital, in which case they are not tied to the same hospital outpatient encounter during which the specimen was collected.

For these reasons, we proposed to exclude cancer-related protein-based MAAAs from the OPPS packaging policy and pay for them separately under the CLFS.

In the CY 2021 OPPS/ASC proposed rule (85 FR 48799), we explained that the AMA CPT 2020 manual currently describes MAAAs, in part, as ''procedures that utilize multiple results derived from panels of analyses of various types, including molecular pathology assays, fluorescent in situ hybridization assays, and non-nucleic acid based assays (for example, proteins, polypeptides, lipids, carbohydrates).'' [1] Additionally, the AMA CPT 2020 manual provides a MAAA code descriptor format which includes several specific characteristics, including but not limited to disease type (for example, oncology, autoimmune, tissue rejection), and material(s) analyzed (for example, DNA, RNA, protein, antibody). We noted that as the AMA CPT 2020 manual describes a MAAA, and the code descriptor of each MAAA distinguishes MAAAs that are cancer-related assays from those that test for other disease types, the AMA CPT manual is a potentially instructive tool to identify cancer-related MAAA tests that are ''protein-based''. Accordingly, in following the AMA CPT 2020 manual intent to identify MAAA tests that are cancer-related, and, of those tests, identifying the ones whose test analytes are proteins, we have determined there are currently six cancer-related protein-based MAAAs: CPT codes 81500, 81503, 81535, 81536, 81538 and 81539. As discussed previously in the CY 2021 OPPS/ASC proposed rule and in this section of the final rule, CPT code 81538 has been designated as an ADLT under section 1834A(d)(5)(A) of the Act as of December 21, 2018 and therefore, is already paid under the CLFS instead of the OPPS. As such, we proposed to assign status indicator ''A'' (''Not paid under OPPS. Paid by MACs under a fee schedule or payment system other than

[1] *Current Procedure Terminology* (CPT®) page 586, copyright 2020 American Medical Association. All Rights Reserved.

OPPS'') to cancer-related protein-based MAAAs as described by CPT codes 81500, 81503, 81535, 81536, and 81539. We also proposed that we would apply this policy to cancer-related protein-based MAAAs that do not currently exist, but that are developed in the future. Additionally, we stated that we intend to continue to study the list of laboratory tests excluded from the OPPS packaging policy and determine whether any additional changes are warranted and may consider proposing future changes to the laboratory DOS policy through notice-and-comment rulemaking.

In the CY 2021 OPPS/ASC proposed rule (85 FR 49032), we noted that commenters to the CY 2018 OPPS/ASC proposed rule also identified CPT code 81490 as a protein-based MAAA that should be excluded from the OPPS packaging policy and paid outside of the OPPS. However, we stated that we believed that the results for the test described by CPT code 81490 are used to determine disease activity in rheumatoid arthritis patients, guide current therapy to reduce further joint damage, and may be tied to the primary hospital outpatient service, that is, the hospital outpatient encounter during which the specimen was collected. Therefore, we stated that we believed that payment for CPT code 81490 remains appropriately packaged under the OPPS.

We refer readers to section XVIII. of the CY 2021 OPPS/ASC proposed rule and section XVIII. of this final rule with comment period, which describe the related proposal to revise the laboratory DOS policy for cancer-related protein-based MAAAs.

We received public comments on the proposal to exclude cancer-related protein-based MAAAs from the OPPS packaging policy and pay for them separately under the CLFS. The following is a summary of the comments we received and our responses.

Comment: Generally, commenters supported the proposal to exclude cancer-related protein-based MAAAs from the OPPS packaging policy and add them to the list of test codes subject to the laboratory DOS exception for the hospital outpatient setting, leading to the test being paid at the CLFS rate and requiring that the laboratory bill Medicare for the test instead of seeking payment from the hospital. Commenters stated that changes to this policy will lead to improved beneficiary access to diagnostic tests while also reducing hospital administrative burden.

Response: We appreciate the support from commenters for our proposed revisions to the OPPS packaging policy for CDLTs. We agree that the revisions to the laboratory DOS policy that we proposed in the CY 2021 OPPS/ASC proposed rule and finalized in section XVIII of this final rule with comment period may potentially serve to reduce delay in access to laboratory tests by minimizing the likelihood that a hospital will postpone ordering a test until at least 14 days after the patient is discharged from the hospital outpatient department, or even cancel the order in order to avoid having to bill Medicare for the test under the laboratory DOS policy.

Comment: In addition to excluding the cancer-related protein-based MAAAs from OPPS packaging, several commenters suggested a similar change for pathology tests. Specifically, they recommended revising the existing laboratory test packaging policy to allow separate payment under the CLFS for the technical component of pathology tests.

Response: We appreciate the feedback and will consider the issue for future rulemaking.

Comment: Some commenters recommended further expansion of the list of test codes excluded from OPPS packaging to include various other CDLTs, including all protein-based MAAAs, AMA CPT Proprietary Laboratory Analyses (PLA) test codes that may have similar characteristics to AMA CPT MAAA tests but are not currently categorized as AMA CPT MAAA test codes, and several specific CPT test codes, including the OVERA test from Aspira Labs (CPT 0003U), EPI assay by Bio-Techne (CPT 0005U), TissueCypher assay from Cernostics (CPT 0108U), and KidneyIntelX (CPT 0105U).

Commenters also noted that while PLA test codes are not automatically included in the outpatient laboratory test packaging exclusion, some tests described by PLA codes are included under these policies if they qualify as a molecular pathology test or Criterion A ADLT. Therefore, the commenters asserted that CMS should continue its historical practice of applying the laboratory test packaging exclusion to PLA test codes as occurs with molecular pathology tests and ADLTs that have been assigned PLA codes.

Response: We believe that the commenters' suggested modifications to the list of codes excluded from OPPS packaging to include various CDLTs, including all protein-based MAAAs, AMA CPT PLA test codes that may have similar characteristics to AMA CPT MAAA tests but are not currently categorized as AMA CPT MAAA codes, and several specific AMA CPT test codes, are inconsistent with the current OPPS packaging policy and would result in allowing the laboratory to bill Medicare directly for a test that should be incorporated into the hospital OPPS bundled rate. CMS does not believe that all AMA CPT PLA test codes demonstrate a different pattern of clinical use that makes them less tied to the primary service in the hospital outpatient setting such that they should be included in the list of codes excepted from the OPPS packaging policy. Commenters asserted that these tests, as a group, should be excluded from OPPS packaging policy because the results of these tests may inform future interventions beyond the hospital outpatient encounter during which the specimen was collected and may be used by other health care providers to developed long-term plans for treatment. However, we are not convinced based on the commenters' descriptions of these tests that they are generally unconnected to the hospital encounter, the chief requirement for exclusion from OPPS packaging. Although commenters noted that the recommended tests may be utilized for the development of longer-term treatment plans, it is not clear that the clinical usage of these tests reaches the threshold of being ''generally unconnected'' to the hospital encounter.

Any addition to the list of test codes excluded from OPPS packaging requires careful evaluation as to whether a different pattern of clinical use makes a test generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that we package. For instance, as noted in the CY 2021 OPPS/ASC proposed rule (85 FR 49035), in response to the changes in the laboratory DOS policy outlined in the CY 2018 OPPS/ASC final rule with comment period, stakeholders stated that some entities performing molecular pathology testing included on the list of codes excluded from OPPS packaging and subject to the laboratory DOS exception, such as blood banks and blood centers, may perform molecular pathology testing to enable hospitals to prevent adverse conditions associated with blood transfusions, rather than perform molecular pathology testing for diagnostic purposes. This led us to consider whether the molecular pathology testing performed by blood banks and centers is appropriately separable from the hospital stay.

We do not believe all protein-based MAAAs would meet this standard for exclusion from OPPS packaging. CMS has considered expanding the list of codes excluded from OPPS packaging to

include various additional categories of codes, including protein-based MAAAs. However, we note that some protein-based MAAAs include simple and commonly used protein analytes that may also be commonly performed to assist in managing patient care during a hospital outpatient encounter. Therefore, we believe that we cannot conclude that this category of tests is generally less tied to a primary service in the hospital outpatient setting, as some protein-based MAAA tests use common routine protein analytes that are appropriately packaged into OPPS payment. For these reasons, CMS does not believe that all protein-based MAAAs should be included in the list of codes excluded from the OPPS packaging policy.

However, we note that a protein-based MAAA that is designated by CMS as an ADLT under paragraph (1) of the definition of an ADLT in § 414.502 would be added to the list of codes excluded from OPPS packaging, in accordance with our established policy.

Comment: Commenters also recommended that we exclude a particular protein-based MAAA test described by CPT code 81490 from the OPPS packaging policy. Commenters asserted that the use of the test described by CPT code 81490 is unconnected to the hospital outpatient encounter during which the specimen is collected and that the results of the test are used to determine potential future interventions outside of the hospital outpatient encounter. Commenters stated that this test appears to be generally less tied to a primary service in the hospital outpatient setting and does not appear to be a common or routine laboratory test that would otherwise be packaged into OPPS payment.

Response: In the CY 2021 OPPS/ASC proposed rule (85 FR 48799), we stated that we believed the results for the test described by CPT code 81490 are used to determine disease activity in rheumatoid arthritis patients, guide current therapy to reduce further joint damage, and may be tied to the primary hospital outpatient service, that is, the hospital outpatient encounter during which the specimen was collected. Therefore, we stated that we believed that payment for CPT code 81490 remains appropriately packaged under the OPPS.

However, given commenter feedback, we are convinced that the pattern of clinical use for CPT code 81490 is generally unconnected to the hospital outpatient encounter during which the specimen is collected as it is typically used to determine potential interventions outside of the hospital outpatient encounter and is generally used by the rheumatologist to make longer-term changes in RA treatment. Commenters informed us that physicians and patients utilize the objective information provided by the results of the test to make longer-term modifications in treatment, to monitor disease activity, and to prevent joint damage progression, and the results generally would not be utilized for purposes of the hospital outpatient encounter. The commenters further stated that the output of the test is used to assess disease activity, including evaluating response to therapy, directing choice of second-line treatment in patients with inadequate response to the current first line therapy, and identifying patients in stable remission for therapy reduction. The test results appear to guide longer-term therapies and treatments; therefore, we believe that this test, identified by CPT code 81490, is generally less tied to the primary service the patient receives in the hospital outpatient setting and does not appear to be a common or routine laboratory test that would otherwise be packaged into OPPS payment. Consequently, we believe that CPT code 81490 should be excluded from OPPS packaging policy.

As stated previously, we intend to continue to study the list of laboratory tests excluded from the OPPS packaging policy to determine whether any additional changes are warranted and may consider proposing future changes to this policy and the laboratory DOS policy through notice-and-comment rulemaking.

In conclusion, we continue to believe that cancer-related protein-based MAAAs, that is, those represented by CPT codes 81500, 81503, 81535, 81536 and 81539, appear to have a different pattern of clinical use that make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged. We also believe that, given the similarity in its clinical pattern of use to the cancer-related protein-based MAAAs, CPT code 81490 should also be added to the list of codes excluded from the OPPS packaging and subject to the laboratory DOS exception at § 414.510(b)(5), which is discussed in section III.XX in this final rule. For the reasons discussed, we are revising the list of test codes excluded from the OPPS packaging policy to include CPT codes 81500, 81503, 81535, 81536, 81539, and 81490. We are also finalizing that we will exclude cancer-related protein-based MAAAs that do not currently exist, but that are developed in the future, from the OPPS packaging policy.

4. Calculation of OPPS Scaled Payment Weights

We established a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68283) of using geometric mean-based APC costs to calculate relative payment weights under the OPPS. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61180 through 61182), we applied this policy and calculated the relative payment weights for each APC for CY 2020 that were shown in Addenda A and B to that final rule with comment period (which were made available via the internet on the CMS website) using the APC costs discussed in sections II.A.1. and II.A.2. of that final rule with comment period. For CY 2021, as we did for CY 2020, we proposed to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2021 using geometric mean-based APC costs.

For CY 2012 and CY 2013, outpatient clinic visits were assigned to one of five levels of clinic visit APCs, with APC 0606 representing a mid-level clinic visit. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75043), we finalized a policy that created alphanumeric HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), representing any and all clinic visits under the OPPS. HCPCS code G0463 was assigned to APC 0634 (Hospital Clinic Visits). We also finalized a policy to use CY 2012 claims data to develop the CY 2014 OPPS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT E/M codes for clinic visits previously recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). In addition, we finalized a policy to no longer recognize a distinction between new and established patient clinic visits.

For CY 2016, we deleted APC 0634 and reassigned the outpatient clinic visit HCPCS code G0463 to APC 5012 (Level 2 Examinations and Related Services) (80 FR 70372). For CY 2021, as we did for CY 2020, we proposed to continue to standardize all of the relative payment weights to APC 5012. We believe that standardizing relative payment weights to the geometric mean of the APC to which HCPCS code G0463 is assigned maintains consistency in calculating unscaled weights that represent the cost of some of the most frequently provided OPPS services. For

CY 2021, as we did for CY 2020, we proposed to assign APC 5012 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the geometric mean cost for APC 5012 to derive the unscaled relative payment weight for each APC. The choice of the APC on which to standardize the relative payment weights does not affect payments made under the OPPS because we scale the weights for budget neutrality.

We note that in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015) and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61365 through 61369), we discuss our policy, implemented on January 1, 2019, to control for unnecessary increases in the volume of covered outpatient department services by paying for clinic visits furnished at excepted off-campus provider-based department (PBD) at a reduced rate. While the volume associated with these visits is included in the impact model, and thus used in calculating the weight scalar, the policy has a negligible effect on the scalar. Specifically, under this policy, there is no change to the relativity of the OPPS payment weights because the adjustment is made at the payment level rather than in the cost modeling. Further, under this policy, the savings that result from the change in payments for these clinic visits are not budget neutral. Therefore, the impact of this policy will generally not be reflected in the budget neutrality adjustments, whether the adjustment is to the OPPS relative weights or to the OPPS conversion factor. We note that the volume control method for clinic visit services furnished by non-excepted off-campus PBDs is subject to litigation. For a full discussion of this policy and the litigation, we refer readers to the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142).

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPPS for CY 2021 is neither greater than nor less than the estimated aggregate weight that would have been calculated without the changes. To comply with this requirement concerning the APC changes, we proposed to compare the estimated aggregate weight using the CY 2020 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2021 unscaled relative payment weights.

For CY 2020, we multiplied the CY 2020 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2019 claims to calculate the total relative payment weight for each service. We then added together the total relative payment weight for each of these services in order to calculate an estimated aggregate weight for the year. For CY 2021, we proposed to apply the same process using the estimated CY 2021 unscaled relative payment weights rather than scaled relative payment weights. We proposed to calculate the weight scalar by dividing the CY 2020 estimated aggregate weight by the unscaled CY 2021 estimated aggregate weight.

For a detailed discussion of the weight scalar calculation, we refer readers to the OPPS claims accounting document available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. Click on the CY 2021 OPPS proposed rule link and open the claims accounting document link at the bottom of the page.

We proposed to compare the estimated unscaled relative payment weights in CY 2021 to the estimated total relative payment weights in CY 2020 using CY 2019 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we proposed to adjust the calculated CY 2021 unscaled relative payment weights for purposes of budget neutrality. We proposed to adjust the estimated CY 2021 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4443 to ensure that the proposed CY 2021 relative payment weights are scaled to be budget neutral. The proposed CY 2021 relative payment weights listed in Addenda A and B to the CY 2021 OPPS/ASC proposed rule (which are available via the internet on the CMS website) are scaled and incorporate the recalibration adjustments discussed in sections II.A.1. and II.A.2. of the CY 2021 OPPS/ASC proposed rule.

Section 1833(t)(14) of the Act provides the payment rates for certain SCODs. Section 1833(t)(14)(H) of the Act provides that additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years. Therefore, the cost of those SCODs (as discussed in section V.B.2. of proposed rule) is included in the budget neutrality calculations for the CY 2021 OPPS.

We did not receive any public comments on the proposed weight scalar calculation. Therefore, we are finalizing our proposal to use the calculation process described in the proposed rule, without modification, for CY 2021. Using updated final rule claims data, we are updating the estimated CY 2021 unscaled relative payment weights by multiplying them by a weight scalar of 1.4341 to ensure that the final CY 2021 relative payment weights are scaled to be budget neutral. The final CY 2021 relative payments weights listed in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website) were scaled and incorporate the recalibration adjustments discussed in sections II.A.1. and II.A.2. of this final rule with comment period.

B. Conversion Factor Update

Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor used to determine the payment rates under the OPPS on an annual basis by applying the OPD fee schedule increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD fee schedule increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act. In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32738), consistent with current law, based on IHS Global, Inc.'s fourth quarter 2019 forecast of the FY 2021 market basket increase, the proposed FY 2021 IPPS market basket update was 3.0 percent. Accordingly, we proposed a CY 2021 OPD fee schedule increase factor of 3.0 percent.

Specifically, section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (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 ''MFP adjustment''). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and

applying the MFP adjustment, and then revised this methodology, as discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49509). In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32739), the proposed MFP adjustment for FY 2021 was 0.4 percentage point.

Therefore, we proposed that the MFP adjustment for the CY 2021 OPPS would be 0.4 percentage point. We also proposed that if more recent data become subsequently available after the publication of the CY 2021 OPPS/ASC proposed rule (for example, a more recent estimate of the market basket increase and/or the MFP adjustment), we would use such updated data, if appropriate, to determine the CY 2021 market basket update and the MFP adjustment, which are components in calculating the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and 1833(t)(3)(F) of the Act, in the CY 2021 OPPS/ASC final rule.

We note that section 1833(t)(3)(F) of the Act provides that application of this subparagraph may result in the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act being less than 0.0 percent for a year, and may result in OPPS payment rates being less than rates for the preceding year. As described in further detail below, we proposed for CY 2021 an OPD fee schedule increase factor of 2.6 percent for the CY 2021 OPPS (which is the proposed estimate of the hospital inpatient market basket percentage increase of 3.0 percent, less the proposed 0.4 percentage point MFP adjustment).

We proposed that hospitals that fail to meet the Hospital OQR Program reporting requirements would be subject to an additional reduction of 2.0 percentage points from the OPD fee schedule increase factor adjustment to the conversion factor that would be used to calculate the OPPS payment rates for their services, as required by section 1833(t)(17) of the Act. For further discussion of the Hospital OQR Program, we refer readers to section XIV. of the proposed rule.

The adjustment described in section 1833(t)(3)(F)(ii) was required only through 2019. The requirement in section 1833(t)(3)(F)(i) of the Act that we reduce the OPD fee schedule increase factor by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II), however, applies for 2012 and subsequent years, and thus, continues to apply. In the CY 2020 OPPS/ASC final rule with comment period, we inadvertently did not amend the regulation at 42 CFR 419.32(b)(1)(iv)(B) to reflect that the adjustment required by section 1833(t)(3)(F)(i) of the Act is the only adjustment under section 1833(t)(3)(F) that applies in CY 2020 and subsequent years. Accordingly, we proposed to amend our regulation at 42 CFR 419.32(b)(1)(iv)(B) by adding a new paragraph (b)(1)(iv)(B)(*11*) to provide that, for CY 2020 and subsequent years, we reduce the OPD fee schedule increase factor by the MFP adjustment as determined by CMS.

To set the OPPS conversion factor for CY 2021, we proposed to increase the CY 2020 conversion factor of $80.793 by 2.6 percent. In accordance with section 1833(t)(9)(B) of the Act, we proposed further to adjust the conversion factor for CY 2021 to ensure that any revisions made to the wage index and rural adjustment were made on a budget neutral basis. We proposed to calculate an overall budget neutrality factor of 1.0017 for wage index changes. This adjustment was comprised of a 1.0027 proposed budget neutrality adjustment, using our standard calculation of comparing proposed total estimated payments from our simulation model using the proposed FY 2021 IPPS wage indexes to those payments using the FY 2020 IPPS wage indexes, as adopted on a calendar year basis for the OPPS as well as a 0.9990 proposed budget neutrality adjustment for the proposed CY 2021 5 percent cap on wage index decreases to ensure that this transition wage index is implemented in a budget neutral manner, consistent with the proposed FY 2021 IPPS wage index policy (85 FR 32706). We stated in the proposed rule that we believed it was appropriate to ensure that the proposed wage index transition policy (that is, the proposed CY 2021 5 percent cap on wage index decreases) did not increase estimated aggregate payments under the OPPS beyond the payments that would be made without this transition policy. We proposed to calculate this budget neutrality adjustment by comparing total estimated OPPS payments using the FY 2021 IPPS wage index, adopted on a calendar year basis for the OPPS, where a 5 percent cap on wage index decreases is not applied to total estimated OPPS payments where the 5 percent cap on wage index decreases is applied. We stated in the proposed rule that these two proposed wage index budget neutrality adjustments would maintain budget neutrality for the proposed CY 2021 OPPS wage index (which, as we discuss in section II.C of the proposed rule, would use the FY 2021 IPPS post-reclassified wage index and any adjustments, including without limitation any adjustments finalized under the IPPS related to the proposed adoption of the revised OMB delineations).

We did not receive any public comments on our proposed methodology for calculating the wage index budget neutrality adjustment as discussed above. Therefore, for the reasons discussed above and in the CY 2021 OPPS/ASC proposed rule (85 FR 48801), we are finalizing our methodology for calculating the wage index budget neutrality adjustment as proposed, without modification. For CY 2021, based on updated data for this final rule with comment period, we are finalizing an overall budget neutrality factor of 1.0012 for wage index changes. This adjustment is comprised of a 1.0020 budget neutrality adjustment using our standard calculation of comparing total estimated payments from our simulation model using the final FY 2021 IPPS wage indexes to those payments using the FY 2020 IPPS wage indexes, as adopted on a calendar year basis for the OPPS, as well as a 0.9992 budget neutrality adjustment for the CY 2021 5 percent cap on wage index decreases to ensure that this transition wage index is implemented in a budget neutral manner.

For the CY 2021 OPPS, we proposed to maintain the current rural adjustment policy, as discussed in section II.E. of the CY 2021 OPPS/ASC proposed rule. Therefore, the proposed budget neutrality factor for the rural adjustment was 1.0000.

We proposed to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act, as discussed in section II.F. of the CY 2021 OPPS/ASC proposed rule. We proposed to calculate a CY 2021 budget neutrality adjustment factor for the cancer hospital payment adjustment by comparing estimated total CY 2021 payments under section 1833(t) of the Act, including the proposed CY 2021 cancer hospital payment adjustment, to estimated CY 2021 total payments using the CY 2020 final cancer hospital payment adjustment, as required under section 1833(t)(18)(B) of the Act. The proposed CY 2021 estimated payments applying the proposed CY 2021 cancer hospital payment adjustment were the same as estimated payments applying the CY 2020 final cancer hospital payment adjustment. Therefore, we proposed to apply a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment. In accordance with section 1833(t)(18)(C), as added by section 16002(b) of the 21st Century Cures Act (Pub. L. 114–255), we

proposed to apply a budget neutrality factor calculated as if the proposed cancer hospital adjustment target payment-to-cost ratio was 0.90, not the 0.89 target payment-to-cost ratio we applied as stated in section II.F. of the proposed rule.

For the CY 2021 OPPS/ASC proposed rule, we estimated that proposed pass-through spending for drugs, biologicals, and devices for CY 2021 would equal approximately $783.2 million, which represented 0.93 percent of total projected CY 2021 OPPS spending. Therefore, we stated that the proposed conversion factor would be adjusted by the difference between the 0.88 percent estimate of pass-through spending for CY 2020 and the 0.93 percent estimate of proposed pass-through spending for CY 2021, resulting in a proposed decrease to the conversion factor for CY 2021 of 0.05 percent.

We also estimated a 0.85 percent upward adjustment to nondrug OPPS payment rates as a result of our payment proposal for separately payable nonpass-through drugs purchased under the 340B Program at a net rate of ASP minus 28.7 percent. Applying the proposed payment policy for drugs purchased under the 340B Program, as described in section V.B.6. of the CY 2021 OPPS/ASC proposed rule, would have resulted in an estimated reduction of approximately $427 million in separately paid OPPS drug payments. To ensure budget neutrality under the OPPS after applying this proposed payment methodology for drugs purchased under the 340B Program, we proposed to apply an offset of approximately $427 million to the OPPS conversion factor, which would result in an adjustment of 1.0085 to the OPPS conversion factor.

Proposed estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2021. We estimated for the proposed rule that outlier payments would be 1.01 percent of total OPPS payments in CY 2020; the 1.00 percent for proposed outlier payments in CY 2021 would constitute a 0.01 percent decrease in payment in CY 2021 relative to CY 2020.

For the CY 2021 OPPS/ASC proposed rule, we also proposed that hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor. For hospitals that fail to meet the requirements of the Hospital OQR Program, we proposed to make all other adjustments discussed above, but use a reduced OPD fee schedule update factor of 0.6 percent (that is, the proposed OPD fee schedule increase factor of 2.6 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2021 of $82.065 for hospitals that fail to meet the Hospital OQR Program requirements (a difference of 1.632 in the conversion factor relative to hospitals that met the requirements).

In summary, for CY 2021, we proposed to amend § 419.32 by adding a new paragraph (b)(1)(iv)(B)(*11*) to reflect the reductions to the OPD fee schedule increase factor that are required for CY 2020, CY 2021, and subsequent years to satisfy the statutory requirements of section 1833(t)(3)(F) of the Act. We proposed to use a reduced conversion factor of $82.065 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.632 in the conversion factor relative to hospitals that met the requirements).

For CY 2021, we proposed to use a conversion factor of $83.697 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the proposed OPD fee schedule increase factor of 2.6 percent for CY 2021, the required proposed wage index budget neutrality adjustment of approximately 1.0017, the proposed cancer hospital payment adjustment of 1.0000, the proposed budget neutrality adjustment of 1.0085 applying the proposed payment methodology of ASP minus 28.7 percent for CY 2021 for drugs purchased under the 340B Program, and the proposed adjustment of 0.05 percentage point of projected OPPS spending for the difference in pass-through spending that resulted in a proposed conversion factor for CY 2021 of $83.697.

Comment: One commenter suggested that we eliminate the MFP adjustment because of economic uncertainty as a result of the COVID–19 pandemic. The commenter stated that CMS rules for fiscal year 2021 had a 0.0 percent multifactor productivity adjustment.

Response: We note that under section 1886(b)(3)(B)(xi)(I) of the Act, the Secretary is required to reduce the hospital market basket percentage increase by the 10-year moving average of changes in annual economy-wide, private nonfarm business MFP.

Comment: Multiple commenters supported our proposed CY 2021 OPD fee schedule increase factor percentage increase of 2.6 percent.

Response: We appreciate the support of the commenters.

After reviewing the public comments we received, we are finalizing these proposals with modification. For CY 2021, we proposed to continue previously established policies for implementing the cancer hospital payment adjustment described in section 1833(t)(18) of the Act (discussed in section II.F. of this final rule with comment period). Based on the final rule updated data used in calculating the cancer hospital payment adjustment in section II.F. of this final rule with comment period, the target payment-to-cost ratio for the cancer hospital payment adjustment, which was 0.89 for CY 2020, is also 0.89 for CY 2021. As a result, we are applying a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment. We are implementing our alternative proposal for CY 2021 for the payment of drugs acquired through the 340B program. Drugs obtained through the 340B program will be paid at a net rate of ASP minus 22.5 percent. This has been the payment rate for drugs acquired through the 340B program in the OPPS since the policy was initially established in CY 2018. Since there is no change in the net payment rate, the final budget neutral adjustment factor regarding the payment of drugs acquired through the 340B program is 1.0000.

For this CY 2021 OPPS/ASC final rule with comment period, as published in the FY 2021 IPPS/LTCH PPS final rule, based on IGI's 2020 second quarter forecast with historical data through the first quarter of 2020, the hospital market basket update for CY 2021 is 2.4 percent.

As described in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58797), it has typically been our practice to base the projection of the market basket price proxies and MFP for the IPPS/LTCH final rule on the second quarter IGI forecast. At the time of the FY 2021 IPPS/LTCH final rule, the 10-year moving average growth of MFP for FY 2021 based on IGI's second quarter 2020 forecast was 0.7 percentage point. However, for the FY 2021 IPPS/LTCH final rule, we finalized the use of the IGI June 2020 macroeconomic forecast for MFP because it represented a more recent forecast, and we believed it was important to use more recent data during this period when economic trends, particularly employment and labor productivity, are notably uncertain because of the COVID–19 pandemic. Based on these more recent data available for the FY 2021 IPPS/LTCH final rule, the current estimate of the 10-year moving average growth of MFP for FY 2021 was −0.1 percentage point (85 FR 58797).

Mechanically subtracting the negative 10-year moving average growth of MFP from the hospital market basket percentage increase using the data from the IGI June 2020 macroeconomic forecast would have resulted in a 0.1 percentage point increase in the FY 2021 market basket update. However, we explained that under section 1886(b)(3)(B)(xi)(I) of the Act, the Secretary is required to reduce (not increase) the hospital market basket percentage increase by changes in economy-wide productivity. Accordingly, we applied a 0.0 percent MFP adjustment to the FY 2021 IPPS market basket percentage increase.

Section 1833(t)(3)(F)(i) of the Act also requires us to reduce (not increase) the OPD fee schedule increase factor by the MFP adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Accordingly, we are applying a 0.0 percentage point MFP adjustment to the CY 2021 OPD fee schedule increase factor for the OPPS.

As a result of these finalized policies, the OPD fee schedule increase factor for the CY 2021 OPPS is 2.4 percent (which reflects the 2.4 percent final estimate of the hospital inpatient market basket percentage increase with a 0.0 percentage point MFP adjustment since the 10-year moving average growth in MFP was estimated to be less than 0.0 percent). For CY 2021, we are using a conversion factor of $82.797 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the OPD fee schedule increase factor of 2.4 percent for CY 2021, the required wage index budget neutrality adjustment of 1.0012, the budget neutrality adjustment of 1.0000 applying the final payment methodology for drugs purchased under the 340B Program for CY 2021 of ASP minus 22.5 percent, and the adjustment of 0.04 percentage point of projected OPPS spending for the difference in pass-through spending that results in a conversion factor for CY 2021 of $82.797.

We also are finalizing our proposal to amend the regulation at 42 CFR 419.32(b)(1)(iv)(B) by adding a new paragraph (b)(1)(iv)(B)(*11*) to provide that, for CY 2020 and subsequent years, we reduce the OPD fee schedule increase factor by the MFP adjustment as determined by CMS.

C. Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner (codified at 42 CFR 419.43(a)). This portion of the OPPS payment rate is called the OPPS labor-related share. Budget neutrality is discussed in section II.B. of the CY 2021 OPPS/ASC proposed rule.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). We proposed to continue this policy for the CY 2021 OPPS (85 FR 48802). We referred readers to section II.H. of the CY 2021 OPPS/ASC proposed rule for a description and an example of how the wage index for a particular hospital is used to determine payment for the hospital. We did not receive any public comments on this proposal. Accordingly, for the reasons discussed above and in the CY 2021 OPPS/ASC proposed rule, we are finalizing our proposal, without modification, to continue this policy for the CY 2021 OPPS.

As discussed in the claims accounting narrative included with the supporting documentation for this final rule with comment period (which is available via the internet on the CMS website), for estimating APC costs, we are standardizing 60 percent of estimated claims costs for geographic area wage variation using the same FY 2021 pre-reclassified wage index that we use under the IPPS to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and copayment amount.

Under 42 CFR 419.41(c)(1) and 419.43(c) (published in the OPPS April 7, 2000 final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Therefore, the wage index that applies to a particular acute care, short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998 OPPS proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained several provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). Section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines a frontier State and amended section 1833(t) of the Act to add paragraph (19), which requires a frontier State wage index floor of 1.00 in certain cases, and states that the frontier State floor shall not be applied in a budget neutral manner. We codified these requirements at § 419.43(c)(2) and (3) of our regulations. For CY 2021, we proposed to implement this provision in the same manner as we have since CY 2011 (85 FR 48802). Under this policy, the frontier State hospitals would receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, the rural floor, and rural floor budget neutrality) is less than 1.00. Because the HOPD receives a wage index based on the geographic location of the specific inpatient hospital with which it is associated, we stated that the frontier State wage index adjustment applicable for the inpatient hospital also would apply for any associated HOPD. We referred readers to the FY 2011 through FY 2020 IPPS/LTCH PPS final rules for discussions regarding this provision, including our methodology for identifying which areas meet the definition of ''frontier States'' as provided for in section 1886(d)(3)(E)(iii)(II) of the Act: for FY 2011, 75 FR 50160 through 50161; for FY 2012, 76 FR 51793, 51795, and 51825; for FY 2013, 77 FR 53369 through 53370; for FY 2014, 78 FR 50590 through 50591; for FY 2015, 79 FR 49971; for FY 2016, 80 FR 49498; for FY 2017, 81 FR 56922; for FY 2018, 82 FR 38142; for FY 2019, 83 FR 41380; and for FY 2020, 84 FR 42312. We did not receive any public comments on this proposal. Accordingly, for the reasons discussed above and in the CY 2021 OPPS/ASC proposed rule, we are finalizing our proposal, without modification, to continue to implement the frontier State floor under the OPPS in the same manner as we have since CY 2011.

In addition to the changes required by the Affordable Care Act, we noted in the CY 2021 OPPS/ASC proposed rule (85

FR 48802) that the FY 2021 IPPS wage indexes continue to reflect a number of adjustments implemented in past years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor provisions, an adjustment for occupational mix, an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment), and an adjustment to the wage index for certain low wage index hospitals to help address wage index disparities between low and high wage index hospitals. We referred readers to the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32695 through 32734) for a detailed discussion of all proposed changes to the FY 2021 IPPS wage indexes.

Furthermore, as discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) and in each subsequent IPPS/LTCH PPS final rule, including the FY 2021 IPPS/LTCH PPS final rule (85 FR 58743), the Office of Management and Budget (OMB) issued revisions to the labor market area delineations on February 28, 2013 (based on 2010 Decennial Census data), that included a number of significant changes, such as new Core Based Statistical Areas (CBSAs), urban counties that became rural, rural counties that became urban, and existing CBSAs that were split apart (OMB Bulletin 13–01). This bulletin can be found at: *https://obamawhitehouse.archives.gov/sites/default/files/omb/bulletins/2013/b13-01.pdf*. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49950 through 49985), for purposes of the IPPS, we adopted the use of the OMB statistical area delineations contained in OMB Bulletin No. 13–01, effective October 1, 2014. For purposes of the OPPS, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66826 through 66828), we adopted the use of the OMB statistical area delineations contained in OMB Bulletin No. 13–01, effective January 1, 2015, beginning with the CY 2015 OPPS wage indexes. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913), we adopted revisions to statistical areas contained in OMB Bulletin No. 15–01, issued on July 15, 2015, which provided updates to and superseded OMB Bulletin No. 13–01 that was issued on February 28, 2013. For purposes of the OPPS, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79598), we adopted the revisions to the OMB statistical area delineations contained in OMB Bulletin No. 15–01, effective January 1, 2017, beginning with the CY 2017 OPPS wage indexes.

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 the 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 CY 2019 OPPS/ASC final rule with comment period (83 FR 58863 through 58865), we adopted the updates set forth in OMB Bulletin No. 17–01, effective January 1, 2019, beginning with the CY 2019 wage index.

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. Typically, interim OMB bulletins (those issued between decennial censuses) have only contained minor modifications to labor market delineations. However, as we stated in the FY 2021 IPPS/LTCH PPS proposed and final rules (85 FR 32696 through 32697 and 58743), the April 10, 2018 OMB Bulletin No. 18–03 and the September 14, 2018 OMB Bulletin No. 18–04 included more modifications to the labor market areas than are typical for OMB bulletins issued between decennial censuses, including some material modifications that have a number of downstream effects, such as IPPS hospital reclassification changes. These bulletins established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A copy of OMB Bulletin No. 18–04 may be obtained at *https://www.whitehouse.gov/wpcontent/uploads/2018/09/Bulletin-18-04.pdf*. According to OMB, ''[t]his bulletin provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010 (75 FR 37246), and Census Bureau data.''

As noted previously, while OMB Bulletin No. 18–04 is not based on new census data, it includes some material changes to the OMB statistical area delineations. Specifically, as we stated in the CY 2021 OPPS/ASC proposed rule (85 FR 48803), under the revised OMB delineations, there would be some new CBSAs, urban counties that would become rural, rural counties that would become urban, and some existing CBSAs that would be split apart. In addition, we stated in the FY 2021 IPPS/LTCH PPS proposed rule that the revised OMB delineations would affect various hospital reclassifications, the outmigration adjustment (established by section 505 of Pub. L. 108–173), and treatment of hospitals located in certain rural counties (that is, ''Lugar'' hospitals) under section 1886(d)(8)(B) of the Act. In the CY 2021 OPPS/ASC proposed rule, we referred readers to the FY 2021 IPPS/LTCH PPS proposed rule for a complete discussion of the revised OMB delineations we proposed to adopt under the IPPS and the effects of these revisions on the FY 2021 IPPS wage indexes (85 FR 32696 through 32707, 32717 through 32728). We stated in the FY 2021 IPPS/LTCH PPS proposed rule that we believe using the revised delineations based on OMB Bulletin No. 18–04 would increase the integrity of the IPPS wage index system by creating a more accurate representation of geographic variations in wage levels. Therefore, in the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to implement the revised OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, effective October 1, 2020 beginning with the FY 2021 IPPS wage index. In addition, in the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to apply a 5 percent cap for FY 2021 on any decrease in a hospital's final wage index from the hospital's final wage index for FY 2020 as a proposed transition wage index to help mitigate any significant negative impacts of adopting the revised OMB delineations (85 FR 32706 through 32707). As discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58742 through 58755), as we proposed, we adopted the revised OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, effective October 1, 2020 beginning with the FY 2021 IPPS wage index and a 5 percent cap for FY 2021 on any decrease in a hospital's final wage index from the hospital's final wage index for FY 2020.

As further discussed below, in the CY 2021 OPPS/ASC proposed rule (85 FR 48803), we proposed to use the FY 2021 IPPS post-reclassified wage index including the updated OMB delineations and related IPPS wage index adjustments to calculate the CY 2021 OPPS wage indexes. Similar to our discussion in the FY 2021 IPPS/LTCH PPS proposed rule, we stated in the CY

2021 OPPS/ASC proposed rule that we believe using the revised delineations based on OMB Bulletin No. 18–04 would increase the integrity of the OPPS wage index system by creating a more accurate representation of geographic variations in wage levels.

A summary of the comments we received regarding the updated OMB delineations and our responses to those comments appear below:

Comment: One commenter supported our proposed adoption of the revised OMB delineations, but several commenters opposed our proposed implementation of the revised OMB delineations. These commenters stated that CMS is not bound to adopt the revised delineations, and suggested that CMS delay adoption of the revised delineations until the completion of the 2020 decennial census. Several comments specifically cited the lack of advance notice and the significant negative financial impacts to hospitals in several counties in the New York-Newark-Jersey City MSA resulting from the adoption of the revised delineations. Additional commenters recommended that CMS engage further with stakeholders to develop more comprehensive wage index reform to address the disparities that exist within the current wage index system.

Response: We appreciate these comments. We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58744 through 58753) for a detailed discussion of the implementation of the revised OMB delineations and for responses to these and other comments relating to the revised delineations.

Consistent with our longstanding policy, we proposed in the CY 2021 OPPS/ASC proposed rule (85 FR 48803) to use the FY 2021 IPPS post-reclassified wage index, which is based on the updated statistical area delineations set forth in OMB Bulletin No. 18–04, in determining the wage adjustments for both the OPPS payment and copayment rates for CY 2021. Thus, as discussed in the CY 2021 OPPS/ASC proposed rule (85 FR 48803), any adjustments for the FY 2021 IPPS post-reclassified wage index, including without limitation a one year 5 percent cap on any wage index decrease, would be reflected in the final CY 2021 OPPS wage index beginning on January 1, 2021. As we explained in the CY 2021 OPPS/ASC proposed rule, we continue to believe that using the IPPS post-reclassified wage index as the source of an adjustment factor for the OPPS is reasonable and logical given the inseparable, subordinate status of the HOPD within the hospital overall. For this reason, as discussed later in this section, we are finalizing our proposal to use the FY 2021 IPPS post-reclassified wage index and applicable IPPS wage index adjustments in determining the wage adjustments for both the OPPS payment rate and the copayment rates for CY 2021. As noted above, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58742 through 58755), for purposes of calculating the IPPS wage index, we adopted the revised OMB delineations as described in OMB Bulletin No. 18–04 effective October 1, 2020. Thus, effective January 1, 2021, the OPPS wage index also will be based on these updated OMB delineations. As we explained in the CY 2021 OPPS/ASC proposed rule, we believe using the revised delineations based on OMB Bulletin No. 18–04 will increase the integrity of the wage index system by creating a more accurate representation of geographic variations in wage levels.

We concur with commenters that CMS is not bound by statute to use the OMB definitions in calculating the OPPS wage index. However, we believe we have broad authority under section 1833(t)(2)(D) of the Act to determine the methodology for calculating the OPPS wage index, including the labor market areas used for the OPPS wage index. As discussed above, we believe using the IPPS post-reclassified wage index, which is based on the revised OMB delineations, in determining the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2021 is reasonable and logical given the inseparable, subordinate status of the HOPD within the hospital overall. In addition, consistent with our discussion in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58745), we believe it is important to use the updated labor market area delineations in order to maintain a more accurate and up-to-date payment system that reflects the reality of current labor market conditions. In response to comments citing a lack of advance notice provided to hospitals regarding the proposed adoption of the revised delineations, as we stated in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58746), the delineation files produced by OMB have been public for nearly 2 years, and OMB definitions and criteria are subject to separate notice and comment rulemaking. Finally, we note that to help mitigate significant negative impacts of the revised OMB delineations, consistent with the FY 2021 IPPS wage index, the CY 2021 OPPS wage index will reflect a 5 percent cap on any wage index decrease compared to a hospital's final CY 2020 wage index. For these reasons, we do not believe it is necessary or appropriate to delay or alter implementation of the revised delineations.

In response to commenters who recommended that CMS engage further with stakeholders to develop a more comprehensive wage index reform to address wage index disparities, we appreciate the continued interest in wage index reform. As we noted in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58745), as a first step toward comprehensive wage index reform, the FY 2021 President's Budget proposes the Secretary conduct and report on a demonstration to improve the Medicare inpatient hospital wage index.

After consideration of the public comments we received, for the reasons discussed above and in the CY 2021 OPPS/ASC proposed rule, we are finalizing, without modification, our proposal to adopt the revised OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, and related IPPS wage index adjustments to calculate the CY 2021 OPPS wage index effective beginning January 1, 2021.

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. The FY 2018 IPPS/LTCH PPS final rule (82 FR 38130) discussed the two different lists of codes to identify counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes for purposes of the IPPS and OPPS wage indexes. However, the SSA county codes are no longer being maintained and updated, although the FIPS codes continue to be maintained by the U.S. Census Bureau. The Census Bureau's most current statistical area information is derived from ongoing census data received since 2010; the most recent data are from 2015. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at: *https://www.census.gov/geo/reference/county-changes.html* (which, as of May 6, 2019, migrated to: *https://www.census.gov/programs-surveys/geography.html*). In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), for purposes of crosswalking counties to CBSAs for the IPPS wage index, we finalized our proposal to discontinue the use of the SSA county codes and begin using only the FIPS county codes. Similarly, for the purposes of crosswalking counties to CBSAs for the OPPS wage index, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59260), we finalized our proposal to discontinue

the use of SSA county codes and begin using only the FIPS county codes. For CY 2021, under the OPPS, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs.

In the CY 2021 OPPS/ASC proposed rule (85 FR 48803), we proposed to use the FY 2021 IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2021. Therefore, we stated that any adjustments for the FY 2021 IPPS post-reclassified wage index, including, but not limited to, any adjustments that we may finalize related to the proposed adoption of the revised OMB delineations (such as a cap on wage index decreases and revisions to hospital reclassifications), would be reflected in the final CY 2021 OPPS wage index beginning on January 1, 2021. (In the proposed rule, we referred readers to the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32695 through 32734) and the proposed FY 2021 hospital wage index files posted on the CMS website.) With regard to budget neutrality for the CY 2021 OPPS wage index, in the proposed rule, we referred readers to section II.B. of the CY 2021 OPPS/ASC proposed rule. We stated that we continue to believe that using the IPPS post-reclassified wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall.

We received comments regarding certain adjustments included in the FY 2021 IPPS post-reclassified wage index (which would be reflected in the CY 2021 OPPS wage index). A summary of those comments and our responses appear below:

Comment: Some commenters, while opposing the proposed adoption of revised OMB delineations, generally supported the concept of the 5 percent cap on any wage index decrease for FY 2021 (if the delineations are finalized). Some commenters requested that CMS reduce the amount of potential reduction in FY 2021, and extend transition adjustments to affected hospitals in future years. Other commenters suggested a multiple year transition period. One commenter requested that we apply the 5 percent cap policy to wage index increases as well.

Response: We thank the commenters for their suggestions. We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 85753 through 58755) for a detailed discussion of our rationale for adopting a one year 5 percent cap on any wage index decrease and for responses to these and other comments regarding this transition wage index.

As discussed previously, in the CY 2021 OPPS/ASC proposed rule (85 FR 48803), we proposed to use the FY 2021 IPPS post-reclassified wage index, including any adjustments such as the one year 5 percent cap on wage index decreases, as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2021. We continue to believe that using the IPPS post-reclassified wage index, including any adjustments, as the source of an adjustment factor for the OPPS is reasonable and logical given the inseparable, subordinate status of the HOPD within the hospital overall, and thus, as discussed below, we are finalizing this proposal without modification.

In response to the commenter that requested we also apply the 5 percent cap to wage index increases, we note that as we explained in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58753 through 58755), the purpose of the 5 percent cap is to mitigate significant wage index decreases and provide wage index stability for affected hospitals in light of our adoption of the revised OMB delineations. The purpose of the 5 percent cap is not to curtail the positive impact of such revisions. Thus, we do not think it would be appropriate to apply the cap to wage index increases as well.

Comments: Many commenters thanked CMS for implementing the IPPS low wage index hospital policy (pursuant to which CMS increases the IPPS wage index for certain low wage index hospitals) beginning in FY 2020 in response to rural and other health care stakeholders' requests that CMS address ''circularity'' in the wage index (the cyclical effect of hospitals with relatively high wages receiving higher reimbursement due to relatively high wage indexes, which allows them to afford paying higher wages) and halt the ''death spiral'' perpetuating wage index disparities where relatively low wage index hospitals are forced to keep wages low due to low Medicare reimbursements that lag behind areas with higher wage indexes.

Other commenters opposed continuing the low wage index hospital policy in FY 2021. The commenters stated that the policy fails to recognize the legitimate differences in geographic labor markets. Commenters also noted that there is no requirement for hospitals to use the increased reimbursement to boost employee compensation, and suggested CMS begin evaluating the cost report data filed by hospitals in the lowest quartile to ascertain whether the increased funds are being used to raise employee compensation in deciding whether to continue this policy for FY 2022. Some commenters stated that the data lag CMS described in its rationale applies equally to all hospitals, not only those in the lowest quartile. Commenters questioned CMS's statutory authority to promulgate this IPPS policy under 42 U.S.C. 1395ww(d)(3)(E), which requires the agency to adjust payments to reflect area differences in wages, because it artificially inflates wage index values and creates a wage index system not based on actual data. These commenters stated that CMS is using the wage index as a policy vehicle, not as a technical correction, and needs Congressional authority to provide additional funding to low-wage hospitals.

Response: We appreciate the many comments we received regarding our policy to provide an increase in the IPPS wage index beginning in FY 2020 for hospitals with wage index values below the 25th percentile wage index value for a year (referred to as the low wage index hospital policy). We note that we did not propose or finalize any changes to this policy in the FY 2021 IPPS/LTCH PPS proposed and final rules. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326 through 42332) and FY 2021 IPPS/LTCH PPS final rule (85 FR 58765 through 58768) for a detailed discussion of the IPPS low wage index hospital policy and for responses to these and other comments regarding this policy. In the CY 2021 OPPS/ASC proposed rule (85 FR 48803), we proposed to use the FY 2021 IPPS post-reclassified wage index including any adjustments, such as the IPPS low wage index hospital policy, as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2021. We continue to believe that using the IPPS post-reclassified wage index, including any adjustments, as the source of an adjustment factor for the OPPS is reasonable and logical given the inseparable, subordinate status of the HOPD within the hospital overall, and thus, as discussed below, we are finalizing this proposal without modification.

Comment: Many commenters supported increasing the wage index values of low-wage hospitals, but suggested that CMS do so in a non-budget-neutral manner. Commenters stated that this redistribution is counterproductive to CMS's larger goals

of high quality care and healthcare access because it forces high-wage, mostly urban hospitals to bear the cost of supporting lower-wage hospitals. Commenters stated that the budget neutrality adjustment penalizes many hospitals, including rural hospitals. Other commenters requested that CMS ensure that the budget neutrality adjustment factor not apply to hospitals falling below the 25th percentile.

Response: We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42328 through 42332) and FY 2021 IPPS/LTCH PPS final rule (85 FR 58765 through 58768) for a detailed discussion of the budget neutrality adjustment for the IPPS low wage index hospital policy and for responses to these and other comments regarding this adjustment.

We refer readers to section II.B. of this final rule with comment period for a discussion of the OPPS wage index budget neutrality adjustment.

Comment: Many commenters recommended that CMS develop a comprehensive, long-term approach to wage index reform in place of the low wage index hospital policy finalized in the FY 2020 IPPS/LTCH PPS final rule. Two commenters suggested alternative solutions to address wage index disparities, including a national wage index floor for all hospitals. Other commenters recommended that CMS proactively address the effects of COVID–19, which the commenters believed would exacerbate wage index disparities, by excluding wage data collected during the public health emergency from future wage index calculations.

Response: We appreciate the commenters' suggested alternatives. We received similar comments in response to the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 58767 through 58768). In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58768), we stated that we considered these comments to be outside the scope of the FY 2021 IPPS/LTCH PPS proposed rule, and thus we did not address them in that final rule but stated that we may consider them in future rulemaking. Similarly, we consider these comments to be outside the scope of the CY 2021 OPPS/ASC proposed rule and thus are not addressing them in this final rule with comment period.

Comment: Multiple commenters specifically supported CMS's continuation of the policy, adopted in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336), to exclude the wage data of urban hospitals that reclassify to rural when calculating each state's rural floor. Commenters stated that the change to the calculation of the rural floor limits the ability of hospitals to game the system and supports the overall goal of making the wage index reflective of variances in labor markets.

Response: We appreciate the commenters' support of our policy to exclude the wage data of hospitals reclassified under § 412.103 from the IPPS rural floor calculation. As stated in the FY 2020 IPPS/LTCH PPS final rule, we believe this policy is necessary and appropriate to address the unanticipated effects of rural reclassifications on the rural floor and the resulting wage index disparities, including the effects of the manipulation of the rural floor by certain hospitals (84 FR 42333 through 42336). We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58768) for a detailed discussion of this policy and for responses to these and other comments regarding this policy.

Comment: One commenter supported our proposals regarding the wage index and requested that we carry over policies from the IPPS to the OPPS to ensure consistency in hospital payments.

Response: We appreciate the commenter's support of our proposals regarding the wage index. As we discuss below, we are finalizing our proposal to use the FY 2021 IPPS post-reclassified wage index for urban and rural areas (including any applicable adjustments for the FY 2021 IPPS post-reclassified wage index), as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2021.

After consideration of the comments received, for the reasons discussed in this final rule with comment period and in the CY 2021 OPPS/ASC proposed rule, we are finalizing, without modification, our proposal to use the FY 2021 IPPS post-reclassified wage index for urban and rural areas, based on the revised OMB delineations set forth in OMB Bulletin No. 18–04, as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2021. Therefore, any applicable adjustments for the FY 2021 IPPS post-reclassified wage index (including, but not limited to, the low wage index hospital policy, the one year 5 percent cap on wage index decreases, the rural floor, and the frontier State floor) will be reflected in the final CY 2021 OPPS wage index beginning on January 1, 2021. We continue to believe that using the IPPS post-reclassified wage index as the source of an adjustment factor for the OPPS is reasonable and logical given the inseparable, subordinate status of the HOPD within the hospital overall.

Hospitals that are paid under the OPPS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPPS, it is our longstanding policy to assign the wage index that would be applicable if the hospital was paid under the IPPS, based on its geographic location and any applicable wage index adjustments. In the CY 2021 OPPS/ASC proposed rule, we proposed to continue this policy for CY 2021, and included a brief summary of the major FY 2021 IPPS wage index policies and adjustments that we proposed to apply to these hospitals under the OPPS for CY 2021, which we have summarized below. We referred readers to the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32695 through 32734) for a detailed discussion of the proposed changes to the FY 2021 IPPS wage indexes.

It has been our longstanding policy to allow non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)). Applying this adjustment is consistent with our policy of adopting IPPS wage index policies for hospitals paid under the OPPS. We note that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage index adjustment if they are located in a section 505 out-migration county. This is the same out-migration adjustment policy that applies if the hospital were paid under the IPPS. For CY 2021, we proposed to continue our policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the outmigration adjustment if they are located in a section 505 out-migration county (section 505 of the MMA). Furthermore, we stated in the proposed rule that the wage index that would apply for CY 2021 to non-IPPS hospitals paid under the OPPS would continue to include the rural floor adjustment and adjustments to the wage index finalized in the FY 2020 IPPS/LTCH PPS final rule to address wage index disparities (84 FR 42325 through 42337). In addition, we proposed that the wage index that would apply to non-IPPS hospitals paid under the OPPS would include any adjustments we may finalize for the FY 2021 IPPS post-reclassified wage index related to the adoption of the revised OMB delineations, as discussed in the CY 2021 OPPS/ASC proposed rule. We did not receive any public comments on these proposals. Accordingly, for the

reasons discussed above and in the CY 2021 OPPS/ASC proposed rule, we are finalizing these proposals, without modification.

For CMHCs, for CY 2021, we proposed to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. We also proposed that the wage index that would apply to CMHCs would include any adjustments we may finalize for the FY 2021 IPPS post-reclassified wage index related to the adoption of the revised OMB delineations, as discussed in the CY 2021 OPPS/ASC proposed rule. In addition, we proposed that the wage index that would apply to CMHCs for CY 2021 would continue to include the rural floor adjustment and adjustments to the wage index finalized in the FY 2020 IPPS/LTCH PPS final rule to address wage index disparities. Also, we proposed that the wage index that would apply to CMHCs would not include the outmigration adjustment because that adjustment only applies to hospitals. We did not receive any public comments on these proposals. Therefore, for the reasons discussed above and in the CY 2021 OPPS/ASC proposed rule, we are finalizing these proposals without modification.

Table 4A associated with the FY 2021 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/index*) identifies counties eligible for the out-migration adjustment. Table 2 associated with the FY 2021 IPPS/LTCH PPS final rule (available for download via the website above) identifies IPPS hospitals that receive the out-migration adjustment for FY 2021. We are including the outmigration adjustment information from Table 2 associated with the FY 2021 IPPS/LTCH PPS final rule as Addendum L to this CY 2021 OPPS/ASC final rule with comment period with the addition of non-IPPS hospitals that will receive the section 505 outmigration adjustment under this CY 2021 OPPS/ASC final rule with comment period. Addendum L is available via the internet on the CMS website. We refer readers to the CMS website for the OPPS at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index*. At this link, readers will find a link to the final FY 2021 IPPS wage index tables and Addendum L.

D. Statewide Average Default Cost-To-Charge Ratios (CCRs)

In addition to using CCRs to estimate costs from charges on claims for ratesetting, we use overall hospital-specific CCRs calculated from the hospital's most recent cost report to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS during the PPS year. For certain hospitals, under the regulations at 42 CFR 419.43(d)(5)(iii), we use the statewide average default CCRs to determine the payments mentioned earlier if it is not possible to determine an accurate CCR for a hospital in certain circumstances. This includes hospitals that are new, hospitals that have not accepted assignment of an existing hospital's provider agreement, and hospitals that have not yet submitted a cost report. We also use the statewide average default CCRs to determine payments for hospitals whose CCR falls outside the predetermined ceiling threshold for a valid CCR or for hospitals in which the most recent cost report reflects an all-inclusive rate status (Medicare Claims Processing Manual (Pub. 100–04), Chapter 4, Section 10.11).

We discussed our policy for using default CCRs, including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009. For details on our process for calculating the statewide average CCRs, we refer readers to the CY 2021 OPPS proposed rule Claims Accounting Narrative that is posted on our website. We proposed to update the default ratios for CY 2021 using the most recent cost report data. We stated that we would update these ratios in this final rule with comment period if more recent cost report data are available.

We are no longer publishing a table in the **Federal Register** containing the statewide average CCRs in the annual OPPS proposed rule and final rule with comment period. These CCRs with the upper limit will be available for download with each OPPS CY proposed rule and final rule on the CMS website. We refer readers to our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*; click on the link on the left of the page titled ''Hospital Outpatient Regulations and Notices'' and then select the relevant regulation to download the statewide CCRs and upper limit in the Downloads section of the web page.

We did not receive any public comments on our proposal to use statewide average default CCRs if a MAC cannot calculate a CCR for a hospital and to use these CCRs to adjust charges to costs on claims data for setting the final CY 2021 OPPS relative payment weights. Therefore, we are finalizing our proposal without modification.

E. Adjustment for Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs) Under Section 1833(t)(13)(B) of the Act for CY 2021

In the CY 2006 OPPS final rule with comment period (70 FR 68556), we finalized a payment increase for rural sole community hospitals (SCHs) of 7.1 percent for all services and procedures paid under the OPPS, excluding drugs, biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Section 1833(t)(13) of the Act provided the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised our regulations at § 419.43(g) to clarify that essential access community hospitals (EACHs) are also eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, two hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of Public Law 105–33, a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outlier payments and

copayments. We stated in the CY 2006 OPPS final rule with comment period (70 FR 68560) that we would not reestablish the adjustment amount on an annual basis, but we may review the adjustment in the future and, if appropriate, would revise the adjustment. We provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2020. Further, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68590), we updated the regulations at § 419.43(g)(4) to specify, in general terms, that items paid at charges adjusted to costs by application of a hospital-specific CCR are excluded from the 7.1 percent payment adjustment.

For CY 2021, we proposed to continue the current policy of a 7.1 percent payment adjustment that is done in a budget neutral manner for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy.

Comment: Multiple commenters supported the proposal to continue the 7.1 percent payment adjustment.

Response: We appreciate the commenters' support.

Comment: Multiple commenters requested that CMS make the 7.1 percent rural adjustment permanent. The commenters appreciated the policy that CMS adopted in CY 2019 and reaffirmed in CY 2020 where we stated that the 7.1 percent rural adjustment would continue to be in place until our data support establishing a different rural adjustment percentage. However, the commenters believed that this policy still does not provide enough certainty for rural SCHs and EACHs to know whether they should take into account the rural SCH adjustment when attempting to calculate expected revenues for their hospital budgets.

Response: We thank the commenters for their input. We believe that our current policy, which states that the 7.1 percent payment adjustment for rural SCHs and EACHs will remain in effect until our data show that a different percentage for the rural payment adjustment is necessary, provides sufficient budget predictability for rural SCHs and EACHs. Providers would receive notice in a proposed rule and have the opportunity to provide comments before any changes to the rural adjustment percentage would be implemented.

Comment: One commenter requested that CMS expand the payment adjustment for rural SCHs and EACHs to additional types of hospitals. The commenter requested that the payment adjustment apply to include urban SCHs because, according to the commenter, urban SCHs care for patient populations similar to rural SCHs and EACHs, face similar financial challenges to rural SCHs and EACHs, and act as safety net providers for rural areas despite their designation as urban providers. The same commenter requested that the payment adjustment also apply to Medicare-dependent hospitals (MDHs) because, according to the commenter, these hospitals face similar financial challenges to rural SCHs and EACHs, and MDHs play a similar safety net role to rural SCHs and EACHs, especially for Medicare. The commenter asked that CMS study whether it would be appropriate to provide a payment adjustment to MDHs that is similar to the current adjustment for rural SCHs.

Response: We thank the commenters for their comments. The analysis we did to compare costs of urban providers to those of rural providers did not support an add-on adjustment for providers other than rural SCHs and EACHs. In addition, section 1833(t)(13)(B) of the Act authorizes an adjustment for rural hospitals only. Accordingly, we do not believe we have a basis to expand the payment adjustment to any providers other than rural SCHs and EACHs under our authority at section 1833(t)(13)(B) of the Act.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue the current policy of a 7.1 percent payment adjustment that is done in a budget neutral manner for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs.

F. Payment Adjustment for Certain Cancer Hospitals for CY 2021

1. Background

Since the inception of the OPPS, which was authorized by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), Medicare has paid the 11 hospitals that meet the criteria for cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act under the OPPS for covered outpatient hospital services. These cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113), the Congress established section 1833(t)(7) of the Act, ''Transitional Adjustment to Limit Decline in Payment,'' to determine OPPS payments to cancer and children's hospitals based on their pre-BBA payment amount (often referred to as ''held harmless'').

As required under section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient services under the OPPS and a ''pre-BBA amount.'' That is, cancer hospitals are permanently held harmless to their ''pre-BBA amount,'' and they receive transitional outpatient payments (TOPs) or hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The ''pre-BBA amount'' is the product of the hospital's reasonable costs for covered outpatient services occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital defined in section 1833(t)(7)(F)(ii) of the Act. The ''pre-BBA amount'' and the determination of the base PCR are defined at 42 CFR 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital Cost Report or the Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10, respectively), as applicable each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

Section 3138 of the Affordable Care Act amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed outpatient costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. Section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by cancer hospitals and other hospitals. Section 1833(t)(18)(B) of the Act provides that, if the Secretary determines that cancer hospitals' costs are higher than those of other hospitals, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. In 2011, after conducting the study required by section 1833(t)(18)(A) of the Act, we determined that outpatient costs incurred by the 11 specified cancer

hospitals were greater than the costs incurred by other OPPS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 through 74201).

Based on these findings, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects their higher outpatient costs, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74202 through 74206). Specifically, we adopted a policy to provide additional payments to the cancer hospitals so that each cancer hospital's final PCR for services provided in a given calendar year is equal to the weighted average PCR (which we refer to as the ''target PCR'') for other hospitals paid under the OPPS. The target PCR is set in advance of the calendar year and is calculated using the most recently submitted or settled cost report data that are available at the time of final rulemaking for the calendar year. The amount of the payment adjustment is made on an aggregate basis at cost report settlement. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs are assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period. For CYs 2012 and 2013, the target PCR for purposes of the cancer hospital payment adjustment was 0.91. For CY 2014, the target PCR was 0.90. For CY 2015, the target PCR was 0.90. For CY 2016, the target PCR was 0.92, as discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70362 through 70363). For CY 2017, the target PCR was 0.91, as discussed in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79603 through 79604). For CY 2018, the target PCR was 0.88, as discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59265 through 59266). For CY 2019, the target PCR was 0.88, as discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58871 through 58873). For CY 2020, the target PCR was 0.89, as discussed in the CY 2020 OPPS/ASC final rule with comment period (83 FR 61190 through 61192).

2. Policy for CY 2021

Section 16002(b) of the 21st Century Cures Act (Pub. L. 114–255) amended section 1833(t)(18) of the Act by adding subparagraph (C), which requires that in applying § 419.43(i) (that is, the payment adjustment for certain cancer hospitals) for services furnished on or after January 1, 2018, the target PCR adjustment be reduced by 1.0 percentage point less than what would otherwise apply. Section 16002(b) also provides that, in addition to the percentage reduction, the Secretary may consider making an additional percentage point reduction to the target PCR that takes into account payment rates for applicable items and services described under section 1833(t)(21)(C) of the Act for hospitals that are not cancer hospitals described under section 1886(d)(1)(B)(v) of the Act. Further, in making any budget neutrality adjustment under section 1833(t) of the Act, the Secretary shall not take into account the reduced expenditures that result from application of section 1833(t)(18)(C) of the Act.

We proposed to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's final PCR is equal to the weighted average PCR (or ''target PCR'') for the other OPPS hospitals, using the most recent submitted or settled cost report data that were available at the time of the development of the proposed rule, reduced by 1.0 percentage point, to comply with section 16002(b) of the 21st Century Cures Act.

We did not propose an additional reduction beyond the 1.0 percentage point reduction required by section 16002(b) for CY 2021. To calculate the proposed CY 2021 target PCR, we used the same extract of cost report data from HCRIS, as discussed in section II.A. of this CY 2021 OPPS/ASC proposed rule, used to estimate costs for the CY 2021 OPPS. Using these cost report data, we included data from Worksheet E, Part B, for each hospital, using data from each hospital's most recent cost report, whether as submitted or settled.

We then limited the dataset to the hospitals with CY 2019 claims data that we used to model the impact of the proposed CY 2021 APC relative payment weights (3,527 hospitals) because it is appropriate to use the same set of hospitals that are being used to calibrate the modeled CY 2021 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2014 to 2019. We then removed the cost report data of the 49 hospitals located in Puerto Rico from our dataset because we did not believe their cost structure reflected the costs of most hospitals paid under the OPPS, and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed the cost report data of 14 hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to a proposed analytic file of 3,464 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimate that, on average, the OPPS payments to other hospitals furnishing services under the OPPS were approximately 90 percent of reasonable cost (weighted average PCR of 0.90). Therefore, after applying the 1.0 percentage point reduction, as required by section 16002(b) of the 21st Century Cures Act, we proposed that the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement would be the additional payment needed to result in a proposed target PCR equal to 0.89 for each cancer hospital.

We did not receive any public comments on our proposals. Therefore, we are finalizing our proposed cancer hospital payment adjustment methodology without modification. For this final rule with comment period, we are using the most recent cost report data through June 30, 2020 to update the adjustment. This update yields a target PCR of 0.90. We limited the dataset to the hospitals with CY 2019 claims data that we used to model the impact of the CY 2021 APC relative payment weights (3,555 hospitals) because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled CY 2021 OPPS. The cost report data for the hospitals in the dataset were from cost report periods with fiscal year ends ranging from 2014 to 2019. We then removed the cost report data of the 47 hospitals located in Puerto Rico from our dataset because we do not believe their cost structure reflects the cost of most hospitals paid under the OPPS and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed the cost report data of 14 hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost report in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to an analytic file of 3,494 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated a target PCR of 0.90. Therefore, after applying the 1.0 percentage point reduction as required by section 1602(b) of the 21st Century

Cures Act, we are finalizing that the payment amount associated with the cancer hospital adjustment to be determined at cost report settlement will be the additional payment needed to result in a PCR equal to 0.89 for each cancer hospital.

Table 5 shows the estimated percentage increase in OPPS payments to each cancer hospital for CY 2021, due to the cancer hospital payment adjustment policy. The actual amount of the CY 2021 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2021 payments and costs. We note that the requirements contained in section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

TABLE 5: ESTIMATED CY 2021 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2021 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	31.3%
050660	USC Norris Cancer Hospital	9.9%
100079	Sylvester Comprehensive Cancer Center	11.6%
100271	H. Lee Moffitt Cancer Center & Research Institute	19.2%
220162	Dana-Farber Cancer Institute	34.3%
330154	Memorial Sloan-Kettering Cancer Center	37.9%
330354	Roswell Park Cancer Institute	12.3%
360242	James Cancer Hospital & Solove Research Institute	11.5%
390196	Fox Chase Cancer Center	9.2%
450076	M.D. Anderson Cancer Center	40.3%
500138	Seattle Cancer Care Alliance	43.2%

G. Hospital Outpatient Outlier Payments

1. Background

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. As explained in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66832 through 66834), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for the prospective year. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain amount of dollars). In CY 2020, the outlier threshold was met when the hospital's cost of furnishing a service exceeded 1.75 times (the multiplier threshold) the APC payment amount and exceeded the APC payment amount plus $5,075 (the fixed-dollar amount threshold) (84 FR 61192 through 61194). If the cost of a service exceeds both the multiplier threshold and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount. Beginning with CY 2009 payments, outlier payments are subject to a reconciliation process similar to the IPPS outlier reconciliation process for cost reports, as discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the OPPS. Our estimate of total outlier payments as a percent of total CY 2019 OPPS payments, using CY 2019 claims available for the CY 2021 OPPS/ASC proposed rule, was approximately 1.0 percent of the total aggregated OPPS payments. Therefore, for CY 2019, we estimated that we paid the outlier target of 1.0 percent of total aggregated OPPS payments. Using an updated claims dataset for this CY 2021 OPPS/ASC final rule, we estimate that we paid approximately 0.97 percent of the total aggregated OPPS payments in outliers for CY 2019.

For the CY 2021 OPPS/ASC proposed rule, using CY 2019 claims data and CY

2020 payment rates, we estimated that the aggregate outlier payments for CY 2020 would be approximately 1.01 percent of the total CY 2020 OPPS payments. We provided estimated CY 2021 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital–Specific Impacts—Provider-Specific Data file on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

2. Outlier Calculation for CY 2021

In the CY 2021 OPPS/ASC proposed rule (85 FR 48807 through 48808), for CY 2021, we proposed to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We proposed that a portion of that 1.0 percent, an amount equal to less than 0.01 percent of outlier payments (or 0.0001 percent of total OPPS payments), would be allocated to CMHCs for PHP outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPPS outlier payments. As discussed in section VIII.C. of the CY 2021 OPPS/ASC proposed rule, we proposed to continue our longstanding policy that if a CMHC's cost for partial hospitalization services, paid under APC 5853 (Partial Hospitalization for CMHCs), exceeds 3.40 times the payment rate for proposed APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed APC 5853 payment rate.

For further discussion of CMHC outlier payments, we refer readers to section VIII.C. of the CY 2021 OPPS/ASC proposed rule and this final rule with comment period.

To ensure that the estimated CY 2021 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we proposed that the hospital outlier threshold be set so that outlier payments would be triggered when a hospital's cost of furnishing a service exceeds 1.75 times the APC payment amount and exceeds the APC payment amount plus $5,300.

We calculated the proposed fixed-dollar threshold of $5,300 using the standard methodology most recently used for CY 2020 (84 FR 61192 through 61194). For purposes of estimating outlier payments for the proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2020 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCRs, which are maintained by the MACs and used by the OPPS Pricer to pay claims. The claims that we use to model each OPPS update lag by 2 years.

In order to estimate the CY 2021 hospital outlier payments for the proposed rule, we inflated the charges on the CY 2019 claims using the same inflation factor of 1.131096 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32908). We used an inflation factor of 1.06353 to estimate CY 2020 charges from the CY 2019 charges reported on CY 2019 claims. The methodology for determining this charge inflation factor is discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42626 through 42630). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65845), we believe that the use of these charge inflation factors is appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and outpatient cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we proposed to apply the same CCR inflation adjustment factor that we proposed to apply for the FY 2021 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2021 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2021, we proposed to apply an adjustment factor of 0.975271 to the CCRs that were in the April 2020 OPSF to trend them forward from CY 2020 to CY 2021. The methodology for calculating the proposed adjustment is discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32908 through 32909).

To model hospital outlier payments for the proposed rule, we applied the overall CCRs from the April 2020 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.97571 to approximate CY 2021 CCRs) to charges on CY 2019 claims that were adjusted (using the proposed charge inflation factor of 1.131096 to approximate CY 2021 charges). We simulated aggregated CY 2021 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiplier threshold constant and assuming that outlier payments would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2021 OPPS payments. We estimated that a proposed fixed-dollar threshold of $5,300, combined with the proposed multiplier threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments. For CMHCs, we proposed that, if a CMHC's cost for partial hospitalization services, paid under APC 5853, exceeds 3.40 times the payment rate for APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC 5853 payment rate.

Section 1833(t)(17)(A) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for the quality measures selected by the Secretary, in the form and manner required by the Secretary under section 1833(t)(17)(B) of the Act, incur a 2.0 percentage point reduction to their OPD fee schedule increase factor; that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that will apply to certain outpatient items and services furnished by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program requirements. For hospitals that fail to meet the Hospital OQR Program requirements, as we proposed, we are continuing the policy that we implemented in CY 2010 that the hospitals' costs will be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the Hospital OQR Program, we refer readers to section XIV. of this CY 2021 OPPS/ASC final rule with comment period.

We received no public comments on our proposal. Therefore, we are finalizing our proposal, without modification, to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS and to use our established methodology to set the OPPS outlier fixed-dollar loss threshold for CY 2021.

3. Final Outlier Calculation

Consistent with historical practice, we used updated data for this final rule with comment period for outlier calculations. For CY 2021, we are

applying the overall CCRs from the October 2020 OPSF file after adjustment (using the CCR inflation adjustment factor of 0.974495 to approximate CY 2021 CCRs) to charges on CY 2019 claims that were adjusted using a charge inflation factor of 1.13218 to approximate CY 2021 charges. These are the same CCR adjustment and charge inflation factors that were used to set the IPPS fixed-dollar threshold for the FY 2021 IPPS/LTCH PPS final rule (85 FR 59039 through 59040). We simulated aggregated CY 2021 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple-threshold constant and assuming that outlier payments will continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payment equaled 1.0 percent of aggregated estimated total CY 2021 OPPS payments. We estimated that a fixed-dollar threshold of $5,300 combined with the multiple-threshold of 1.75 times the APC payment rate, will allocate the 1.0 percent of aggregated total OPPS payments to outlier payments.

For CMHCs, if a CMHC's cost for partial hospitalization services, paid under APC 5853, exceeds 3.40 times the payment rate the outlier payment will be calculated as 50 percent of the amount by which the cost exceeds 3.40 times APC 5853.

H. Calculation of an Adjusted Medicare Payment From the National Unadjusted Medicare Payment

The basic methodology for determining prospective payment rates for HOPD services under the OPPS is set forth in existing regulations at 42 CFR part 419, subparts C and D. For this CY 2021 OPPS/ASC final rule with comment period, the payment rate for most services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section II.B. of this final rule with comment period and the relative payment weight determined under section II.A. of this final rule with comment period. Therefore, the national unadjusted payment rate for most APCs contained in Addendum A to this final rule with comment period (which is available via the internet on the CMS website) and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this final rule with comment period (which is available via the internet on the CMS website) was calculated by multiplying the final CY 2021 scaled weight for the APC by the CY 2021 conversion factor.

We note that section 1833(t)(17) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to submit data required to be submitted on quality measures selected by the Secretary, in the form and manner and at a time specified by the Secretary, incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP)) requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the Hospital OQR Program, we refer readers to section XIV of this final rule with comment period.

We demonstrate the steps used to determine the APC payments that will be made in a CY under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: ''J1'', ''J2'', ''P'', ''Q1'', ''Q2'', ''Q3'', ''Q4'', ''R'', ''S'', ''T'', ''U'', or ''V'' (as defined in Addendum D1 to the final rule, which is available via the internet on the CMS website), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of ''Q1'' and ''Q2'') qualify for separate payment. We noted that, although blood and blood products with status indicator ''R'' and brachytherapy sources with status indicator ''U'' are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

Individual providers interested in calculating the payment amount that they will receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the ''full'' national unadjusted payment rate. We refer to the national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the ''reduced'' national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.9805 times the ''full'' national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements to receive the full CY 2021 OPPS fee schedule increase factor.

Step 1. Calculate 60 percent (the labor-related portion) of the national unadjusted payment rate. Since the initial implementation of the OPPS, we have used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18496 through 18497) for a detailed discussion of how we derived this percentage. During our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553), we confirmed that this labor-related share for hospital outpatient services is appropriate.

The formula below is a mathematical representation of Step 1 and identifies the labor-related portion of a specific payment rate for a specific service.

X is the labor-related portion of the national unadjusted payment rate.

$X = .60 * (\text{national unadjusted payment rate})$.

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. We note that, for the CY 2021 OPPS wage index, we are adopting the updated OMB delineations based on OMB Bulletin No. 18–04 and any related IPPS wage index adjustments that were finalized in the FY 2021 IPPS/LTCH PPS final rule, as discussed in section II.C. of this final rule with comment period. The wage index values assigned to each area reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2021 under the IPPS, reclassifications through the Medicare Geographic Classification Review Board (MGCRB), section 1886(d)(8)(B) ''Lugar'' hospitals, and reclassifications under section 1886(d)(8)(E) of the Act, as implemented in § 412.103 of the regulations. We also are continuing to apply for the CY 2021

OPPS wage index any other adjustments for the FY 2021 IPPS post-reclassified wage index, including, but not limited to, the rural floor adjustment, a wage index floor of 1.00 in frontier states, in accordance with section 10324 of the Affordable Care Act of 2010, and an adjustment to the wage index for certain low wage index hospitals. For further discussion of the wage index we are applying for the CY 2021 OPPS, we refer readers to section II.C. of this final rule with comment period.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of Public Law 108–173. Addendum L to this final rule with comment period (which is available via the internet on the CMS website) contains the qualifying counties and the associated wage index increase developed for the final FY 2021 IPPS wage index, which are listed in Table 2 associated with the FY 2021 IPPS/LTCH PPS final rule and available via the internet on the CMS website at: *http://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 2021 IPPS Final Rule Home Page'' and select ''FY 2021 Final Rule Tables.'') This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined under Step 1 that represents the labor-related portion of the national unadjusted payment rate.

The formula below is a mathematical representation of Step 4 and adjusts the labor-related portion of the national unadjusted payment rate for the specific service by the wage index.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

X_a = .60 * (national unadjusted payment rate) * applicable wage index.

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add that amount to the resulting product of Step 4. The result is the wage index adjusted payment rate for the relevant wage index area.

The formula below is a mathematical representation of Step 5 and calculates the remaining portion of the national payment rate, the amount not attributable to labor, and the adjusted payment for the specific service.

Y is the nonlabor-related portion of the national unadjusted payment rate.

Y = .40 * (national unadjusted payment rate).

Adjusted Medicare Payment = $Y + X_a$.

Step 6. If a provider is an SCH, as set forth in the regulations at § 412.92, or an EACH, which is considered to be an SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103, multiply the wage index adjusted payment rate by 1.071 to calculate the total payment.

The formula below is a mathematical representation of Step 6 and applies the rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071.

We are providing examples below of the calculation of both the full and reduced national unadjusted payment rates that will apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined previously. For purposes of this example, we are using a provider that is located in Brooklyn, New York that is assigned to CBSA 35614. This provider bills one service that is assigned to APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage). The final CY 2021 full national unadjusted payment rate for APC 5071 is $621.97. The reduced national unadjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is $609.84. This reduced rate is calculated by multiplying the reporting ratio of 0.9805 by the full unadjusted payment rate for APC 5071.

The final FY 2021 wage index for a provider located in CBSA 35614 in New York, which includes the adoption of IPPS 2021 wage index policies, is 1.3468. The labor-related portion of the final full national unadjusted payment is approximately $502.60 (.60 * $621.97 * 1.3468). The labor-related portion of the reduced national unadjusted payment is approximately $492.80 (.60 * $609.84 * 1.3468). The nonlabor-related portion of the full national unadjusted payment is approximately $248.79 (.40 * $621.97). The nonlabor-related portion of the reduced national unadjusted payment is approximately $243.94 (.40 * $609.84). The sum of the labor-related and nonlabor-related portions of the full national adjusted payment is approximately $751.39 ($502.60 + $248.79). The sum of the portions of the reduced national adjusted payment is approximately $736.74 ($492.80 + $243.94).

We did not receive any public comments on these steps under the methodology that we included in the proposed rule to determine the APC payments for CY 2021. Therefore, we are using the steps in the methodology specified above, to demonstrate the calculation of the final CY 2021 OPPS payments using the same parameters.

I. Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services. Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, the effective copayment rate for a covered OPD service paid under the OPPS in CY 2006, and in CYs thereafter, shall not exceed 40 percent of the APC payment rate.

Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted copayment amount cannot be less than 20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure (including items such as drugs and biologicals) performed in a year to the amount of the inpatient hospital deductible for that year.

Section 4104 of the Affordable Care Act eliminated the Medicare Part B coinsurance for preventive services furnished on and after January 1, 2011, that meet certain requirements, including flexible sigmoidoscopies and screening colonoscopies, and waived the Part B deductible for screening colonoscopies that become diagnostic during the procedure. Our discussion of the changes made by the Affordable Care Act with regard to copayments for preventive services furnished on and after January 1, 2011, may be found in section XII.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72013).

2. OPPS Copayment Policy

For CY 2021, we proposed to determine copayment amounts for new

and revised APCs using the same methodology that we implemented beginning in CY 2004. (We refer readers to the November 7, 2003 OPPS final rule with comment period (68 FR 63458).) In addition, we proposed to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. (We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles.) The proposed national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2021 are included in Addenda A and B to the proposed rule with comment period (which are available via the internet on the CMS website).

We did not receive any public comments on the proposed copayment amounts for new and revised APCs using the same methodology we implemented beginning in CY 2004 or the standard rounding principles we apply to our copayment amounts. Therefore, we are finalizing our proposed copayment policies, without modification.

As discussed in section XIV.E. of the CY 2021 OPPS/ASC proposed rule and this final rule with comment period, for CY 2021, the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We note that OPPS copayments may increase or decrease each year based on changes in the calculated APC payment rates, due to updated cost report and claims data, and any changes to the OPPS cost modeling process. However, as described in the CY 2004 OPPS final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPPS APC payments (68 FR 63458 through 63459).

In the CY 2004 OPPS final rule with comment period (68 FR 63459), we adopted a new methodology to calculate unadjusted copayment amounts in situations including reorganizing APCs, and we finalized the following rules to determine copayment amounts in CY 2004 and subsequent years.

- When an APC group consists solely of HCPCS codes that were not paid under the OPPS the prior year because they were packaged or excluded or are new codes, the unadjusted copayment amount would be 20 percent of the APC payment rate.
- If a new APC that did not exist during the prior year is created and consists of HCPCS codes previously assigned to other APCs, the copayment amount is calculated as the product of the APC payment rate and the lowest coinsurance percentage of the codes comprising the new APC.
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is equal to or *greater than* the prior year's rate, the copayment amount remains constant (unless the resulting coinsurance percentage is less than 20 percent).
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is *less than* the prior year's rate, the copayment amount is calculated as the product of the new payment rate and the prior year's coinsurance percentage.
- If HCPCS codes are added to or deleted from an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in a decrease in the coinsurance percentage for the reconfigured APC, the copayment amount would not change (unless retaining the copayment amount would result in a coinsurance rate less than 20 percent).
- If HCPCS codes are added to an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in an increase in the coinsurance percentage for the reconfigured APC, the copayment amount would be calculated as the product of the payment rate of the reconfigured APC and the lowest coinsurance percentage of the codes being added to the reconfigured APC.

We noted in the CY 2004 OPPS final rule with comment period that we would seek to lower the copayment percentage for a service in an APC from the prior year if the copayment percentage was greater than 20 percent. We noted that this principle was consistent with section 1833(t)(8)(C)(ii) of the Act, which accelerates the reduction in the national unadjusted coinsurance rate so that beneficiary liability will eventually equal 20 percent of the OPPS payment rate for all OPPS services to which a copayment applies, and with section 1833(t)(3)(B) of the Act, which achieves a 20-percent copayment percentage when fully phased in and gives the Secretary the authority to set rules for determining copayment amounts for new services. We further noted that the use of this methodology would, in general, reduce the beneficiary coinsurance rate and copayment amount for APCs for which the payment rate changes as the result of the reconfiguration of APCs and/or recalibration of relative payment weights (68 FR 63459).

3. Calculation of an Adjusted Copayment Amount for an APC Group

Individuals interested in calculating the national copayment liability for a Medicare beneficiary for a given service provided by a hospital that met or failed to meet its Hospital OQR Program requirements should follow the formulas presented in the following steps.

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its payment rate. For example, using APC 5071, $124.40 is approximately 20 percent of the full national unadjusted payment rate of $621.97. For APCs with only a minimum unadjusted copayment in Addenda A and B to this final rule (which are available via the internet on the CMS website), the beneficiary payment percentage is 20 percent.

The formula below is a mathematical representation of Step 1 and calculates the national copayment as a percentage of national payment for a given service.

B is the beneficiary payment percentage.

B = National unadjusted copayment for APC/national unadjusted payment rate for APC.

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as indicated in Steps 2 through 4 under section II.H. of this final rule with comment period. Calculate the rural adjustment for eligible providers, as indicated in Step 6 under section II.H. of this final rule with comment period.

Step 3. Multiply the percentage calculated in Step 1 by the payment rate calculated in Step 2. The result is the wage-adjusted copayment amount for the APC.

The formula below is a mathematical representation of Step 3 and applies the beneficiary payment percentage to the adjusted payment rate for a service calculated under section II.H. of this final rule with comment period, with and without the rural adjustment, to

calculate the adjusted beneficiary copayment for a given service.

Wage-adjusted copayment amount for the APC = Adjusted Medicare Payment * *B.*

Wage-adjusted copayment amount for the APC (SCH or EACH) = (Adjusted Medicare Payment * 1.071) * *B.*

Step 4. For a hospital that failed to meet its Hospital OQR Program requirements, multiply the copayment calculated in Step 3 by the reporting ratio of 0.9805.

The finalized unadjusted copayments for services payable under the OPPS that will be effective January 1, 2021, are shown in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website). We note that the finalized national unadjusted payment rates and copayment rates shown in Addenda A and B to this final rule with comment period reflect the CY 2021 OPD fee schedule increase factor discussed in section II.B. of this final rule with comment period.

In addition, as noted earlier, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

III. OPPS Ambulatory Payment Classification (APC) Group Policies

A. OPPS Treatment of New and Revised HCPCS Codes

Payments for OPPS procedures, services, and items are generally based on medical billing codes, specifically, Healthcare Common Procedure Coding System (HCPCS) codes, that are reported on hospital outpatient department (HOPD) claims. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of Current Procedural Terminology (CPT), a numeric and alphanumeric coding system maintained by the American Medical Association (AMA), and consists of Category I, II, and III CPT codes. Level II, which is maintained by Centers for Medicare & Medicaid Services (CMS), is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. HCPCS codes are used to report surgical procedures, medical services, items, and supplies under the hospital OPPS. Specifically, CMS recognizes the following codes on OPPS claims:

- Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes (also known as alphanumeric codes), which are used primarily to identify drugs, devices, ambulance services, durable medical equipment, orthotics, prosthetics, supplies, temporary surgical procedures, and medical services not described by CPT codes.

CPT codes are established by the AMA while the Level II HCPCS codes are established by the CMS HCPCS Workgroup. These codes are updated and changed throughout the year. CPT and Level II HCPCS code changes that affect the OPPS are published through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). Generally, these code changes are effective January 1, April 1, July 1, or October 1. CPT code changes are released by the AMA via their website while Level II HCPCS code changes are released to the public via the CMS HCPCS website. CMS recognizes the release of new CPT and Level II HCPCS codes and makes the codes effective (that is, the codes can be reported on Medicare claims) outside of the formal rulemaking process via OPPS quarterly update CRs. Based on our review, we assign the new codes to interim status indicators (SIs) and APCs. These interim assignments are finalized in the OPPS/ASC final rules with comment period. This quarterly process offers hospitals access to codes that more accurately describe items or services furnished and provides payment for these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit public comments on the new CPT and Level II HCPCS codes and finalize policies for these codes through our annual rulemaking process.

We note that, under the OPPS, the APC assignment determines the payment rate for an item, procedure, or service. Those items, procedures, or services not paid separately under the hospital OPPS are assigned to appropriate SIs. Certain payment SIs provide separate payment while other payment SIs do not. In section XI. (CY 2021 OPPS Payment Status and Comment Indicators) of this final rule with comment period, we discuss the various SIs used under the OPPS. We also provide a complete list of the SIs and their definitions in Addendum D1 to this CY 2021 OPPS/ASC final rule with comment period.

1. HCPCS Codes That Were Effective April 1, 2020 for Which We Solicited Public Comments in the CY 2021 OPPS/ASC Proposed Rule

For the April 2020 update, there were no new CPT codes. However, thirteen new Level II HCPCS codes were established and made effective on April 1, 2020. These codes and their long descriptors were included in Table 6 of the proposed rule and are now listed in Table 6 of this final rule with comment period. Through the April 2020 OPPS quarterly update CR (Transmittal 10013, Change Request 11691, dated March 25, 2020), we recognized several new Level II HCPCS codes for separate payment under the OPPS. In the CY 2021 OPPS/ASC proposed rule (85 FR 48812 through 48813), we solicited public comments on the proposed APC and status indicator (SI) assignments for these Level II HCPCS codes, which were listed in Table 6 of the proposed rule.

We did not receive any public comments on the proposed OPPS APC and SI assignments for the new Level II HCPCS codes implemented in April 2020. Therefore, we are finalizing the proposed APC and SI assignments for these codes, as indicated in Table 6. We note that several of the HCPCS C-codes have been replaced with HCPCS J-codes, effective January 1, 2021. Their replacement codes are listed in Table 6. The final payment rates for these codes can be found in Addendum B to this final rule with comment period. In addition, the SI definitions can be found in Addendum D1 to this final rule with comment period. Both Addendum B and Addendum D1 are available via the internet on the CMS website.

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TABLE 6: New HCPCS Codes Effective April 1, 2020

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 SI	Final CY 2021 APC
C9053*	J0791	Injection, crizanlizumab-tmca, 5 mg	G	9359
C9056**	J0223	Injection, givosiran, 0.5 mg	G	9343
C9057#	J1201	Injection, cetirizine hydrochloride, 0.5 mg	G	9361
C9058##	Q5120	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo)	G	9345
0163U	0163U	Oncology (colorectal) screening, biochemical enzyme-linked immunosorbent assay (ELISA) of 3 plasma or serum proteins (teratocarcinoma derived growth factor-1 [TDGF-1, Cripto-1], carcinoembryonic antigen [CEA], extracellular matrix protein [ECM]), with demographic data (age, gender, CRC-screening compliance) using a proprietary algorithm and reported as likelihood of CRC or advanced adenomas	E1	N/A
0164U	0164U	Gastroenterology (irritable bowel syndrome [IBS]), immunoassay for anti-CdtB and anti-vinculin antibodies, utilizing plasma, algorithm for elevated or not elevated qualitative results	Q4	N/A
0165U	0165U	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, individual epitope results and probability of peanut allergy	Q4	N/A
0166U	0166U	Liver disease, 10 biochemical assays (α2-macroglobulin, haptoglobin, apolipoprotein A1, bilirubin, GGT, ALT, AST, triglycerides, cholesterol, fasting glucose) and biometric and demographic data, utilizing serum, algorithm reported as scores for fibrosis, necroinflammatory activity, and steatosis with a summary interpretation	Q4	N/A
0167U	0167U	Gonadotropin, chorionic (hCG), immunoassay with direct optical observation, blood	Q4	N/A
0168U	0168U	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma without fetal fraction cutoff, algorithm reported as a risk score for each trisomy	Q4	N/A
0169U	0169U	NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants	A	N/A
0170U	0170U	Neurology (autism spectrum disorder [ASD]), RNA, next-generation sequencing, saliva, algorithmic	A	N/A

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 SI	Final CY 2021 APC
		analysis, and results reported as predictive probability of ASD diagnosis		
0171U	0171U	Targeted genomic sequence analysis panel, acute myeloid leukemia, myelodysplastic syndrome, and myeloproliferative neoplasms, DNA analysis, 23 genes, interrogation for sequence variants, rearrangements and minimal residual disease, reported as presence/absence	A	N/A

*HCPCS code C9053, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J0791 (Injection, crizanlizumab-tmca, 5 mg) effective July 1, 2020.

**HCPCS code C9056, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J0223 (Injection, givosiran, 0.5 mg) effective July 1, 2020.

#HCPCS code C9057, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J1201 (Injection, cetirizine hydrochloride, 0.5 mg) effective July 1, 2020.

##HCPCS code C9058, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code Q5120 (Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg) effective July 1, 2020.

TABLE 7: NEW HCPCS CODES EFFECTIVE JULY 1, 2020

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 SI	Final CY 2021 APC
C1748	C1748	Endoscope, single-use (that is, disposable), Upper GI, imaging/illumination device (insertable)	H	2029
C1849	C1849	Skin substitute, synthetic, resorbable, per square centimeter	N	N/A
C9059	J1738	Injection, meloxicam, 1 mg	G	9371
C9061	J3241	Injection, teprotumumab-trbw, 10 mg	G	9355
C9063	J3032	Injection, eptinezumab-jjmr, 1 mg	G	9357
C9122	C9122	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	G	9346
C9759	C9759	Transcatheter intraoperative blood vessel microinfusion(s) (for example, intraluminal, vascular wall and/or perivascular) therapy, any vessel, including radiological supervision and interpretation, when performed	N	N/A
C9760	C9760	Non-randomized, non-blinded procedure for NYHA Class II, III, IV heart failure; transcatheter implantation of interatrial shunt-including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (e.g., ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study	T	1592
C9762	C9762	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with strain imaging	Q3	5524
C9763	C9763	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with stress imaging	Q3	5524
C9764	C9764	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed	J1	5192
C9765	C9765	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and	J1	5193

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 SI	Final CY 2021 APC
		transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed		
C9766	C9766	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed	J1	5193
C9767	C9767	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel (s), when performed	J1	5194
G2170*	G2170*	Percutaneous arteriovenous fistula creation (AVF), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (eg, transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed	J1	5194
G2171**	G2171**	Percutaneous arteriovenous fistula creation (AVF), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (eg, vascular coil embolization with radiologic supervision and interpretation, wen performed) and fistulogram(s), angiography, enography, and/or ultrasound, with radiologic supervision and interpretation, when performed	J1	5194
J0223	J0223	Injection, givosiran, 0.5 mg	G	9343
J0591	J0591	Injection, deoxycholic acid, 1 mg	E1	N/A
J0691	J0691	Injection, lefamulin, 1 mg	G	9332
J0742	J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	G	9362
J0791	J0791	Injection, crizanlizumab-tmca, 5 mg	G	9359
J0896	J0896	Injection, luspatercept-aamt, 0.25 mg	G	9347
J1201	J1201	Injection, cetirizine hydrochloride, 0.5 mg	G	9361
J1429	J1429	Injection, golodirsen, 10 mg	G	9356
J1558	J1558	Injection, immune globulin (Xembify), 100 mg	K	9372
J3399	J3399	Injection, Onasemnogene abeparvovec-xioi, per treatment, up to 5x1015 vector genomes	K	9373
J7169	J7169	Injection, coagulation factor Xa (recombinant), inactivated-zhzo (Andexxa), 10 mg	G	9198

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 SI	Final CY 2021 APC
J7204	J7204	Injection, factor VIII, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per iu	G	9354
J7333	J7333	Hyaluronan or derivative, visco-3, for intraarticular injection, per dose	N	N/A
J9177	J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	G	9364
J9198	J9198	Gemcitabine hydrochloride, (Infugem), 100 mg	G	9387
J9246	J9246	Injection, melphalan (evomela), 1 mg	K	9375
J9358	J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	G	9353
Q4227#	Q4227#	Amniocore, per square centimeter	N	N/A
Q4228#	Q4228#	BioNextPATCH, per square centimeter	N	N/A
Q4229#	Q4229#	Cogenex amniotic membrane, per square centimeter	N	N/A
Q4230#	Q4230#	Cogenex flowable amnion, per 0.5 cc	N	N/A
Q4231#	Q4231#	Corplex P, per cc.	N	N/A
Q4232#	Q4232#	Corplex, per square centimeter	N	N/A
Q4233#	Q4233#	Surfactor or Nudyn, per 0.5 cc	N	N/A
Q4234#	Q4234#	Xcellerate, per square centimeter	N	N/A
Q4235#	Q4235#	Amniorepair or altiply, per square centimeter	N	N/A
Q4236#	Q4236#	CarePATCH, per square centimeter	N	N/A
Q4237#	Q4237#	Cryo-cord, per square centimeter	N	N/A
Q4238#	Q4238#	Derm-maxx, per square centimeter	N	N/A
Q4239#	Q4239#	Amnio-maxx or Amnio-maxx lite, per square centimeter	N	N/A
Q4240#	Q4240#	Corecyte, for topical use only, per 0.5 cc	N	N/A
Q4241#	Q4241#	Polycyte, for topical use only, per 0.5 cc	N	N/A
Q4242#	Q4242#	Amniocyte plus, per 0.5 cc	N	N/A
Q4244#	Q4244#	Procenta, per 200 mg	N	N/A
Q4245#	Q4245#	Amniotext, per cc	N	N/A
Q4246#	Q4246#	Coretext or Protext, per cc	N	N/A
Q4247#	Q4247#	Amniotext patch, per square centimeter	N	N/A
Q4248#	Q4248#	Dermacyte Amniotic Membrane Allograft, per square centimeter	N	N/A
Q5119	Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	G	9367
Q5120	Q5120	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg	G	9345
Q5121	Q5121	Injection, infliximab-axxq, biosimilar, (AVSOLA), 10 mg	G	9381
0594T	0594T	Osteotomy, humerus, with insertion of an externally controlled intramedullary lengthening device, including intraoperative imaging, initial and subsequent alignment assessments, computations of	J1	5114

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 SI	Final CY 2021 APC
		adjustment schedules, and management of the intramedullary lengthening device		
0596T	0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement	T	5372
0597T	0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement	T	5372
0598T	0598T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (eg, lower extremity)	T	5722
0599T	0599T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; each additional anatomic site (eg, upper extremity) (List separately in addition to code for primary procedure)	N	N/A
0600T	0600T	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous	J1	5362
0601T	0601T	Ablation, irreversible electroporation; 1 or more tumors, including fluoroscopic and ultrasound guidance, when performed, open	J1	5362
0602T	0602T	Glomerular filtration rate (GFR) measurement(s), transdermal, including sensor placement and administration of a single dose of fluorescent pyrazine agent	Q4	N/A
0603T	0603T	Glomerular filtration rate (GFR) monitoring, transdermal, including sensor placement and administration of more than one dose of fluorescent pyrazine agent, each 24 hours	Q4	N/A
0604T	0604T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; initial device provision, set-up and patient education on use of equipment	V	5012
0605T	0605T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; remote surveillance center technical support, data analyses and reports, with a minimum of 8 daily recordings, each 30 days	Q1	5741
0606T	0606T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; review, interpretation and report by the prescribing physician or other qualified health care professional of remote surveillance center data analyses, each 30 days	M	N/A

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 SI	Final CY 2021 APC
0607T	0607T	Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (eg, ECG data), transmitted to a remote 24-hour attended surveillance center; set-up and patient education on use of equipment	V	5012
0608T	0608T	Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (eg, ECG data), transmitted to a remote 24-hour attended surveillance center; analysis of data received and transmission of reports to the physician or other qualified health care professional	S	5741
0609T	0609T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); acquisition of single voxel data, per disc, on biomarkers (ie, lactic acid, carbohydrate, alanine, laal, propionic acid, proteoglycan, and collagen) in at least 3 discs	Q3	5523
0610T	0610T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); transmission of biomarker data for software analysis	N	N/A
0611T	0611T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); postprocessing for algorithmic analysis of biomarker data for determination of relative chemical differences between discs	S	5523
0612T	0612T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); interpretation and report	M	N/A
0613T	0613T	Percutaneous transcatheter implantation of interatrial septal shunt device, including right and left heart catheterization, intracardiac echocardiography, and imaging guidance by the proceduralist, when performed	E1	N/A
0614T	0614T	Removal and replacement of substernal implantable defibrillator pulse generator	J1	5231
0615T	0615T	Eye-movement analysis without spatial calibration, with interpretation and report	Q1	5734
0616T	0616T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed;	J1	5491

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 SI	Final CY 2021 APC
		without removal of crystalline lens or intraocular lens, without insertion of intraocular lens		
0617T	0617T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with removal of crystalline lens and insertion of intraocular lens	J1	5492
0618T	0618T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens placement or intraocular lens exchange	J1	5492
0619T	0619T	Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed	J1	5375
0172U	0172U	Oncology (solid tumor as indicated by the label), somatic mutation analysis of BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) and analysis of homologous recombination deficiency pathways, DNA, formalin-fixed paraffin-embedded tissue, algorithm quantifying tumor genomic instability score	A	N/A
0173U	0173U	Psychiatry (ie, depression, anxiety), genomic analysis panel, includes variant analysis of 14 genes	A	N/A
0174U	0174U	Oncology (solid tumor), mass spectrometric 30 protein targets, formalin-fixed paraffin-embedded tissue, prognostic and predictive algorithm reported as likely, unlikely, or uncertain benefit of 39 chemotherapy and targeted therapeutic oncology agents	Q4	N/A
0175U	0175U	Psychiatry (eg, depression, anxiety), genomic analysis panel, variant analysis of 15 genes	A	N/A
0176U	0176U	Cytolethal distending toxin B (CdtB) and vinculin IgG antibodies by immunoassay (ie, ELISA)	Q4	N/A
0177U	0177U	Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status	A	N/A
0178U	0178U	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, report of minimum eliciting exposure for a clinical reaction	Q4	N/A
0179U	0179U	Oncology (non-small cell lung cancer), cell-free DNA, targeted sequence analysis of 23 genes (single nucleotide variations, insertions and deletions, fusions without prior knowledge of	A	N/A

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 SI	Final CY 2021 APC
		partner/breakpoint, copy number variations), with report of significant mutation(s)		
0180U	0180U	Red cell antigen (ABO blood group) genotyping (ABO), gene analysis Sanger/chain termination/conventional sequencing, ABO (ABO, alpha 1-3-N-acetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase) gene, including subtyping, 7 exons	A	N/A
0181U	0181U	Red cell antigen (Colton blood group) genotyping (CO), gene analysis, AQP1 (aquaporin 1 [Colton blood group]) exon 1	A	N/A
0182U	0182U	Red cell antigen (Cromer blood group) genotyping (CROM), gene analysis, CD55 (CD55 molecule [Cromer blood group]) exons 1-10	A	N/A
0183U	0183U	Red cell antigen (Diego blood group) genotyping (DI), gene analysis, SLC4A1 (solute carrier family 4 member 1 [Diego blood group]) exon 19	A	N/A
0184U	0184U	Red cell antigen (Dombrock blood group) genotyping (DO), gene analysis, ART4 (ADP-ribosyltransferase 4 [Dombrock blood group]) exon 2	A	N/A
0185U	0185U	Red cell antigen (H blood group) genotyping (FUT1), gene analysis, FUT1 (fucosyltransferase 1 [H blood group]) exon 4	A	N/A
0186U	0186U	Red cell antigen (H blood group) genotyping (FUT2), gene analysis, FUT2 (fucosyltransferase 2) exon 2	A	N/A
0187U	0187U	Red cell antigen (Duffy blood group) genotyping (FY), gene analysis, ACKR1 (atypical chemokine receptor 1 [Duffy blood group]) exons 1-2	A	N/A
0188U	0188U	Red cell antigen (Gerbich blood group) genotyping (GE), gene analysis, GYPC (glycophorin C [Gerbich blood group]) exons 1-4	A	N/A
0189U	0189U	Red cell antigen (MNS blood group) genotyping (GYPA), gene analysis, GYPA (glycophorin A [MNS blood group]) introns 1, 5, exon 2	A	N/A
0190U	0190U	Red cell antigen (MNS blood group) genotyping (GYPB), gene analysis, GYPB (glycophorin B [MNS blood group]) introns 1, 5, pseudoexon 3	A	N/A
0191U	0191U	Red cell antigen (Indian blood group) genotyping (IN), gene analysis, CD44 (CD44 molecule [Indian blood group]) exons 2, 3, 6	A	N/A
0192U	0192U	Red cell antigen (Kidd blood group) genotyping (JK), gene analysis, SLC14A1 (solute carrier family 14 member 1 [Kidd blood group]) gene promoter, exon 9	A	N/A

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 SI	Final CY 2021 APC
0193U	0193U	Red cell antigen (JR blood group) genotyping (JR), gene analysis, ABCG2 (ATP binding cassette subfamily G member 2 [Junior blood group]) exons 2-26	A	N/A
0194U	0194U	Red cell antigen (Kell blood group) genotyping (KEL), gene analysis, KEL (Kell metallo-endopeptidase [Kell blood group]) exon 8	A	N/A
0195U	0195U	KLF1 (Kruppel-like factor 1), targeted sequencing (ie, exon 13)	A	N/A
0196U	0196U	Red cell antigen (Lutheran blood group) genotyping (LU), gene analysis, BCAM (basal cell adhesion molecule [Lutheran blood group]) exon 3	A	N/A
0197U	0197U	Red cell antigen (Landsteiner-Wiener blood group) genotyping (LW), gene analysis, ICAM4 (intercellular adhesion molecule 4 [Landsteiner-Wiener blood group]) exon 1	A	N/A
0198U	0198U	Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis Sanger/chain termination/conventional sequencing, RHD (Rh blood group D antigen) exons 1-10 and RHCE (Rh blood group CcEe antigens) exon 5	A	N/A
0199U	0199U	Red cell antigen (Scianna blood group) genotyping (SC), gene analysis, ERMAP (erythroblast membrane associated protein [Scianna blood group]) exons 4, 12	A	N/A
0200U	0200U	Red cell antigen (Kx blood group) genotyping (XK), gene analysis, XK (X-linked Kx blood group) exons 1-3	A	N/A
0201U	0201U	Red cell antigen (Yt blood group) genotyping (YT), gene analysis, ACHE (acetylcholinesterase [Cartwright blood group]) exon 2	A	N/A

*HCPCS code C9754, which was effective January 1, 2019, was deleted June 30, 2020 and replaced with HCPCS code G2170 effective July 1, 2020.
**HCPCS code C9755, which was effective January 1, 2019, was deleted June 30, 2020 and replaced with HCPCS code G2171 effective July 1, 2020.
#HCPCS codes Q4227 through Q4248: The availability of an HCPCS code for a particular human cell, tissue, or cellular or tissue-based product (HCT/P) does not mean that that product is appropriately regulated solely under section 361 of the PHS Act and the FDA regulations in 21 CFR part 1271. Manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.

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3. October 2020 HCPCS Codes for Which We Are Soliciting Public Comments in This CY 2021 OPPS/ASC Final Rule With Comment Period

As has been our practice in the past, we incorporate those new HCPCS codes that are effective October 1 in the final rule with comment period, thereby updating the OPPS for the following calendar year, as displayed in Table 8 of the proposed rule and reprinted as Table 8 of this final rule with comment period. These codes are released to the public through the October OPPS

quarterly update CRs and via the CMS HCPCS website (for Level II HCPCS codes). For CY 2021, these codes are flagged with comment indicator ''NI'' in Addendum B to this OPPS/ASC final rule with comment period to indicate that we are assigning them an interim payment status which is subject to public comment. Specifically, the interim SI and APC assignments for codes flagged with comment indicator ''NI'' are open to public comment in this final rule with comment period, and we will respond to these public comments in the OPPS/ASC final rule with comment period for the next year's OPPS/ASC update.

In the CY 2021 OPPS/ASC proposed rule (85 FR 48823), we proposed to continue this process for CY 2021. Specifically, for CY 2021, we proposed to include in Addendum B to the CY 2021 OPPS/ASC final rule with comment period the new HCPCS codes effective October 1, 2020 that would be incorporated in the October 2020 OPPS quarterly update CR. Also, as stated above, the October 1, 2020 codes are flagged with comment indicator ''NI'' in Addendum B to this CY 2021 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2021. We are inviting public comments on the interim SI and APC assignments for these codes, if applicable, that will be finalized in the CY 2021 OPPS/ASC final rule with comment period.

We note that we received a comment related to HCPCS codes C9757 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar) and P9099 (Blood component or product not otherwise classified), which were assigned to comment indicator ''NI'' (new code; comments will be accepted on the interim APC assignment) in Addendum B of the CY 2020 OPPS/ASC final rule with comment period. The comments and our responses can be found in section II.A.2(a)(1) (Blood Products) and III.D. (APC-Specific Policies) of this CY 2021 OPPS/ASC final rule with comment period.

4. January 2021 HCPCS Codes

a. New Level II HCPCS Codes for Which We Are Soliciting Public Comments in this CY 2021 OPPS/ASC Final Rule With Comment Period

As shown in Table 8, and as stated in the CY 2021 OPPS/ASC proposed rule (85 FR 48823 through 48825), consistent with past practice, we solicit comments on the new Level II HCPCS codes that will be effective January 1 in the OPPS/ASC final rule with comment period, thereby allowing us to finalize the SIs and APC assignments for the codes in the next OPPS/ASC final rule with comment period. Unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Consequently, for CY 2021, we proposed to include in Addendum B to the CY 2021 OPPS/ASC final rule with comment period the new Level II HCPCS codes effective January 1, 2021, that would be incorporated in the January 2021 OPPS quarterly update CR. These codes will be released to the public through the January OPPS quarterly update CRs and via the CMS HCPCS website (for Level II HCPCS codes). For CY 2021, the Level II HCPCS codes effective January 1, 2021 are flagged with comment indicator ''NI'' in Addendum B to this CY 2021 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim OPPS payment status for CY 2021. We are inviting public comments on the interim SI and APC assignments for these codes, if applicable, that will be finalized in the CY 2021 OPPS/ASC final rule with comment period.

b. CPT Codes For Which We Solicited Public Comments in the CY 2021 OPPS/ASC Proposed Rule

For CY 2021, we received the CY 2021 CPT code updates that would be effective January 1, 2021, from AMA in time for inclusion in the CY 2021 OPPS/ASC proposed rule. We note that in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and SIs for new and revised Category I and III CPT codes that would be effective January 1. Specifically, for the new/revised CPT codes that we receive in a timely manner from the AMA's CPT Editorial Panel, we finalized our proposal to include the codes that would be effective January 1 in the OPPS/ASC proposed rules, along with proposed APC and SI assignments for them, and to finalize the APC and SI assignments in the OPPS/ASC final rules beginning with the CY 2016 OPPS update. For those new/revised CPT codes that were received too late for inclusion in the OPPS/ASC proposed rule, we finalized our proposal to establish and use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and SI assignments for a year until we can propose APC and SI assignments in the following year's rulemaking cycle. We note that even if we find that we need to create HCPCS G-codes in place of certain CPT codes for the PFS proposed rule, we do not anticipate that these HCPCS G-codes will always be necessary for OPPS purposes. We will make every effort to include proposed APC and SI assignments for all new and revised CPT codes that the AMA makes publicly available in time for us to include them in the annual proposed rule, and to avoid the resort to HCPCS G-codes and the resulting delay in utilization of the most current CPT codes. Also, we finalized our proposal to make interim APC and SI assignments for CPT codes that are not available in time for the proposed rule and that describe wholly new services (such as new technologies or new surgical procedures), solicit public comments, and finalize the specific APC and SI assignments for those codes in the following year's final rule.

As stated above, for the CY 2021 OPPS update, we received the CY 2021 CPT codes from AMA in time for inclusion in the CY 2021 OPPS/ASC proposed rule. The new, revised, and deleted CY 2021 Category I and III CPT codes were included in Addendum B to the proposed rule (which is available via the internet on the CMS website). We noted in the proposed rule that the new and revised codes are assigned to new comment indicator ''NP'' to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year with a proposed APC assignment, and that comments will be accepted on the proposed APC and SI assignments.

Further, we reminded readers that the CPT code descriptors that appear in Addendum B are short descriptors and do not accurately describe the complete procedure, service, or item described by the CPT code. Therefore, we included the 5-digit placeholder codes and their long descriptors for the new and revised CY 2021 CPT codes in Addendum O to

the proposed rule (which is available via the internet on the CMS website) so that the public could adequately comment on the proposed APCs and SI assignments. The 5-digit placeholder codes were included in Addendum O, specifically under the column labeled ''CY 2021 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code,'' to the proposed rule. We noted that the final CPT code numbers would be included in this CY 2021 OPPS/ASC final rule with comment period. We also noted that not every code listed in Addendum O is subject to public comment. For the new and revised Category I and III CPT codes, we requested public comments on only those codes that are assigned comment indicator ''NP''.

In summary, in the CY 2021 OPPS/ASC proposed rule, we solicited public comments on the proposed CY 2021 SI and APC assignments for the new and revised Category I and III CPT codes that will be effective January 1, 2021. The CPT codes were listed in Addendum B to the proposed rule with short descriptors only. We listed them again in Addendum O to the proposed rule with long descriptors. We also proposed to finalize the SI and APC assignments for these codes (with their final CPT code numbers) in the CY 2021 OPPS/ASC final rule with comment period. The proposed SI and APC assignments for these codes were included in Addendum B to the proposed rule (which is available via the internet on the CMS website).

Commenters addressed several of the new CPT codes that were assigned to comment indicator ''NP'' in Addendum B to the CY 2021 OPPS/ASC proposed rule. We have responded to those public comments in sections III.C. (New Technology APCs), III.D. (OPPS APC-Specific Policies), and IV. (OPPS Payment for Devices) of this CY 2021 OPPS/ASC final rule with comment period.

The final SIs, APC assignments, and payment rates for the new CPT codes that are effective January 1, 2021 can be found in Addendum B to this final rule with comment period. In addition, the SI meanings can be found in Addendum D1 (OPPS Payment Status Indicators for CY 2021) to this final rule with comment period. Both Addendum B and D1 are available via the internet on the CMS website.

Finally, Table 8, which is a reprint of Table 8 from the CY 2021 OPPS/ASC proposed rule, shows the comment timeframe for new and revised HCPCS codes. The table provides information on our current process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing the treatment of these codes under the OPPS.

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TABLE 8: COMMENT TIMEFRAME FOR NEW AND REVISED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2020	HCPCS (CPT and Level II codes)	April 1, 2020	CY 2021 OPPS/ASC proposed rule	CY 2021 OPPS/ASC final rule with comment period
July 2020	HCPCS (CPT and Level II codes)	July 1, 2020	CY 2021 OPPS/ASC proposed rule	CY 2021 OPPS/ASC final rule with comment period
October 2020	HCPCS (CPT and Level II codes)	October 1, 2020	CY 2021 OPPS/ASC final rule with comment period	CY 2022 OPPS/ASC final rule with comment period
January 2021	CPT Codes	January 1, 2021	CY 2021 OPPS/ASC proposed rule	CY 2021 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2021	CY 2021 OPPS/ASC final rule with comment period	CY 2022 OPPS/ASC final rule with comment period

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B. OPPS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. Section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in regulations at 42 CFR 419.31. We use Level I (also known as CPT codes) and Level II HCPCS codes (also known as alphanumeric codes) to identify and

group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices that are not packaged into the payment for the procedure.

We have packaged into the payment for each procedure or service within an APC group the costs associated with those items and services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support. Therefore, we do not make separate payment for these packaged items or services. In general, packaged items and services include, but are not limited to, the items and services listed in regulations at 42 CFR 419.2(b). A further discussion of packaged services is included in section II.A.3. of this final rule with comment period.

Under the OPPS, we generally pay for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. In the CY 2021 OPPS/ASC proposed rule (85 FR 48799), for CY 2021, we proposed that each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in APC 5012 (Clinic Visits and Related Services). The APC relative payment weights are scaled to APC 5012 because it is the hospital clinic visit APC and clinic visits are among the most frequently furnished services in the hospital outpatient setting.

2. Application of the 2 Times Rule

Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the APC groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act also requires the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights. We note that the Hospital Outpatient Payment (HOP) Panel recommendations for specific services for the CY 2021 OPPS update are discussed in the relevant specific sections throughout this CY 2021 OPPS/ASC final rule with comment period.

In addition, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same group (referred to as the ''2 times rule''). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act). In determining the APCs with a 2 times rule violation, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant procedure codes for examination under the 2 times rule, we consider procedure codes that have more than 1,000 single major claims or procedure codes that both have more than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832). This longstanding definition of when a procedure code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 or fewer claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a procedure code for which there are fewer than 99 single claims and that comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost (75 FR 71832). In the CY 2021 OPPS/ASC proposed rule (85 FR 48826 through 48827), for CY 2021, we proposed to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as for certain low-volume items and services.

In the CY 2021 OPPS/ASC proposed rule, we identified the APCs with violations of the 2 times rule. Therefore, we proposed changes to the procedure codes assigned to these APCs in Addendum B to the proposed rule. We noted that Addendum B does not appear in the printed version of the **Federal Register** as part of the CY 2021 OPPS/ASC proposed rule. Rather, it is published and made available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. To eliminate a violation of the 2 times rule and improve clinical and resource homogeneity, we proposed to reassign these procedure codes to new APCs that contain services that are similar with regard to both their clinical and resource characteristics. In many cases, the proposed procedure code reassignments and associated APC reconfigurations for CY 2021 included in the proposed rule were related to changes in costs of services that were observed in the CY 2019 claims data newly available for CY 2021 ratesetting. Addendum B to the CY 2021 OPPS/ASC proposed rule identified with a comment indicator ''CH'' those procedure codes for which we proposed a change to the APC assignment or SI, or both, that were initially assigned in the July 1, 2020 OPPS Addendum B Update (available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html*), which was the latest payment rate file for 2019 prior to issuance of the proposed rule.

3. APC Exceptions to the 2 Times Rule

Taking into account the APC changes that we proposed to make for CY 2021 in the CY 2021 OPPS/ASC proposed rule, we reviewed all of the APCs to determine which APCs would not meet the requirements of the 2 times rule. We used the following criteria to evaluate whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity;
- Clinical homogeneity;
- Hospital outpatient setting utilization;
- Frequency of service (volume); and
- Opportunity for upcoding and code fragments.

Based on the CY 2019 claims data available for the CY 2021 proposed rule, we found 18 APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs for which we proposed to make exceptions under the 2 times rule for CY 2021, and found that all of the 18 APCs we identified met the criteria for an exception to the 2 times rule based on the CY 2019 claims data available for the proposed rule. We did not include in that determination those APCs where

a 2 times rule violation was not a relevant concept, such as APC 5401 (Dialysis), which only has two HCPCS codes assigned to it that have a similar geometric mean costs and do not create a 2 time rule violation. Therefore, we only identified those APCs, including those with criteria-based costs, with violations of the 2 times rule.

We note that, for cases in which a recommendation by the HOP Panel appears to result in or allow a violation of the 2 times rule, we may accept the HOP Panel's recommendation because those recommendations are based on explicit consideration (that is, a review of the latest OPPS claims data and group discussion of the issue) of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates.

Table 9 of the proposed rule listed the 18 APCs for which we proposed to make an exception for under the 2 times rule for CY 2021 based on the criteria cited above and claims data submitted between January 1, 2019, and December 31, 2019, and processed on or before December 31, 2019. In the proposed rule, we stated that for the final rule with comment period, we intended to use claims data for dates of service between January 1, 2019, and December 31, 2019, that were processed on or before June 30, 2020, and updated CCRs, if available. We stated that the proposed geometric mean costs for covered hospital outpatient services for these and all other APCs that were used in the development of the proposed rule could be found on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*.

Based on the updated final rule CY 2019 claims data used for this CY 2021 final rule with comment period, we found a total of 23 APCs with violations of the 2 times rule. Of these 23 total APCs, 18 were identified in the proposed rule and five are newly identified APCs. The five newly identified APCs with violations of the 2 times rule include the following:

- APC 5101 (Level 1 Strapping and Cast Application)
- APC 5161 (Level 1 ENT Procedures)
- APC 5593 (Level 3 Nuclear Medicine and Related Services)
- APC 5673 (Level 3 Pathology)
- APC 5734 (Level 4 Minor Procedures)

Although we did not receive any comments on Table 9 of the proposed rule, we did receive comments on APC assignments for specific HCPCS codes. The comments, and our responses, can be found in section III.D. (OPPS APC-Specific Policies) of this final rule with comment period.

After considering the public comments we received on APC assignments and our analysis of the CY 2019 costs from hospital claims and cost report data available for this CY 2021 final rule with comment period, we are finalizing our proposals with some modifications. Specifically, we are finalizing our proposal to except 18 of the 18 proposed APCs from the 2 times rule for CY 2021 and also excepting five additional APCs (APCs 5101, 5161, 5593, 5673, and 5734) for a total of 23 APCs.

In summary, Table 9 lists the 23 APCs that we are excepting from the 2 times rule for CY 2021 based on the criteria described earlier and a review of updated claims data for dates of service between January 1, 2019 and December 31, 2019, that were processed on or before June 30, 2020, and updated CCRs, if available. We note that, for cases in which a recommendation by the HOP Panel appears to result in or allow a violation of the 2 times rule, we generally accept the HOP Panel's recommendation because those recommendations are based on explicit consideration of resource use, clinical homogeneity, site of service, and the quality of the claims data used to determine the APC payment rates. The geometric mean costs for hospital outpatient services for these and all other APCs that were used in the development of this final rule with comment period can be found on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*.

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TABLE 9: APC EXCEPTION TO THE 2 TIMES RULE FOR CY 2021

CY 2021 APC	CY 2021 APC Title
5051	Level 1 Skin Procedures
5055	Level 5 Skin Procedures
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5101	Level 1 Strapping and Cast Application
5112	Level 2 Musculoskeletal Procedures
5161	Level 1 ENT Procedures
5301	Level 1 Upper GI Procedures
5311	Level 1 Lower GI Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5571	Level 1 Imaging with Contrast
5593	Level 3 Nuclear Medicine and Related Services
5612	Level 2 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5673	Level 3 Pathology
5691	Level 1 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5734	Level 4 Minor Procedures
5821	Level 1 Health and Behavior Services
5823	Level 3 Health and Behavior Services

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C. New Technology APCs

1. Background

In the CY 2002 OPPS final rule (66 FR 59903), we finalized changes to the time period in which a service can be eligible for payment under a New Technology APC. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

In the CY 2004 OPPS final rule with comment period (68 FR 63416), we restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs, one set with a status indicator of ''S'' (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment) and the other set with a status indicator of ''T'' (Significant Procedure, Multiple Reduction Applies. Paid under OPPS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently.

For CY 2020, there were 52 New Technology APC levels, ranging from the lowest cost band assigned to APC 1491 (New Technology—Level 1A ($0–$10)) through the highest cost band assigned to APC 1908 (New Technology—Level 52 ($145,001–$160,000)). We note that the cost bands for the New Technology APCs, specifically, APCs 1491 through 1599 and 1901 through 1908, vary with increments ranging from $10 to $14,999. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example, payment for New Technology APC 1507 (New Technology—Level 7 ($501–$600)) is made at $550.50.

Under the OPPS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is budget neutral and increases are limited to the annual hospital inpatient market basket increase adjusted for multifactor productivity. We believe that our payment rates reflect the costs that are associated with providing care to Medicare beneficiaries and are adequate to ensure access to services (80 FR 70374).

For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the technologies and their clinical

utility. Quite often, parties request that Medicare make higher payment amounts under the New Technology APCs for new procedures in that transitional phase. These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per-use costs for which requesters believe Medicare should make full payment. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on projected utilization for Medicare beneficiaries and does not set its payment rates based on initial projections of low utilization for services that require expensive capital equipment. For the OPPS, we rely on hospitals to make informed business decisions regarding the acquisition of high-cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare's and other payers' payment policies. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68314) for further discussion regarding this payment policy.

We note that, in a budget neutral system, payments may not fully cover hospitals' costs in a particular circumstance, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high-cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCs, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings. As the OPPS acquires claims data regarding hospital costs associated with new procedures, we regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPS payments remain appropriate for procedures as they transition into mainstream medical practice (77 FR 68314). For CY 2021, we included the proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 in Addendum A to this CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

2. Establishing Payment Rates for Low-Volume New Technology Services

Services that are assigned to New Technology APCs are typically new services that do not have sufficient claims history to establish an accurate payment for the services. One of the objectives of establishing New Technology APCs is to generate sufficient claims data for a new service so that it can be assigned to an appropriate clinical APC. Some services that are assigned to New Technology APCs have very low annual volume, which we consider to be fewer than 100 claims. We consider services with fewer than 100 claims annually to be low-volume services because there is a higher probability that the payment data for a service may not have a normal statistical distribution, which could affect the quality of our standard cost methodology that is used to assign services to an APC. In addition, services with fewer than 100 claims per year are not generally considered to be a significant contributor to the APC ratesetting calculations and, therefore, are not included in the assessment of the 2 times rule. As we explained in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58890), we were concerned that the methodology we use to estimate the cost of a service under the OPPS by calculating the geometric mean for all separately paid claims for a HCPCS service code from the most recent available year of claims data may not generate an accurate estimate of the actual cost of the service for these low-volume services.

In accordance with section 1833(t)(2)(B) of the Act, services classified within each APC must be comparable clinically and with respect to the use of resources. As described earlier, assigning a service to a new technology APC allows us to gather claims data to price the service and assign it to the APC with services that use similar resources and are clinically comparable. However, where utilization of services assigned to a New Technology APC is low, it can lead to wide variation in payment rates from year to year, resulting in even lower utilization and potential barriers to access to new technologies, which ultimately limits our ability to assign the service to the appropriate clinical APC. To mitigate these issues, we determined in the CY 2019 OPPS/ASC final rule with comment period that it was appropriate to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how we determined the costs for low-volume services assigned to New Technology APCs (83 FR 58892 through 58893). We have utilized our equitable adjustment authority at section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to estimate an appropriate payment amount for low-volume new technology services in the past (82 FR 59281). Although we have used this adjustment authority on a case-by-case basis in the past, we stated in the CY 2019 OPPS/ASC final rule with comment period that we believe it is appropriate to adopt an adjustment for low-volume services assigned to New Technology APCs in order to mitigate the wide payment fluctuations that have occurred for new technology services with fewer than 100 claims and to provide more predictable payment for these services.

For purposes of this adjustment, we stated that we believe that it is appropriate to use up to 4 years of claims data in calculating the applicable payment rate for the prospective year, rather than using solely the most recent available year of claims data, when a service assigned to a New Technology APC has a low annual volume of claims, which, for purposes of this adjustment, we define as fewer than 100 claims annually. We adopted a policy to consider services with fewer than 100 claims annually as low-volume services because there is a higher probability that the payment data for a service may not have a normal statistical distribution, which could affect the quality of our standard cost methodology that is used to assign services to an APC. We explained that we were concerned that the methodology we use to estimate the cost of a service under the OPPS by calculating the geometric mean for all separately paid claims for a HCPCS procedure code from the most recent available year of claims data may not generate an accurate estimate of the actual cost of the low-volume service. Using multiple years of claims data will potentially allow for more than 100 claims to be used to set the payment rate, which would, in turn, create a more statistically reliable payment rate.

In addition, to better approximate the cost of a low-volume service within a New Technology APC, we stated that we believe using the median or arithmetic mean rather than the geometric mean (which ''trims'' the costs of certain claims out) could be more appropriate in some circumstances, given the extremely low volume of claims. Low claim volumes increase the impact of ''outlier'' claims; that is, claims with either a very low or very high payment

rate as compared to the average claim, which would have a substantial impact on any statistical methodology used to estimate the most appropriate payment rate for a service. We also explained that we believe having the flexibility to utilize an alternative statistical methodology to calculate the payment rate in the case of low-volume new technology services would help to create a more stable payment rate. Therefore, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58893), we established that, in each of our annual rulemakings, we will seek public comments on which statistical methodology should be used for each low-volume service assigned to a New Technology APC. In the preamble of each annual rulemaking, we stated that we would present the result of each statistical methodology and solicit public comment on which methodology should be used to establish the payment rate for a low-volume new technology service. In addition, we will use our assessment of the resources used to perform a service and guidance from the developer or manufacturer of the service, as well as other stakeholders, to determine the most appropriate payment rate. Once we identify the most appropriate payment rate for a service, we will assign the service to the New Technology APC with the cost band that includes its payment rate.

Accordingly, for CY 2021, we proposed to continue the policy we adopted in CY 2019 under which we will utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median using multiple years of claims data to select the appropriate payment rate for purposes of assigning services with fewer than 100 claims per year to a New Technology APC. Additional details on our policy is available in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58892 through 58893).

We did not receive any public comments on our proposal. Therefore, we are finalizing our proposal without modification.

3. Procedures Assigned to New Technology APC Groups for CY 2021

As we described in the CY 2002 OPPS final rule with comment period (66 FR 59902), we generally retain a procedure in the New Technology APC to which it is initially assigned until we have obtained sufficient claims data to justify reassignment of the procedure to a clinically appropriate APC.

In addition, in cases where we find that our initial New Technology APC assignment was based on inaccurate or inadequate information (although it was the best information available at the time), where we obtain new information that was not available at the time of our initial New Technology APC assignment, or where the New Technology APCs are restructured, we may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that more appropriately reflects its cost (66 FR 59903).

Consistent with our current policy, for CY 2021, we proposed to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to a clinically appropriate APC. The flexibility associated with this policy allows us to reassign a service from a New Technology APC in less than 2 years if sufficient claims data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient claims data upon which to base a decision for reassignment have not been obtained (66 FR 59902). We received no public comments on our proposal. Therefore, we will implement our proposal without modification.

a. Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS)

Currently, there are four CPT/HCPCS codes that describe magnetic resonance image-guided, high-intensity focused ultrasound (MRgFUS) procedures, three of which we proposed to continue to assign to standard APCs, and one that we proposed to continue to assign to a New Technology APC for CY 2021. These codes include CPT codes 0071T, 0072T, and 0398T, and HCPCS code C9734. CPT codes 0071T and 0072T describe procedures for the treatment of uterine fibroids, CPT code 0398T describes procedures for the treatment of essential tremor, and HCPCS code C9734 describes procedures for pain palliation for metastatic bone cancer.

For the procedure described by CPT code 0398T, we have identified 169 paid claims for CY 2019 with a geometric mean of $12,027.76. The number of claims for the service means that the procedure is no longer a low-volume new technology service, and we will use the geometric mean of the CY 2019 claims data to determine the cost of the service for its APC assignment. We reviewed the OPPS to determine whether CPT code 0398T could be assigned to a clinical APC. The most appropriate clinical APC family for the service would be the Neurostimulator and Related Procedures APC series (APCs 5461 through 5464). However, there was a large payment rate difference between Level 2 Neurostimulator and Related Procedures (APC 5462) with a payment rate of $6,169.27 and Level 3 Neurostimulator and Related Procedures (APC 5463) with a payment rate of $19,737.37. Based on the geometric mean cost of CPT code 0398T available for the CY 2021 OPPS/ASC proposed rule, we believe the payment rate for APC 5462 would be too low for CPT code 0398T since it is more than $6,000 less than the geometric mean cost for CPT code 0398T, and we believe the payment rate for APC 5463 would be too high since it is around $6,800 more than the geometric mean cost for CPT code 0398T.

In addition, given the significant difference in the payment rate between APC 5462 and 5463, we believed a restructuring of the APC family would be appropriate. We believed that creating an additional payment level between the two existing APC levels would allow for a smoother distribution of the costs between the different levels based on their resource costs and clinical characteristics. Please refer to section III.D.1 for detailed explanation of our proposal to reorganize the Neurostimulator and Related Procedures APCs (APCs 5461–5464). Reorganizing the Neurostimulator and Related Procedures APCs would create a proposed Level 3 APC to be referred to as ''Proposed APC 5463'' with a payment rate of approximately $12,286 that is close to the geometric mean of CPT code 0398T which is approximately $12,798. The payment rate of proposed APC 5463 is representative of the cost of the service described by CPT code 0398T. Therefore, we proposed to reassign the service described by CPT code 0398T to the proposed new Level 3 APC for Neurostimulator and Related Procedures (Proposed APC 5463) for CY 2021.

Comment: Multiple commenters supported our proposal to reassign CPT code 0398T to proposed new APC 5463 (Level 3 Neurostimulator and Related Procedures).

Response: We appreciate the support of the commenters for our proposal.

The final rule data shows the payment rate for the new APC 5463 (Level 3 Neurostimulator and Related Procedures) is $11,236.21. While this payment rate is lower than what was calculated for the proposed rule, we continue to believe APC 5463 is an appropriate placement for CPT code 0398T. After our review of the public comments, we have decided to

implement our proposal to assign CPT code 0398T to APC 5463 for CY 2021. The final APC assignment, status indicator, and payment rate for CPT code 0398T are found in Table 10. We refer readers to Addendum B of the final rule for the final payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 10: FINAL CY 2021 STATUS INDICATOR (SI), APC ASSIGNMENT, AND PAYMENT RATE FOR THE MAGNETIC RESONANCE IMAGE GUIDED HIGH INTENSITY FOCUSED ULTRASOUND (MRGFUS) PROCEDURE

CPT/ HCPCS Code	Long Descriptor	CY 2020 OPPS SI	CY 2020 OPPS APC	CY 2020 OPPS Payment Rate	Final CY 2021 OPPS SI	Final CY 2021 OPPS APC	Final CY 2021 OPPS Payment Rate
0398T	Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed.	S	1575	$12,500.50	J1	5463	Refer to OPPS Addendum B.

Retinal Prosthesis Implant Procedure

CPT code 0100T (Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy) describes the implantation of a retinal prosthesis, specifically, a procedure involving the use of the Argus® II Retinal Prosthesis System. This first retinal prosthesis was approved by FDA in 2013 for adult patients diagnosed with severe to profound retinitis pigmentosa. Pass-through payment status was granted for the Argus® II device under HCPCS code C1841 (Retinal prosthesis, includes all internal and external components) beginning October 1, 2013, and this status expired on December 31, 2015. We note that after pass-through payment status expires for a medical device, the payment for the device is packaged into the payment for the associated surgical procedure. Consequently, for CY 2016, the device described by HCPCS code C1841 was assigned to OPPS status indicator ''N'' to indicate that payment for the device is packaged and included in the payment rate for the surgical procedure described by CPT code 0100T. For CY 2016, the procedure described by CPT code 0100T was assigned to New Technology APC 1599, with a payment rate of $95,000, which was the highest paying New Technology APC for that year. This payment included both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841). However, stakeholders (including the device manufacturer and hospitals) believed that the CY 2016 payment rate for the procedure involving the Argus® II System was insufficient to cover the hospital cost of performing the procedure, which includes the cost of the retinal prosthesis at the retail price of approximately $145,000.

For CY 2017, analysis of the CY 2015 OPPS claims data used for the CY 2017 OPPS/ASC final rule with comment period showed 9 single claims (out of 13 total claims) for the procedure described by CPT code 0100T, with a geometric mean cost of approximately $142,003 based on claims submitted between January 1, 2015, through December 31, 2015, and processed through June 30, 2016. Based on the CY 2015 OPPS claims data available for the final rule with comment period and our understanding of the Argus® II procedure, we reassigned the procedure described by CPT code 0100T from New Technology APC 1599 to New Technology APC 1906, with a final payment rate of $150,000.50 for CY 2017. We noted that this payment rate included the cost of both the surgical procedure (CPT code 0100T) and the retinal prosthesis device (HCPCS code C1841).

For CY 2018, the reported cost of the Argus® II procedure based on CY 2016 hospital outpatient claims data for 6 claims used for the CY 2018 OPPS/ASC final rule with comment period was approximately $94,455, which was more than $55,000 less than the payment rate for the procedure in CY 2017, but closer to the CY 2016 payment rate for the procedure. We noted that the costs of the Argus® II procedure are extraordinarily high compared to many other procedures paid under the OPPS. In addition, the number of claims submitted has been very low and has not exceeded 10 claims within a single year. We believed that it is important to mitigate significant payment differences, especially shifts of several tens of thousands of dollars, while also basing payment rates on available cost information and claims data. In CY 2016, the payment rate for the Argus® II procedure was $95,000.50. The payment rate increased to $150,000.50 in CY 2017. For CY 2018, if we had established the payment rate based on updated final rule claims data, the

payment rate would have decreased to $95,000.50 for CY 2018, a decrease of $55,000 relative to CY 2017. We were concerned that these large fluctuations in payment could potentially create an access to care issue for the Argus® II procedure, and we wanted to establish a payment rate to mitigate the potential sharp decline in payment from CY 2017 to CY 2018.

In accordance with section 1833(t)(2)(B) of the Act, we must establish that services classified within each APC are comparable clinically and with respect to the use of resources. Therefore, for CY 2018, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to maintain the payment rate for this procedure, despite the lower geometric mean costs available in the claims data used for the final rule with comment period. For CY 2018, we reassigned the Argus® II procedure to APC 1904 (New Technology—Level 50 ($115,001–$130,000)), which established a payment rate for the Argus® II procedure of $122,500.50, which was the arithmetic mean of the payment rates for the procedure for CY 2016 and CY 2017.

For CY 2019, the reported cost of the Argus® II procedure based on the geometric mean cost of 12 claims from the CY 2017 hospital outpatient claims data was approximately $171,865, which was approximately $49,364 more than the payment rate for the procedure for CY 2018. In the CY 2019 OPPS/ASC final rule with comment period, we continued to note that the costs of the Argus® II procedure are extraordinarily high compared to many other procedures paid under the OPPS (83 FR 58897 through 58898). In addition, the number of claims submitted continued to be very low for the Argus® II procedure. We stated that we continued to believe that it is important to mitigate significant payment fluctuations for a procedure, especially shifts of several tens of thousands of dollars, while also basing payment rates on available cost information and claims data because we are concerned that large decreases in the payment rate could potentially create an access to care issue for the Argus® II procedure. In addition, we indicated that we wanted to establish a payment rate to mitigate the potential sharp increase in payment from CY 2018 to CY 2019, and potentially ensure a more stable payment rate in future years.

As discussed in section III.C.2. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58892 through 58893), we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to establish a payment rate that is more representative of the likely cost of the service. We stated that we believed the likely cost of the Argus® II procedure is higher than the geometric mean cost calculated from the claims data used for the CY 2018 OPPS/ASC final rule with comment period but lower than the geometric mean cost calculated from the claims data used for the CY 2019 OPPS/ASC final rule with comment period.

For CY 2019, we analyzed claims data for the Argus® II procedure using 3 years of available data from CY 2015 through CY 2017. These data included claims from the last year that the Argus® II received transitional device pass-through payments (CY 2015) and the first 2 years since device pass-through payment status for the Argus® II expired. We found that the geometric mean cost for the procedure was approximately $145,808, the arithmetic mean cost was approximately $151,367, and the median cost was approximately $151,266. As we do each year, we reviewed claims data regarding hospital costs associated with new procedures. We regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that OPPS payments remain appropriate for procedures like the Argus® II procedure as they transition into mainstream medical practice (77 FR 68314). We noted that the proposed payment rate included both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841). For CY 2019, the estimated costs using all three potential statistical methods for determining APC assignment under the New Technology low-volume payment policy fell within the cost band of New Technology APC 1908, which is between $145,001 and $160,000. Therefore, we reassigned the Argus® II procedure (CPT code 0100T) to APC 1908 (New Technology—Level 52 ($145,001–$160,000)), with a payment rate of $152,500.50 for CY 2019.

For CY 2020, we identified 35 claims reporting the procedure described by CPT code 0100T for the 4-year period of CY 2015 through CY 2018. We found the geometric mean cost for the procedure described by CPT code 0100T to be approximately $146,059, the arithmetic mean cost to be approximately $152,123, and the median cost to be approximately $151,267. All of the resulting estimates from using the three statistical methodologies fell within the same New Technology APC cost band ($145,001–$160,000), where the Argus® II procedure was assigned for CY 2019. Consistent with our policy stated in section III.C.2, we presented the result of each statistical methodology in the proposed rule, and we sought public comments on which method should be used to assign procedures described by CPT code 0100T to a New Technology APC. All three potential statistical methodologies used to estimate the cost of the Argus® II procedure fell within the cost band for New Technology APC 1908, with the estimated cost being between $145,001 and $160,000. Accordingly, we assigned CPT code 0100T in APC 1908 (New Technology—Level 52 ($145,001–$160,000)), with a payment rate of $152,500.50 for CY 2020.

For CY 2021, the number of reported claims for the Argus® II procedure continues to be very low with a substantial fluctuation in cost from year to year. The high annual variability of the cost of the Argus® II procedure continues to make it difficult to establish a consistent and stable payment rate for the procedure. As previously mentioned, in accordance with section 1833(t)(2)(B) of the Act, we are required to establish that services classified within each APC are comparable clinically and with respect to the use of resources. Therefore, for CY 2021, we proposed to apply the policy we adopted in CY 2019, under which we utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median costs using multiple years of claims data to select the appropriate payment rate for purposes of assigning the Argus® II procedure (CPT code 0100T) to a New Technology APC.

For CY 2021, we identified 35 claims reporting the procedure described by CPT code 0100T for the 4-year period of CY 2016 through CY 2019. We found the geometric mean cost for the procedure described by CPT code 0100T to be approximately $148,807, the arithmetic mean cost to be approximately $154,504, and the median cost to be approximately $151,974. All three potential statistical methodologies used to estimate the cost of the Argus® II procedure fall within the cost band for New Technology APC 1908, with the estimated cost being between $145,001 and $160,000.

Accordingly, we proposed to maintain the assignment of the procedure

described by CPT code 0100T in APC 1908 (New Technology—Level 52 ($145,001–$160,000)), with a proposed payment rate of $152,500.50 for CY 2021. We note that the proposed payment rate includes both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841). We refer readers to Addendum B to the proposed rule for the proposed payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

For our analysis for the CY 2021 final rule, we identified 35 claims reporting the procedure described by CPT code 0100T for the 4-year period of CY 2016 through CY 2019. We found the geometric mean cost for the procedure described by CPT code 0100T to be approximately $148,148, the arithmetic mean cost to be approximately $153,682, and the median cost to be approximately $151,974. The slight differences from the calculations using the proposed rule data are caused by changes to the wage indexes of a few providers. All three potential statistical methodologies used to estimate the cost of the Argus® II procedure fall within the cost band for New Technology APC 1908, with the estimated cost being between $145,001 and $160,000.

We received no public comments on our proposal. Therefore, we are finalizing our proposal without modification. We will maintain the assignment of the procedure described by CPT code 0100T in APC 1908 (New Technology—Level 52 ($145,001–$160,000)), with a payment rate of $152,500.50 for CY 2021. We note that the final payment rate includes both the surgical procedure (CPT code 0100T) and the use of the Argus® II device (HCPCS code C1841). We refer readers to Addendum B to the final rule for the final payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

c. Administration of Subretinal Therapies Requiring Vitrectomy (APC 1561)

CPT code J3398 (*Injection, voretigene neparvovec-rzyl, 1 billion vector genomes*) is a gene therapy for a rare mutation-associated retinal dystrophy. Voretigene neparvovec-rzyl (Luxturna®), was approved by FDA in December of 2017, and is indicated as an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.[2] This therapy is administered through a subretinal injection, which stakeholders describe as an extremely delicate and sensitive surgical procedure. The FDA package insert describes one of the steps for administering Luxturna as, ''after completing a vitrectomy, identify the intended site of administration. The subretinal injection can be introduced via pars plana.'' [1]

Stakeholders, including the manufacturer of Luxturna®, recommended HCPCS code 67036 (*Vitrectomy, mechanical, pars plana approach*) for the administration of the gene therapy.[3] However, the manufacturer contends the administration is not currently described by any existing codes as HCPCS code 67036 (*Vitrectomy, mechanical, pars plana approach*) does not account for the administration itself. For HCPCS code J3398, a typical patient would receive a standard dose of 150 billion vector genomes, with an approximate payment rate of $432,480 (we refer readers to Addendum B of the CY 2021 OPPS/ASC Final Rule with comment period rule for the payment rate associated with HCPCS code J3398).

It is important to note that HCPCS code J3398 was granted drug pass-through status under the OPPS as of July 1, 2018 and is assigned status indicator ''G''. (We refer readers to Addendum D of the CY 2021 OPPS/ASC Final rule for the list of status indicator definitions for CY2021). HCPCS code J3398 is scheduled to have its drug pass-through status expire June 30, 2021, at which point the code would be packaged into the payment for any primary service with which it is billed when that primary service is assigned to a comprehensive APC (C–APC). A C–APC packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure. (For a full discussion and background on C–APCs, see section II.A.2.b). Based on information from the manufacturer of Luxturna, we believe that HCPCS code J3398 (*Injection, voretigene neparvovec-rzyl, 1 billion vector genomes*) would commonly be billed with the service described by HCPCS code 67036 (*Vitrectomy, mechanical, pars plana approach*), which describes the administration of the gene therapy, and which is assigned to a comprehensive APC, (APC 5492—Level 2 Intraocular Procedures). Thus, when its pass-through status expires, payment for HCPCS code J3398, the primary therapy, would be packaged into payment for HCPCS code 67036, its administration procedure.

CMS recognizes the need to accurately describe the unique administration procedure that is required to administer the therapy described by HCPCS code J3398. We proposed to establish a new HCPCS code, C97X1 (*Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent*) to describe this process. We believe that this new HCPCS code accurately describes the service associated with intraocular administration of HCPCS code J3398. CMS recognized that HCPCS code 67036 represents a similar procedure and process that approximates similar resource utilization that is associated with C97X1. CMS also recognized that it is not prudent for the code that describes the administration of this gene therapy, C97X1, to be assigned to the same C–APC to which HCPCS code 67036 is assigned, as this would package the primary therapy, HCPCS code J3398, into the code that represents the process to administer the gene therapy.

For CY 2021, we proposed to assign the services described by C97X1 to a new technology payment band based on the geometric mean cost for HCPCS code 67036. For the CY 2021 OPPS/ASC Proposed Rule, HCPCS code 67036 had a geometric mean cost of $3,407.84. Therefore, for the proposed rule we proposed to assign C97X1 to APC 1561—New Technology—Level 24 ($3001–$3500). See Table 11 for proposed descriptors and APC assignment.

[2] Luxturna. FDA Package Insert. Available: *https://www.fda.gov/media/109906/download.*

[3] LUXTURNA REIMBURSEMENT GUIDE FOR TREATMENT CENTERS. *https://mysparkgeneration.com/pdf/Reimbursement_Guide_for_Treatment_Centers_Interactive_010418_FINAL.pdf.*

TABLE 11: CY 2021 PROPOSED OPPS APC AND STATUS INDICATOR FOR HCPCS CODE C97X1 ASSIGNED TO NEW TECHNOLOGY APC

CY 2021 Placeholder HCPCS Code	Long Descriptor	Proposed CY 2021 OPPS SI	Proposed CY 2021 OPPS APC
C97X1	Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent	T	1561

Comment: Commenters were largely supportive of our proposal to create a ''C'' code to describe the administration of J3398 and assign this newly created ''C'' code to New Technology APC 1561. Commenters largely advised CMS to finalize our proposal as proposed.

Response: We thank the commenters for their support on our proposal.

Comment: A small minority of commenters supported our approach to create a ''C'' code to describe the administration of J3398 and assign the newly created ''C'' code to a New Technology APC, but suggested alternate APC placements. The commenters' suggested alternate APC placements included APC 1562, based on a crosswalk of HCPCS code 67042, as well as APC 1564. Additionally, one commenter expressed uncertainty about when it would be appropriate to bill this code.

Response: We thank commenters for their feedback. Based on our review, we believe assigning C9770 to APC 1561 based on the geometric mean costs of HCPCS code 67036 is the most appropriate APC placement for this code. Our clinical review along with an overwhelming number of stakeholders have found that HCPCS code 67036 represents a similar procedure and process that approximates similar resource utilization that is associated with C9770. Additionally, regarding when C9770 may be billed, we remind stakeholders that HOPDs and ASCs may bill C9770 under Medicare in the HOPD and ASC settings when reasonable and necessary services are furnished. HCPCS C-codes are reportable only on Medicare OPPS and ASC claims. HOPDs and ASCs are expected to make appropriate coding decisions based on instructions and other information available to them (for example, federal regulations, CMS instructions, MAC instructions, etc.).

Based on the above discussion, for CY 2021 we are finalizing our proposal without modification to establish C9770 and assign the code to a New Technology APC based on the geometric mean cost of HCPCS code 67036. For CY 2021, HCPCS code 67036 has a geometric mean cost of $3,435.61. Therefore, as shown in Table 12, for CY 2021 we are finalizing our proposal to create C9770 (*Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent*) and assign this code to APC 1561 (New Technology—Level 24 ($3001–$3500)).

TABLE 12: CY 2021 FINALIZED OPPS APC AND STATUS INDICATOR FOR HCPCS CODE C9770 ASSIGNED TO NEW TECHNOLOGY APC

CY 2021 Finalized HCPCS Code	Long Descriptor	Finalized CY 2021 OPPS SI	Finalized CY 2021 OPPS APC
C9770	Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent	T	1561

d. Bronchoscopy With Transbronchial Ablation of Lesion(s) by Microwave Energy

Effective January 1, 2019, CMS established HCPCS code C9751 (Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3–D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (for example, aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)). This microwave ablation procedure utilizes a flexible catheter to access the lung tumor via a working channel and may be used as an alternative procedure to a percutaneous microwave approach. Based on our review of the New Technology APC application for this service and the service's clinical similarity to existing services paid under the OPPS, we estimated the likely cost of the procedure would be between $8,001 and $8,500.

In claims data available for CY 2019 for the CY 2021 OPPS/ASC proposed rule, there were 4 claims reported for bronchoscopy with transbronchial ablation of lesions by microwave energy. Given the low volume of claims for the service, we proposed for CY 2021 to apply the policy we adopted in CY 2019, under which we utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median costs to calculate an

appropriate payment rate for purposes of assigning bronchoscopy with transbronchial ablation of lesions by microwave energy to a New Technology APC. We found the geometric mean cost for the service to be approximately $4,051, the arithmetic mean cost to be approximately $4,067, and the median cost to be approximately $4,067. All three potential statistical methodologies used to estimate the cost of the service procedure fall within the cost band for New Technology APC 1563, with the estimated cost being between $4,001 and $4,500. Accordingly, we proposed to change the assignment of the HCPCS code C9751 to APC 1563 (New Technology—Level 26 ($4001–$4500)), with a proposed payment rate of $4,250.50 for CY 2021.

Comment: Two commenters did not support our proposal to assign HCPCS code C9751 to APC 1563 (New Technology—Level 26 ($4001–$4500)), with a proposed payment rate of $4,250.50 for CY 2021. The commenters stated that there was not enough claims data to change the APC assignment for HCPCS code C9751, and that HCPCS code C9751 should continue to be assigned to APC 1571 (New Technology—Level 34 ($8001–$8500)) with a proposed payment rate of $8,250.50.

Response: Because of the low number of claims for HCPCS C9751, we utilized our equitable adjustment authority under section 1833(t)(2)(E) of the Act for our final rule analysis to calculate the geometric mean, arithmetic mean, and median costs to calculate a payment rate to assign bronchoscopy with transbronchial ablation of lesions by microwave energy to a New Technology APC. Even though the number of claims are small, it is the best data available to determine the cost of the procedure. The assignment of HCPCS code C9751 to APC 1571 was based on guidance from the developer of the procedure and our best estimates of the cost of the procedure. The claims data, however limited, provide evidence of the cost of the procedure based on service utilization rather than having to forecast the cost of procedure.

Therefore, we decided to use our low-volume methodology for new technology services to determine the payment rate for the service described by HCPCS code C9751. We found for our final rule analysis that the geometric mean cost for the service to be approximately $2,693, the arithmetic mean cost to be approximately $3,086, and the median cost to be approximately $3,708. The median was the statistical methodology that estimated the highest cost for the service and provides a reasonable estimate of the midpoint cost of the three claims that have been paid for this service. The payment rate calculated using this methodology falls within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3501–$4000)). Based on our updated analysis of the data, we have decided to implement our original proposal with modifications. For CY 2021, we will change the assignment of HCPCS code C9751 to APC 1562 (New Technology—Level 25 ($3501–$4000)) using our equitable adjustment authority under section 1833(t)(2)(E) of the Act and our low-volume new technology service methodology. The payment rate for C9751 will be based on the median cost of claims reported for the service since CY 2019 as the median cost is the highest estimated cost for the service, and the median provides a reasonable estimate of the midpoint cost of the three claims that have been paid for this service. Details regarding HCPCS code C9751 are shown in Table 13. We refer readers to Addendum B of the final rule for the final payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

TABLE 13: CY 2021 OPPS APC AND STATUS INDICATOR FOR HCPCS CODE C9751 ASSIGNED TO NEW TECHNOLOGY APC

CY 2021 HCPCS Code	Long Descriptor	Final CY 2021 OPPS SI	Final CY 2021 OPPS APC	Final CY 2021 OPPS Payment Rate
C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]	T	1562	Refer to OPPS Addendum B.

e. Fractional Flow Reserve Derived From Computed Tomography (FFRCT)

Fractional Flow Reserve Derived from Computed Tomography (FFRCT), also known by the trade name HeartFlow, is a noninvasive diagnostic service that allows physicians to measure coronary artery disease in a patient through the use of coronary CT scans. The HeartFlow procedure is intended for clinically stable symptomatic patients with coronary artery disease, and, in many cases, may avoid the need for an invasive coronary angiogram procedure. HeartFlow uses a proprietary data analysis process performed at a central facility to develop a three-dimensional image of a patient's coronary arteries, which allows physicians to identify the fractional flow reserve to assess whether or not patients should undergo further invasive testing (that is, a coronary angiogram).

For many services paid under the OPPS, payment for analytics that are performed after the main diagnostic/

image procedure are packaged into the payment for the primary service. However, in CY 2018, we determined that HeartFlow should receive a separate payment because the service is performed by a separate entity (that is, a HeartFlow technician who conducts computer analysis offsite) rather than the provider performing the CT scan. We assigned CPT code 0503T, which describes the analytics performed, to New Technology APC 1516 (New Technology—Level 16 ($1,401–$1,500)), with a payment rate of $1,450.50 based on pricing information provided by the developer of the procedure that indicated the price of the procedure was approximately $1,500. We did not have Medicare claims data in CY 2019 for CPT code 0503T, and we continued to assign the service to New Technology APC 1516 (New Technology—Level 16 ($1,401–$1,500)), with a payment rate of $1,450.50.

CY 2020 was the first year we had Medicare claims data to calculate the cost of HCPCS code 0503T. For the CY 2020 OPPS/ASC final rule, there were 957 claims with CPT code 0503T of which 101 of the claims were single frequency claims that were used to calculate the geometric mean of the procedure. We planned to use the geometric mean to report the cost of HeartFlow. However, the number of single frequency claims for CPT code 0503T was below the low-volume payment policy threshold for the proposed rule, and the number of single frequency claims was only two claims above the threshold for the new technology APC low-volume policy for the final rule. Therefore, we decided to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median using the CY 2018 claims data to determine an appropriate payment rate for HeartFlow using our new technology APC low-volume payment policy. While the number of single frequency claims was just above our threshold to use the low-volume payment policy, we still had concerns about the normal cost distribution of the claims used to calculate the payment rate for HeartFlow, and we decided the low-volume payment policy would be the best approach to address those concerns.

Our analysis found that the geometric mean cost for CPT code 0503T was $768.26, the arithmetic mean cost for CPT code 0503T was $960.12 and that the median cost for CPT code 0503T was $900.28. Of the three cost methods, the highest amount was for the arithmetic mean. The arithmetic mean fell within the cost band for New Technology APC 1511 (New Technology—Level 11 ($901–$1000)) with a payment rate of $950.50. The arithmetic mean helped to account for some of the higher costs of CPT code 0503T identified by the developer and other stakeholders that may not have been reflected by either the median or the geometric mean.

For CY 2021, we observed a significant increase in the number of claims billed with CPT code 0503T that were available for the CY 2021 OPPS/ASC proposed rule. Specifically, using the most recently available data for the CY 2021 OPPS/ASC proposed rule (that is, CY 2019), we identified 2,820 claims billed with CPT code 0503T including 415 single frequency claims. These totals were well above the threshold of 100 claims for a procedure to be evaluated using the new technology APC low-volume policy. Therefore, we proposed to use our standard methodology rather than the low-volume methodology we previously used to determine the cost of CPT code 0503T.

Our analysis of the available claims data for the proposed rule found the geometric mean cost for CPT code 0503T was approximately $851. Therefore, we proposed to reassign the service described by CPT code 0503T in order to adjust the payment rate to better reflect the cost for the service. While we considered proposing to reassign CPT code 0503T to APC 5724 (Level 4—Diagnostic Tests and Related Services), which had a proposed payment rate of around $903 based on the clinical and resource similarity to other services within that APC, we did not propose such reassignment because the payment rate for the new technology APC was closer to the geometric mean costs of CPT code 0503T. Nonetheless, we welcomed comments on whether reassignment to the clinical APC would be more appropriate. Therefore, we proposed to reassign the service described by CPT code 0503T to New Technology APC 1510 (New Technology—Level 10 ($801–$900)), with a proposed payment rate of $850.50 for CY 2021.

Comment: The developer of HeartFlow and multiple other commenters stated that the CPT code 0503T should not be assigned to New Technology APC 1510. Instead, they suggested that the HeartFlow procedure be assigned to APC 5593 (Level 3 Nuclear Medicine and Related Services) with a payment rate of around $1,270. The developer asserted that even though the payment for APC 5593 is substantially higher than the estimated cost of CPT code 0503T, the cost of the service fits reasonably well with the cost of other procedures assigned to APC 5593. The developer and other commenters also assert that the HeartFlow procedure has enough clinical similarity to other procedures currently assigned to the nuclear medicine and related services family. According to the developer and the other commenters, HeartFlow is comparable to other nuclear medicine procedures that are image analysis tests characterizing organ-specific function. The developer and the other commenters also note that cardiac CT procedures, which are used to identify coronary artery disease, are assigned to the nuclear medicine APC family. Finally, the developer cited two examples of procedures in the OPPS that are assigned to APCs where the procedure in question does not have clinical similarity to the other procedures in the APC.

Response: We disagree with the suggestion that CPT code 0503T should be assigned to APC 5593. The nuclear medicine and related procedures APC family describes diagnostic and therapeutic procedures, many of them involving imaging, where radiopharmaceuticals and other nuclear materials are critical supplies for the performance of the procedure. In comparison, HeartFlow is a computer algorithm that does not directly take images nor is it used on its own to generate a diagnosis for a patient. Instead, HeartFlow analyzes diagnostic images obtained through other medical procedures and assists with the interpretation of those diagnostic images to determine if a patient has coronary artery disease. There is little clinical similarity between the HeartFlow procedure and the procedures currently assigned to the nuclear medicine and related procedures, and we cannot support assigning CPT code 0503T to APC 5593.

Comment: Several commenters asserted the proposed payment rate for CPT code 0503T is too low and does not reflect their individual hospital's cost to use HeartFlow. Commenters mentioned cost issues, including the $1,100 list price for each individual HeartFlow service and the staff resources involved to transmit data to the HeartFlow analysis facility and review the results of the analyses performed by HeartFlow. Commenters suggested a range of potential payments for a HeartFlow procedure from $1,051 up to $1,451, and they encouraged CMS to use our equitable adjustment authority at section 1833(t)(2)(E) of the Act to establish a payment rate that would more closely reflect the costs the

commenters believe they are incurring to perform the HeartFlow procedure.

Response: For this CY 2021 OPPS/ASC final rule, we identified 3,188 claims billed with CPT code 0503T including 465 single frequency claims for CPT code 0503T. Our analysis has found that the geometric mean for CPT code 0503T is $804.35, and the geometric mean cost falls within the cost band for New Technology APC 1510 (New Technology—Level 10 ($801–$900)), which is similar to our results for the proposed rule. However, multiple commenters have noted that the FFRCT service costs $1,100 and that there are additional staff costs related to the submission of coronary CT image data for processing by HeartFlow.

HeartFlow is one of the first procedures utilizing artificial intelligence to be separately payable in the OPPS, and providers are still learning how to accurately report their charges to Medicare when billing for artificial intelligence services. This is especially the case for allocating the cost of staff resources between the HeartFlow procedure and the coronary CT imaging services. Therefore, we feel it would be appropriate to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to assign CPT code 0503T to the same New Technology APC in CY 2021 as in CY 2020 in order to provide payment stability and equitable payment for providers as they continue to become more familiar with the proper cost reporting for HeartFlow and other artificial intelligence services. As mentioned earlier in this section, CPT code 0503T was assigned to New Technology APC 1511 (New Technology—Level 11 ($901–$1000)) with a payment rate of $950.50 for CY 2020, and we will continue to assign CPT code 0503T to New Technology APC 1511 for CY 2021.

After reviewing all of the public comments, we have decided to finalize our proposal with modification by using our equitable adjustment authority under section 1833(t)(2)(E) of the Act to continue to assign CPT code 0503T to New Technology APC 1511 (New Technology—Level 11 ($901–$1000)) for CY 2021. We refer readers to Addendum B of the final rule for the final payment rates for all codes reportable under the OPPS. Addendum B is available via the internet on the CMS website.

f. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies

Effective January 1, 2020, we assigned three CPT codes (78431, 78432, and 78433) that describe the services associated with cardiac PET/CT studies to New Technology APCs. CPT code 78431 was assigned to APC 1522 (New Technology—Level 22 ($2001–$2500)) with a payment rate of $2,250.50. CPT codes 78432 and 78433 were assigned to APC 1523 (New Technology—Level 23 ($2501–$3000)) with a payment rate of $2,750.50.

We had not received any claims billed with CPT codes 78431, 78432, or 78433 prior to the proposed rule. Therefore, we proposed to continue to assign these CPT codes to the same new technology APCs as they were in CY 2020. The proposed CY 2021 payment rate for the codes can be found in Addendum B to the CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website).

Comment: Several commenters expressed their support for our proposal to assign CPT code 78431 to APC 1522 (New Technology—Level 22 ($2001–$2500)) with a payment rate of $2,250.50, and to assign CPT codes 78432 and 78433 to APC 1523 (New Technology—Level 23 ($2501–$3000)) with a payment rate of $2,750.50.

Response: We appreciate the support of the commenters for our proposal.

We have not received any claims for these services prior to this final rule. After our review of the public comments, we have decided to implement our proposal without modification. Table 14 reports code descriptors, status indicators, and APC assignments for these CPT codes.

TABLE 14: CY 2021 OPPS APC AND STATUS INDICATOR FOR CPT CODES 78431, 78432, AND 78433 ASSIGNED TO NEW TECHNOLOGY APCS

CPT Code	Long Descriptor	CY 2020 OPPS SI	OPPS CY 2020 APC	Final CY 2021 OPPS SI	Final OPPS CY 2021 APC
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	S	1522	S	1522
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability);	S	1523	S	1523
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability); with concurrently acquired computed tomography transmission scan	S	1523	S	1523

g. Pathogen Test for Platelets/Rapid Bacterial Testing

For the July 2017 update, the HCPCS Workgroup established HCPCS code Q9987 (Pathogen(s) test for platelets) effective July 1, 2017. This new code and the OPPS APC assignment was announced in the July 2017 OPPS quarterly update CR (Transmittal 3783, Change Request 10122, dated May 26, 2017). Because HCPCS code Q9987 represented a test to identify bacterial or other pathogen contamination in blood platelets, we assigned the code to a new technology APC, specifically, New Technology APC 1493 (New Technology—Level 1C ($21–$30)) with a status indicator ''S'' and a payment rate of $25.50. We note that temporary HCPCS code Q9987 was subsequently deleted on December 31, 2017, and replaced with permanent HCPCS code P9100 (Pathogen(s) test for platelets) effective January 1, 2018. For the January 2018 update, we continued to assign the new code to the same APC and status indicator as its predecessor code. Specifically, we assigned HCPCS code P9100 to New Technology APC 1493 and status indicator ''S''. For the CY 2019 update, we made no change to the APC or status indicator assignment for P9100, however, for the CY 2020 update, we revised the APC assignment from New Technology APC 1493 to 1494 (New Technology—Level 1D ($31–$40) based on the latest claims data used to set the payment rates for CY 2020. We discussed the revision in the CY 2020 OPPS/ASC final rule (84 FR 61219) and indicated that the reassignment to APC 1494 appropriately reflected the cost of the service.

For the CY 2021 OPPS/ASC proposed rule, we stated that we believed we had sufficient claims data to reassign the code from a New Technology APC to a clinical APC, and noted that HCPCS code P9100 has been assigned to a New Technology APC for over 3 years. As stated in section III.D. (New Technology APCs), a service is paid under a New Technology APC until sufficient claims data have been collected to allow CMS to assign the procedure to a clinical APC group that is appropriate in clinical and resource terms. We expect this to occur within two to three years from the time a new HCPCS code becomes effective. However, if we are able to collect sufficient claims data in less than 2 years, we would consider reassigning the service to an appropriate clinical APC. Since HCPCS code P9100 has been assigned to a new technology APC since July 2017, we believe that we should reassign the code to a clinical APC. Specifically, our claims data for the CY 2021 OPPS/ASC proposed rule showed a geometric mean cost of approximately $30 for HCPCS code P9100 based on 70 single claims (out of 1,835 total claims).

Based on resource cost and clinical homogeneity to the other services assigned to APC 5732 (Level 2 Minor Procedures), we believed that HCPCS code P9100 should be reassigned to clinical APC 5732, which had a geometric mean cost of approximately $33.

As we have stated several times since the implementation of the OPPS on August 1, 2000, we review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our analysis of the latest claims data. For the CY 2021 OPPS update, based on claims submitted between January 1, 2019, and December 30, 2019, our analysis of the latest claims data for the CY 2021 OPPS/ASC proposed rule supports reassigning HCPCS code P9100 to APC 5732 based on its clinical and resource homogeneity to the procedures and services in the APC. Therefore, we proposed to reassign HCPCS code P9100 from New Technology APC 1494 to clinical APC 5732 for CY 2021. The proposed CY 2021 payment rate for HCPCS code P9100 can be found in Addendum B to the CY 2021 OPPS/ASC proposed rule with comment period. In addition, we refer readers to Addendum D1 of the CY 2021 OPPS/ASC proposed rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

Comment: Two commenters expressed their support for our proposal.

Response: We appreciate the support of the commenters.

After reviewing the public comments for this proposal, we have decided to finalize our proposal without modification to reassign HCPCS code P9100 from New Technology APC 1494 to clinical APC 5732 for CY 2021. The final rule data supports our decision. The data show a geometric mean cost of approximately $31 for HCPCS code P9100 based on 75 single claims (out of 2,038 total claims), which is close to the payment rate of around $33 for APC 5732. The final CY 2021 payment rate for HCPCS code P9100 can be found in Addendum B to this CY 2021 OPPS/ASC final rule with comment period. In addition, we refer readers to Addendum D1 of this CY 2021 OPPS/ASC final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

h. V-Wave Medical Interatrial Shunt Procedure

A randomized, double-blinded, controlled IDE study is currently in progress for the V-Wave interatrial shunt. The V-Wave interatrial shunt is for patients with severe symptomatic heart failure and is designed to regulate left atrial pressure in the heart. All participants who passed initial screening for the study receive a right heart catheterization procedure described by CPT code 93451 (Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed). Participants assigned to the experimental group also receive the V-Wave interatrial shunt procedure while participants assigned to the control group only receive right heart catheterization. The developer of V-Wave was concerned that the current coding of these services by Medicare would reveal to the study participants whether they have received the interatrial shunt because an additional procedure code, CPT code 93799 (Unlisted cardiovascular service or procedure), would be included on the claims for participants receiving the interatrial shunt. Therefore, we created a temporary HCPCS code to describe the V-wave interatrial shunt procedure for both the experimental group and the control group in the study. Specifically, we established HCPCS code C9758 (Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study) to describe the service, and we assigned the service to New Technology APC 1589 (New Technology—Level 38 ($10,001–$15,000)).

No claims have been reported for HCPCS code C9758. Therefore, we proposed to continue to assign the service to New Technology APC 1589 for CY 2021. The proposed CY 2021 payment rate for V-Wave interatrial shunt procedure can be found in Addendum B to the proposed rule (which is available via the internet on the CMS website).

Comment: Three commenters including the developer of the V-Wave interatrial shunt procedure and the developer of the Corvia Medical interatrial shunt procedure requested that we delete HCPCS code C9758 because V-Wave has decided to no longer seek Medicare payment for its interatrial shunt procedure trial. The commenters believe that deleting HCPCS code C9758 will help prevent provider confusion with billing procedures describing the implementation of interatrial shunts.

Response: We do not intend to delete HCPCS code C9758 and believe that HCPCS code C9758 is sufficiently distinct from HCPCS code C9760 (Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study) that providers will not be confused about the appropriate service code to report.

Comment: Two commenters, including the developer of the V-Wave interatrial shunt procedure and the developer of the Corvia Medical interatrial shunt procedure, provided information about procedures that had comparable non-device service costs similar to the interatrial shunt procedures. One commenter suggested using the non-device cost of CPT code 93580 (Percutaneous transcatheter closure of congenital interatrial communication (that is, fontan fenestration, atrial septal defect) with implant) to approximate non-device costs for this procedure. The other commenter suggested that interatrial septal shunt procedures and percutaneous intracardiac closure procedures (CPTs 93580–93591) assigned to APC 5194 (Level 4—Endovascular Procedures) would describe the non-device costs of the interatrial shunt procedures.

Response: Based on the suggestions of the commenters, we averaged the non-device costs of the interatrial septal shunt procedures and percutaneous intracardiac closure procedures to estimate the non-device costs of the interatrial shunt procedures. Our estimate of the non-device costs of both the V-Wave interatrial shunt and Corvia Medical interatrial shunt procedures was around $6,500.

Comment: One commenter requested that we assign the V-Wave interatrial shunt procedure to a New Technology APC that reflects the cost of the procedure.

Response: We will assign the V-Wave interatrial shunt procedure to an APC that reasonably reflects the cost of the

procedure both when the device is implanted and when a placebo treatment occurs.

After reviewing the public comments and analyzing the cost of both the V-Wave interatrial shunt procedure and the Corvia Medical interatrial shunt procedure, we will finalize our proposal with modifications. We believe that similar resources and device costs are involved with the V-Wave interatrial shunt procedure and the Corvia Medical interatrial shunt procedure. Therefore, the difference in the payment for HCPCS codes C9758 and C9760 is based on how often the interatrial shunt is implanted when each code is billed. An interatrial shunt is implanted one-half of the time HCPCS code C9758 is billed. Therefore, we will reassign HCPCS code C9758 to New Technology APC 1590, which reflects the cost of having surgery every time and receiving the interatrial shunt one-half of the time when the procedure is performed. Details about the HCPCS code and its APC assignment are shown in Table 15. The final CY 2021 payment rate for the V-Wave interatrial shunt procedure can be found in Addendum B to the final rule.

TABLE 15: CY 2021 OPPS APC AND STATUS INDICATOR FOR BLINDED INTRATRIAL SHUNT PROCEDURE ASSIGNED TO A NEW TECHNOLOGY APC

HCPCS Code	Long Descriptor	2021 OPPS SI	2021 OPPS APC
C9758	Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study	T	1590

i. Corvia Medical Interatrial Shunt Procedure

Corvia Medical is currently conducting their pivotal trial for their interatrial shunt procedure. The trial started in Quarter 1 of CY 2017 and is scheduled to continue through CY 2021. On July 1, 2020, we established HCPCS code C9760 (Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study) to facilitate the implantation of the Corvia Medical interatrial shunt.

In the CY 2021 OPPS/ASC proposed rule, we proposed to assign HCPCS code C9760 to New Technology APC 1589. The proposed CY 2021 payment rate for Corvia Medical interatrial shunt procedure was found in Addendum B to the proposed rule (which is available via the internet on the CMS website).

Comment: Several commenters recommended revising the code descriptor for HCPCS code C9760 since the current descriptor inaccurately suggests that the code may include placebo control subjects who would not receive a shunt implant. The commenters specifically requested deleting the phrase ''or placebo control'' to eliminate any confusion on how this code should be reported.

Response: We agree with the commenters and have revised the long descriptor effective January 1, 2021 to read ''*Non-randomized, non-blinded procedure for NYHA Class II, III, IV heart failure; transcatheter implantation of interatrial shunt, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study.*'' The revised long descriptor for HCPCS code C9760 can also be found in the 2021 Alpha Numeric HCPCS File that is posted on the CMS HCPCS website, specifically, at *https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS*.

Comment: Two commenters, including the developer of the Corvia Medical interatrial shunt procedure and the developer of the V-Wave interatrial shunt procedure, provided information about procedures that had comparable non-device service costs similar to the interatrial shunt procedures. One commenter suggested using the non-device cost of CPT code 93580 (Percutaneous transcatheter closure of congenital interatrial communication (that is, fontan fenestration, atrial septal defect) with implant). The other commenter suggested that interatrial septal shunt procedures and percutaneous intracardiac closure procedures (CPTs 93580–93591) assigned to APC 5194 (Level 4—Endovascular Procedures) would describe the non-device costs of the interatrial shunt procedures.

Response: Based on the suggestions of the commenters, we averaged the non-device costs of the interatrial septal shunt procedures and percutaneous intracardiac closure procedures to estimate the non-device costs of the interatrial shunt procedures. Our estimated cost of the non-device costs of the both the Corvia Medical interatrial shunt and V-Wave interatrial shunt procedures was around $6,500.

Comment: Multiple commenters, including the developer of the Corvia Medical interatrial shunt procedure and the developer of the V-Wave interatrial shunt procedure, requested a higher payment rate for the procedure. Several commenters were concerned that the payment rate established for HCPCS

code C9760 would discourage providers from participating in the clinical trial, and the developer of the Corvia Medical interatrial shunt procedure stated that they had to assume all costs for the trial because of inadequate payment for the Corvia Medical interatrial shunt procedure. The developer of the V-Wave interatrial shunt procedure mentioned that HCPCS code C9760 is the service code they will use to report interatrial shunt procedures for their continuing study.

Response: As mentioned earlier, we decided to estimate the non-device costs of both the Corvia Medical interatrial shunt procedure and the V-Wave interatrial shunt procedure. We also plan to combine the non-device costs of the procedures with the costs of the interatrial shunt device to create a new estimate of the payment rate for HCPCS code C9760. HCPCS code C9760 can be used to report any non-randomized, non-blinded study related to the implantation of interatrial shunts where the device is implanted for every procedure reported.

After our review of the public comments, we intend to finalize our proposal with modifications. We believe that similar resources and device costs are involved with the Corvia Medical interatrial shunt procedure and the V-Wave interatrial shunt procedure. Therefore, the difference in the payment for HCPCS codes C9760 and C9758 is based on how often the interatrial shunt is implanted when each code is billed. The Corvia Medical interatrial shunt is implanted every time HCPCS code C9760 is billed. Therefore, we will reassign HCPCS code C9760 to New Technology APC 1592. We also will implement the commenters' suggestion to modify the code descriptor for HCPCS code C9760 to remove the phrase ''or placebo control,'' from the descriptor. Details about the HCPCS code and its APC assignment are shown in Table 16. The final CY 2021 payment rate for the Corvia Medical interatrial shunt procedure can be found in Addendum B to the final rule.

TABLE 16: CY 2021 OPPS APC AND STATUS INDICATOR FOR NON-RANDOMIZED, NON-BLINDED INTRATRIAL SHUNT PROCEDURE ASSIGNED TO A NEW TECHNOLOGY APC

HCPCS Code	Long Descriptor	2021 OPPS SI	2021 OPPS APC
C9760	Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (eg, ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study	T	1592

j. Supervised Visits for Esketamine Self-Administration (HCPCS Codes G2082 and G2083 APCs 1508 and 1511)

On March 5, 2019, FDA approved Spravato™ (esketamine) nasal spray, used in conjunction with an oral antidepressant, for treatment of depression in adults who have tried other antidepressant medicines but have not benefited from them (treatment-resistant depression (TRD)). Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by Spravato administration, and the potential for abuse and misuse of the product, it is only available through a restricted distribution system under a Risk Evaluation and Mitigation Strategy (REMS). A REMS is a drug safety program that FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

A treatment session of esketamine consists of instructed nasal self-administration by the patient, followed by a period of post-administration observation of the patient under direct supervision of a health care professional. Esketamine is a noncompetitive N-methyl D-aspartate (NMDA) receptor antagonist. It is a nasal spray supplied as an aqueous solution of esketamine hydrochloride in a vial with a nasal spray device. This is the first FDA approval of esketamine for any use. Each device delivers two sprays containing a total of 28 mg of esketamine. Patients would require either two (2) devices (for a 56mg dose) or three (3) devices (for an 84 mg dose) per treatment.

Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by Spravato administration, and the potential for abuse and misuse of the product, Spravato is only available through a restricted distribution system under a REMS; patients must be monitored by a health care provider for at least 2 hours after receiving their Spravato dose; the prescriber and patient must both sign a Patient Enrollment Form; and the product will only be administered in a certified medical office where the health care provider can monitor the patient. Please refer to the CY 2020 PFS final rule and interim final rule for more information about supervised visits for esketamine self-administration (84 FR 63102 through 63105).

To facilitate prompt beneficiary access to the new, potentially life-saving treatment for TRD using esketamine, we created two new HCPCS G codes, G2082 and G2083, effective January 1, 2020. HCPCS code G2082 is for an outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration and includes 2 hours post-administration observation. HCPCS code G2082 was assigned to New Technology APC 1508 (New

Technology—Level 8 ($601–$700)) with a payment rate of $650.50. HCPCS code G2083 describes a similar service to HCPCS code G2082, but involves the administration of more than 56 mg of esketamine. HCPCS code G2083 was assigned to New Technology APC 1511 (New Technology—Level 11 ($901–$1000)) with a payment rate of $950.50.

No Medicare OPPS claims had been reported for either HCPCS code G2082 or G2083 prior to the CY 2021 OPPS/ASC proposed rule. Therefore, we proposed to continue to assign HCPCS code G2082 to New Technology APC 1508 and to assign HCPCS code G2083 to New Technology APC 1511. The proposed CY 2021 payment rate for esketamine self-administration can be found in Addendum B to proposed rule (which is available via the internet on the CMS website).

Comment: Two commenters supported our proposal.

Response: We appreciate the support of the commenters.

We have not received any OPPS claims for this code prior to this final rule. After reviewing the public comments for this proposal, we have decided to implement our proposal without modification to assign HCPCS code G2082 to New Technology APC 1508 and to assign HCPCS code G2083 to New Technology APC 1511. Details about the HCPCS codes and their APC assignments are shown in Table 17. The final CY 2021 payment rate for esketamine self-administration can be found in Addendum B to the proposed rule (which is available via the internet on the CMS website).

TABLE 17: CY 2021 OPPS APC AND STATUS INDICATOR FOR ESKETAMINE SELF-ADMINISTRATION HCPCS CODES ASSIGNED TO NEW TECHNOLOGY APCS

CPT Code	Long Descriptor	CY 2020 OPPS SI	OPPS CY 2020 APC	Final CY 2021 OPPS SI	Final OPPS CY 2021 APC
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation	S	1508	S	1508
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation	S	1511	S	1511

D. APC-Specific Policies

1. Administration of Lacrimal Ophthalmic Insert Into Lacrimal Canaliculus (APC 5692)

HCPCS code J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0.1 mg*) is a drug indicated ''for the treatment of ocular inflammation and pain following ophthalmic surgery.''[4] Stakeholders assert that this drug is administered through CPT code 0356T (*Insertion of drug-eluting implant (including punctal dilation and implant removal when performed) into lacrimal canaliculus, each*). Stakeholders also state the drug is inserted in a natural opening in the eyelid (called the punctum) and that the drug is designed to deliver a tapered dose of dexamethasone to the ocular surface for up to 30 days.

HCPCS code J1096 is currently on pass-through status and assigned to APC 9308 (Dexametha opth insert 0.1 mg) with status indicator ''G''. Please see section V.A.5. of this final rule with comment period for further information

[4] 1 Dextenza. FDA Package Insert. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208742s001lbl.pdf.*

regarding the pass-through status of J1096. CPT code 0356T is currently assigned to status indicator ''Q1,'' indicating conditionally packaged payment under the OPPS. Packaged payment applies if a code assigned status indicator ''Q1'' is billed on the same claim as a HCPCS code assigned status indicator ''S'', ''T'', or ''V''. Accordingly, based on the OPPS assigned status indicator, CPT code 0356T is assigned to payment indicator ''N1'' in the ASC setting, meaning a packaged service/item.

We refer readers to Addendum D1 of this final rule for a list of OPPS status indicators and their definitions, available via the internet on the CMS website. We also refer readers to Addendum AA for ASC payment indicator assignments and to Addendum DD1 for payment indicator definitions, available via the internet on the CMS website.

CPT code 0356T is assigned to APC 5692 (Level 2 Drug Administration). With regards to APCs 5691 (Level 1 Drug Administration) and APC 5692 (Level 2 Drug Administration), and as stated in the CY 2018 OPPS/ASC final rule with comment period, our overarching goal is to make OPPS payments for all services paid under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule. To achieve this goal, it is important that we are consistent in our approach to packaging items and services under the established packaging categories. Therefore, in the CY 2018 OPPS/ASC final rule with comment period, after consideration of the public comments we received, we finalized, without modification, the proposed policy to conditionally package low-cost drug administration services assigned to APC 5691 and APC 5692 (82 FR 52391 through 52393). Additionally, conditional packaging for Levels 1 and 2 Drug Administration services is consistent with the ancillary packaging policy that was adopted in the 2015 OPPS/ASC Final Rule with comment period (79 FR 66819 through 66822). Accordingly, in the CY 2021 OPPS/ASC Proposed Rule, we did not propose to change the OPPS status indicator assignment and APC placement, or ASC payment indicator assignment for CPT code 0356T.

Comment: Several commenters had concerns with continuing the same APC placement of APC 5692 for CPT code 0356T for CY 2021. Commenters generally advocated for separate payment for this CPT code through a change in status indicator. A few commenters suggested alternative APC placements, such as APC 5501 (Level 1 Extraocular, Repair, and Plastic Eye Procedures), APC 5693 (Level 3 Drug Administration), or APC 1504 (New Technology—Level 4), whereas other commenters requested a larger payment in general without a specific APC placement suggestion. Several stakeholders commented that the clinical importance of providing HCPCS code J1096 to patients is that it reduces ocular pain, inflammation, and reduces the burden of topical eyedrop application.

Additionally, providers stated that they usually perform CPT code 0356T to administer HCPCS code J1096 after the conclusion of ophthalmic surgeries. Most commonly, providers cited using CPT code 0356T to administer HCPCS code J1096 after surgeries such as cataract, glaucoma, and corneal surgeries. Commenters believe the procedure is a distinct surgical procedure that requires additional operating room time and resources. Commenters were concerned that the lack of increased or separate payment may reduce access to HCPCS J1096, particularly in the ASC setting.

Response: We thank commenters for their feedback. After careful consideration of the statements from commenters, we continue to believe that assignment of CPT code 0356T to APC 5692, with an OPPS status indicator ''Q1'' and an associated ASC payment indicator of ''N1'', is appropriate based on its clinical and resource use similarity to other services assigned to that APC. Commenters have stated that CPT code 0356T is performed during ophthalmic surgeries such as cataract surgeries. We do not find it appropriate to compare CPT code 0356T to that of an independent procedure when performed during these other ophthalmic surgeries. We continue to believe that conditionally packaging the payment for CPT code 0356T into the payment for these primary procedures is appropriate. This is consistent with our policy to conditionally package low-cost drug administration services assigned to APC 5691 (Level 1 Drug Administration) and APC 5692 (Level 2 Drug Administration). We note the policy established in the CY 2018 OPPS to conditionally package low-cost drug administration services assigned to APC 5691 and APC 5692 (82 FR 52391 through 52393). Also, we note that the conditional packaging of drug administration supports our overarching goal to make payments for all services paid under the OPPS and ASC payment system more consistent with those of a prospective payment system and less like those of a per-service fee schedule. We believe that packaging encourages efficiency and is an essential component of a prospective payment system, and that packaging payments for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service is a fundamental part of the OPPS.

After consideration of the public comments, we are finalizing our proposed policy without modification to assign CPT code 0356T to APC 5692 (Level 2 Drug Administration) with OPPS status indicator ''Q1'' in the CY 2021 OPPS. Based on those assignments, we are also finalizing an ASC payment indicator for CPT code 0356T of ''N1'' under the CY 2021 ASC payment system.

2. Chimeric Antigen Receptor T-Cell (CAR T-Cell) Therapy (APCs 5694, 9035, 9194, and 9391)

Chimeric Antigen Receptor T-Cell (CAR T-cell) therapy is a cell-based gene therapy in which T-cells are collected and genetically engineered to express a chimeric antigen receptor that will bind to a certain protein on a patient's cancerous cells. The CAR T-cells are then administered to the patient to attack certain cancerous cells and the individual is observed for potential serious side effects that would require medical intervention. We refer readers to previous discussions in the OPPS/ASC final rules with comment period for background regarding the specific CAR T-cell products, in both the CY 2020 OPPS/ASC final rule with comment period (84 FR 61231 through 61234) and the CY 2019 OPPS/ASC final rule with comment period (83 FR 58904 through 58908). In addition, for discussion about CY 2021 OPPS payment policies for separately paid drugs with pass-through status expiring or continuing in CY 2021, please see sections V.A.4. and V.A.5. of this final rule with comment period.

The AMA created four Category III CPT codes that are related to CAR T-cell therapy, effective January 1, 2019. As discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58904 through 58908) and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61231 through 61234), we finalized our proposal to assign procedures described by CPT codes 0537T, 0538T, and 0539T to status indicator ''B'' (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x)) to indicate that the services are not paid under the OPPS. The procedures described by CPT codes 0537T, 0538T, and 0539T describe 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. We also finalized that the procedures described by CPT code 0540T would be assigned status indicator ''S'' (Procedure or Service, Not Discounted when Multiple) and APC 5694 (Level 4 Drug Administration) for CY 2019 and CY 2020, and made no proposal to change the assignment for CY 2021. Additionally, the National Uniform Billing Committee (NUBC) established CAR T-cell-related revenue codes and a value code to be reportable on Hospital Outpatient Department (HOPD) claims effective for claims received on or after April 1, 2019.

We made no specific proposal related to the CAR T-cell preparation codes, as described by CPT codes 0537T, 0538T, 0539T. As listed in Addendum B of the CY 2021 OPPS/ASC proposed rule, we proposed to continue to assign procedures described by these CPT codes, 0537T, 0538T, and 0539T, to status indicator ''B'' (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x)) to indicate that the services are not paid under the OPPS. We proposed to continue to assign CPT code 0540T to status indicator ''S'' (Procedure or Service, Not Discounted when Multiple) and APC 5694 (Level IV Drug Administration).

Comment: Several commenters opposed our proposal to continue to assign status indicator ''B'' to CPT codes 0537T, 0538T, and 0539T for CY 2021. Commenters stated that a change in status indicator would be appropriate, with a preference for assigning CPT codes 0537T, 0538T, and 0539T to status indicator ''Q1''. Commenters believed that the procedures these CPT codes describe did not represent the steps required to manufacture the CAR T-cell product, as CMS has stated. Generally, those advocating for a change in status indicator contend this change is necessary to allow services furnished to the patient to be eligible for payment and for hospitals to be paid appropriately for the services they provide during each step of the CAR T-cell process. Commenters asked CMS to release new cost centers and to revise the instructions in MLN Matters Article SE19009 accordingly.

Response: We thank the commenters for their feedback. CMS does not believe that separate or packaged payment under the OPPS is necessary for the procedures described by CPT codes 0537T, 0538T, and 0539T for CY 2021. The procedures described by CPT codes 0537T, 0538T, and 0539T describe 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. Additionally, we note that CAR T-cell therapy is a unique therapy approved as a biologic, with unique preparation procedures, that cannot be directly compared to other therapies or existing CPT codes. We note that the current HCPCS coding for the currently approved CAR T-cell therapies include leukapheresis and dose preparation procedures, as these services are included in the manufacturing of these biologicals. Therefore, payment for these services is incorporated into the drug codes. Please see Table 18 for HCPCS coding for CAR T-cell therapies.

TABLE 18. – CAR-T THERAPIES FINAL SI AND APC ASSIGNMENT FOR HCPCS CODES Q2041, Q2042, AND C9073 FOR CY 2021

HCPCS Code	Long Descriptor	Final CY 2021 APC
Q2041*	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	9035
Q2042*	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	9194
C9073*	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	9391

*The final CY 2021 OPPS payment rates are located in Addendum B to this CY 2021 OPPS/ASC final rule.

We note that although there is no payment associated with CPT codes 0537T, 0538T, and 0539T for reasons stated previously, these codes can still be reported to CMS for tracking purposes. We thank commenters for their feedback related to cost centers and our guidance contained in MLN Matters Article SE19009.[5] We are not revising this document at this time, but appreciate the feedback from stakeholders. Also, we would like to note that HOPDs can bill Medicare for reasonable and necessary services that are otherwise payable under the OPPS, and we believe that the comments in reference to payment for services in settings not payable under the OPPS are outside the scope of this proposed rule. Accordingly, we are not revising the existing codes for CAR T-cell therapies to remove leukapheresis and dose preparation procedures, and we are not accepting the recommendations at this time to revise the status indicators for procedures described by CPT codes 0537T, 0538T, and 0539T. We will continue to evaluate and monitor payment for CAR T-cell therapies.

In summary, after consideration of the public comments we received, we are finalizing our proposal to assign status indicator ''B'' to CPT codes 0537T, 0538T, and 0539T for CY 2021. Additionally, we are continuing our policy from CY 2019 to assign status indicator ''S'' to CPT code 0540T for CY 2021. Table 19 below shows the final SI

[5] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE19009.pdf.*

and APC assignments for HCPCS codes 0537T, 0538T, 0539T, and 0540T for CY 2021. For more information on CY 2021 OPPS final status indicators, APC assignments, and payment rates for HCPCS codes, including the CAR T-cell drug codes, we refer readers to Addendum B to this final rule with comment period. In addition, the status indicator definitions can be found in Addendum D1 (OPPS Payment Status Indicators for CY 2021) to this final rule with comment period. Both Addendum B and D1 are available via the internet on the CMS website.

TABLE 19.-CAR-T PREPARATION AND ADMINISTRATION FINAL SI AND APC ASSIGNMENT FOR CPT CODES 0537T, 0538T, 0539T, AND 0540T FOR CY 2021

CPT Code	Long Descriptors	Proposed CY 2021 SI	Final CY 2021 SI	Final CY 2021 APC
0537T	Chimeric antigen receptor t-cell (car-t) therapy; harvesting of blood-derived t lymphocytes for development of genetically modified autologous car-t cells, per day	B	B	N/A
0538T	Chimeric antigen receptor t-cell (car-t) therapy; preparation of blood-derived t lymphocytes for transportation (eg, cryopreservation, storage)	B	B	N/A
0539T	Chimeric antigen receptor t-cell (car-t) therapy; receipt and preparation of car-t cells for administration	B	B	N/A
0540T	Chimeric antigen receptor t-cell (car-t) therapy; car-t cell administration, autologous	S	S	5694

3. Eustachian Tube Balloon Dilation Procedure (APC 5165)

For the CY 2021 update, the CPT Editorial Panel established CPT codes 69705 and 69706 to describe the eustachian tube balloon dilation (ETBD) surgical procedure effective January 1, 2021. Prior to CY 2021, this surgical procedure was described by HCPCS code C9745.

In 2017, CMS received a new technology application for the transnasal flexible balloon catheter eustachian tube dilation surgical procedure, which is associated with the Acclarent Aera Eustachian Tube Balloon Dilation System, and established a new code, specifically, HCPCS code C9745. Based on the estimated cost for the bilateral placement of the eustachian tube balloon dilation devices, we assigned the code to APC 5165 (Level 5 ENT Procedures) with a payment rate of $4,130.94 effective July 1, 2017. We announced the new code, interim SI and APC assignments, and payment rate in the July 2017 quarterly update to the OPPS (Transmittal 3783, Change Request 10122, dated May 26, 2017).

For the CY 2018 update, we made no change to the APC assignment and continued to assign HCPCS code C9745 to APC 5165 with a payment rate of $4,338.79. We note that OPPS payment rates for the CY 2018 update were based on claims submitted between January 1, 2016 through December 30, 2016, that were processed on or before June 30, 2017. Because HCPCS code C9745 was established on July 1, 2017, we had no claims data for the procedure for use in CY 2018 ratesetting.

For the CY 2019 update, based on our analysis of the claims data, we made no change to the payment assignment and continued to assign HCPCS code C9745 to APC 5165. Specifically, our claims data showed a geometric mean cost of approximately $4,385 for HCPCS code C9745 based on 217 single claims (out of 218 total claims), which was consistent with the geometric mean cost of about $4,462 for APC 5165. Consequently, we retained HCPCS code C9745 in APC 5165.

Similarly, for CY 2020, we made no change to the APC assignment for HCPCS code C9745, consistent with our claims data. Based on claims submitted between January 1, 2018 through December 30, 2018, that were processed on or before June 30, 2019, the geometric mean cost for HCPCS code C9745 was approximately $4,547 based on 577 single claims (out of 582 total claims), which is in line with the geometric mean cost of $4,746 for APC 5165. Therefore, we maintained HCPCS code C9745 in APC 5165.

For CY 2021, we proposed to delete HCPCS code C9745 and assign CPT code 69705 to APC 5164 (Level 4 ENT Procedures) with a proposed OPPS payment of $2,776.63 and assign CPT code 69706 to APC 5165 (Level 5 ENT Procedures) with a proposed OPPS payment of $5,150.60. Because HCPCS code C9745 was on the ASC Covered Surgical Procedures list, we also proposed to assign CPT code 69705 to ASC payment indicator ''J8'' (device-intensive) with a proposed ASC payment of $1,564.17. Similarly, we proposed to assign CPT code 69706 to ASC payment indicator ''J8'' (device-intensive) with a proposed ASC payment of $3,453.23. We note that CPT codes 69705 and 69706 were listed as placeholder codes 697XX and 697X1, respectively, in OPPS Addendum B and ASC Addendum AA to the CY 2021 OPPS/ASC proposed rule.

Comment: Some commenters expressed concern with the proposed assignment to APC 5164 for CPT code 69705 (unilateral procedure) and stated that the proposed assignment will negatively affect the reimbursement of the procedure in the ASC setting, and ultimately decrease access to the procedure. They stated that the major portion of the procedure cost is the device used in the procedure, and reported the device cost is about $2,180, which is used for each procedure, regardless of whether it is a unilateral or bilateral procedure. In addition, they stated that in the CY 2021 Physician Fee Schedule (PFS) proposed rule, the

estimate for the non-facility payment for CPT codes 69705 and 69706 includes the full cost of the device kit, specifically, $3,092.81 for CPT code 69705 (unilateral) and $3,183.14 for CPT code 69706 (bilateral). To ensure fair reimbursement for unilateral procedures, they recommended that CMS assign both codes to APC 5165. However, in the event the recommendation is not accepted, they urged CMS to reconsider the device-intensive calculation for CPT code 69705 to reflect the cost of the device kit for unilateral procedures in the ASC setting; otherwise, commenters contended the ASC payment will be reduced below the actual cost of the device kit.

Response: Our medical advisors advised that the procedure described by CPT code 69705, while performed in the hospital outpatient setting, will primarily be performed in either the physician office or ASC setting. To ensure that Medicare beneficiaries have access to the procedure, we believe that it is appropriate to reassign CPT code 69705 (unilateral) to the same APC as CPT code 69706 (bilateral). That is, we believe that reassigning CPT code 69705 to APC 5165 will better reflect the device cost to perform this procedure either unilaterally or bilaterally when furnished in either the hospital outpatient or the ASC setting.

In summary, after consideration of the public comments, we are finalizing our proposal, without modification, to assign CPT code 69706 to APC 5165. However, we are finalizing our proposal, with modification, to assign CPT code 69705 to APC 5165 for CY 2021. We note that we are deleting HCPCS code C9745 on December 31, 2020, since it has been replaced with CPT codes 69705 and 69706 effective January 1, 2021. Table 20 lists the final SI and APC assignments for the two codes. The final CY 2021 OPPS payment rate for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

TABLE 20.— FINAL APC AND SI ASSIGNMENTS FOR CPT CODES 69705 and 69706 FOR CY 2021

CPT Code	CY 2021 OPPS/ASC Proposed Rule Placeholder Code	Long Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
C9745	N/A	Nasal endoscopy, surgical; balloon dilation of eustachian tube	D	N/A	D	N/A
69705	697XX	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); unilateral	J1	5164	J1	5165
69706	697X1	Nasopharyngoscopy, surgical, with dilation of eustachian tube (that is, balloon dilation); bilateral	J1	5165	J1	5165

4. Eye-Movement Analysis Without Spatial Calibration (APC 5734)

For July 2020, the CPT Editorial Panel established a new CPT code 0615T, effective July 1, 2020, to describe eye-movement analysis without spatial calibration that involves the use of the EyeBOX system as an aid in the diagnosis of concussion, also known as mild traumatic brain injury (mTBI). The EyeBOX is intended to measure and analyze eye movements as an aid in the diagnosis of concussion within one week of head injury in patients 5 through 67 years of age in conjunction with a standard neurological assessment of concussion. A negative EyeBOX classification may correspond to eye movement that is consistent with a lack of concussion. A positive EyeBOX classification corresponds to eye movement that may be present in both patients with or without a concussion.

We included this new code in the July quarterly OPPS update CR (Transmittal 10224, Change Request 11814, dated July 15, 2020). Effective July 1, 2020, we assigned CPT code 0615T to APC 5734 (Level 4 Minor Procedures) with status indicator ''Q1'' (conditionally packaged) and a CY 2020 OPPS payment rate of $109.03 as reflected in the Addendum B to the July 2020 quarterly OPPS update.

As displayed in the Addendum B to the 2021 ASC/OPPS Proposed Rule, we proposed to assign 0615T to APC 5734 with status indicator ''Q1'' and a proposed OPPS payment rate of $113.23 for CY 2021. We also assigned this code to comment indicator ''NP'' in Addendum B to indicate that this code is new effective July 1, 2020, and that public comments would be accepted on its proposed status indicator assignment.

Comment: A commenter was concerned that what they believed was a lack of adequate, separate payment would strongly discourage hospitals from providing this important new technology to their patients. The commenter urged CMS to: (1) Change the APC assignment of CPT code 0615T to APC 5722 (Level 2 Diagnostic Tests and Related Services) with a proposed OPPS payment rate of $269.85 and (2) change the status indicator for the service to ''S'' to allow for a separate payment under the OPPS.

The commenter asked that CMS assign CPT code 0615T to APC 5722 for two reasons: (1) The current and proposed reimbursement rates for services in APC 5734 are inadequate to pay hospitals appropriately for the costs

of furnishing the EyeBOX test; and (2) the clinical characteristics and resources associated with 0615T are more similar to codes in APC 5722 than services in APC 5734.

Response: We note that OPPS payment rates for the CY 2021 final rule are based on claims submitted between January 1, 2019 through December 31, 2019, that were processed on or before June 30, 2020. Because HCPCS code 0615T was established on July 1, 2020, we did not have claims data for CY 2021 OPPS ratesetting.

In terms of the resource similarity of CPT code 0615T to other eye-related diagnostic tests that are assigned to APC 5722, such as CPT code 92240 (Indocyanine-green angiography (includes multiframe imaging) with interpretation and report, unilateral or bilateral) and CPT code 92242 (Fluorescein angiography and indocyanine-green angiography (includes multiframe imaging) performed at the same patient encounter with interpretation and report, unilateral or bilateral), the EyeBOX test does not involve an injection. Therefore, we do not believe that the resource costs for CPT code 0615T are comparable to other eye-related diagnostic tests in APC 5722. Updated claims data for this final rule with comment period indicate that the geometric mean cost of APC 5722 is $257.61, while the geometric mean cost of APC 5734 is $109.05. However, because there were no claims for CPT code 0615T in the CY 2021 updated data set, we have decided not to make any changes to the proposed CY 2021 APC assignment and to assign the code to the APC with the lower geometric mean cost. Based on these findings, we believe that maintaining assignment of APC 5734 for CPT code 0615T for CY 2021 is appropriate.

In response to the comment related to status indicator ''Q1'', we note that status indicator ''Q1'' listed in the OPPS Addendum D1 to this 2021 OPPS/ASC final rule with comment period allows for up to three potential payment assignments:

- Packaged APC payment if billed on the same claim as a HCPCS code assigned status indicator ''S'', ''T'', or ''V''; or
- Composite APC payment if billed with specific combinations of services based on OPPS composite-specific payment criteria. Payment is packaged into a single payment for specific combinations of services; or
- In other circumstances, payment is made through a separate APC payment.

Depending on the procedures submitted on the claim and whether the procedure described by CPT code 0615T is performed with any other services on the same day, the procedure described by CPT code 0615T may be paid separately through an APC (in this case APC 5734) or receive packaged payment when accompanying a more significant procedure that is reported on the claim. Based on the nature of this procedure, which may be performed by itself or with other procedures on the same claim, we believe that the continued assignment of status indicator ''Q1'' is appropriate for the procedure described by CPT code 0615T.

As we do every year, we will reevaluate the APC assignment for CPT code 0615T for the next rulemaking cycle. We note that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to assign CPT code 0615T to status indicator ''Q1'' and APC 5734 for CY 2021. The final CY 2021 payment rate for the CPT code can be found in Addendum B to this final rule with comment period (which is available via the internet on the CMS website).

5. Gynecologic Procedures and Services (APC 5416)

For CY 2021, we proposed to continue to assign CPT code 0404T (Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency) to APC 5416 (Level 6 Gynecologic Procedures) with a proposed payment of $6,929.92. CPT code 0404T describes the procedure associated with the Sonata System, which is used for the treatment of symptomatic uterine fibroids. We note that CPT code 0404T was effective on January 1, 2016.

Comment: Several commenters stated that the proposed APC payment rate is insufficient to compensate hospital outpatient departments for the resources needed to perform the procedure. They indicated that the combined cost of the single-use handpiece, capital equipment, supplies, screening labs, anesthesia, medication, and facility and personnel overhead are higher than the OPPS payment rate. The commenters asserted that the proposed payment will significantly limit patient access to the procedure because it does not cover the total cost of the surgery. One commenter acknowledged that the proposed payment appropriately reimburses for hospital outpatient costs, but believed the ASC proposed payment of $2,763.68 significantly underpays for the procedure in the ASC setting. The same commenter explained that CMS has no claims data for the code because the procedure is rarely performed on Medicare patients, and also due to the device's commercial availability. Although the CPT code was effective January 2016, because of manufacturing issues, the company was unable to submit their FDA application until a couple of years later. The company eventually received market approval from the FDA in August 2018 and the device was commercially available in late summer/early Fall 2019. To ensure access to the procedure, the commenters suggested reassigning CPT code 0404T to either:

- APC 5362 (Level 2 Laparoscopy and Related Services) with a proposed payment rate of $9,041.94 because the procedure cost is similar to these procedures:
  - CPT code 43210 (Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed);
  - CPT code 50593 (Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy);
  - CPT code 58546 (Laparoscopy, surgical, myomectomy, excision; 5 or more intramural myomas and/or intramural myomas with total weight greater than 250 g); and
  - CPT code 58674 (Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency), or
- APC 5376 (Level 6 Urology and Related Services) with a proposed payment of $8,395.62 because the procedure cost is similar to these procedures:
  - CPT code 55873 (Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring); and
  - CPT code 0421T (Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed)).

Response: For CY 2021, OPPS payments are developed based on claims submitted between January 1, 2019 through December 31, 2019, and processed through June 30, 2020. For this final rule with comment period, we have no claims data for this code. As explained by a commenter, CPT code 0404T is a procedure not commonly performed on Medicare beneficiaries. In addition, we disagree with the commenters' assessment that CPT code

0404T is similar to the codes they have referenced. CPT code 0404T is not a urology, kidney, or esophagogastroduodenum-related procedure, nor is it a laparoscopy procedure. We believe that the code is appropriately placed in APC 5416 based on its clinical homogeneity and resource costs to the other gynecology-related procedures in the APC. We agree with the commenter who believed that the proposed OPPS payment for the service is adequate to cover the cost of providing the procedure in the hospital outpatient setting.

For a discussion on the ASC payment for CPT code 0404T, we refer readers to the ASC payment section of this CY 2021 OPPS/ASC final rule with comment period, specifically, section XIII. (Updates to the Ambulatory Surgical Center (ASC) Payment System).

Comment: Some commenters suggested designating CPT code 0404T as device-intensive under the OPPS so that facilities can be paid appropriately for furnishing the procedure in the ASC setting. They also recommended establishing an offset percentage that is higher than the default 31 percent based on invoice pricing data provided to CMS by the device manufacturer so that payment for the procedure in the ASC setting includes the cost of the device.

Response: We refer readers to section IV. B. (Device-Intensive Procedures) for the discussion related to the OPPS device offset for the code. For a discussion of the ASC procedures designed as device intensive, please see section XIII.C.1. of this final rule with comment period.

In summary, after consideration of the public comments, we are finalizing our proposal, without modification, and assigning CPT code 0404T to APC 5416 for CY 2021. The final CY 2021 OPPS payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) assignments for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

6. Hemodialysis Arteriovenous Fistula (AVF) Procedures (APC 5194)

For CY 2019, based on two new technology applications received by CMS for hemodialysis arteriovenous fistula creation, CMS established two new HCPCS codes to describe the surgical procedure associated with the two technologies since no specific CPT codes exist. Specifically, CMS established HCPCS code C9754 for the Ellipsys System and C9755 for the WavelinQ System effective January 1, 2019. The complete descriptors for both codes are as follows:

- C9754 (Creation of arteriovenous fistula, percutaneous; direct, any site, including all imaging and radiologic supervision and interpretation, when performed and secondary procedures to redirect blood flow (*e.g.,* transluminal balloon angioplasty, coil embolization, when performed))
- C9755 (Creation of arteriovenous fistula, percutaneous using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (*e.g.,* vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, venography, and/or ultrasound, with radiologic supervision and interpretation, when performed)

Both HCPCS codes were assigned to APC 5193 (Level 3 Endovascular Procedures) with a payment rate of $9,669.04 for CY 2019. For CY 2020, as discussed in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61246), we revised the assignment for both codes to APC 5194 (Level 4 Endovascular Procedures) with a payment rate of $15,939.97.

For the July 2020 update, we deleted HCPCS codes C9754 and C9755 on June 30, 2020, and replaced them with G-codes effective July 1, 2020 to enable physicians to report the procedures when performed in the physician office setting. Specifically, we deleted HCPCS code C9754 on June 30, 2020 because it was replaced with HCPCS code G2170 effective July 1, 2020. Similarly, we deleted HCPCS code C9755 on June 30, 2020 because it was replaced with HCPCS code G2171 effective July 1, 2020. Below are the complete descriptors for HCPCS codes G2170 and G2171:

- G2170 (Percutaneous arteriovenous fistula creation (AVF), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (*e.g.,* transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed)
- G2171 (Percutaneous arteriovenous fistula creation (AVF), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (*e.g.,* vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, enography, and/or ultrasound, with radiologic supervision and interpretation, when performed)

We deleted the C-codes based on concerns from stakeholders that physicians are reluctant to perform the Ellipsys procedure in the physician office setting without a specific HCPCS code. With the deletion of the C-codes, we crosswalked the APC assignment and payment rate for the C-codes to the new G-codes. We note that C-codes are not reportable on Medicare physician office claims, whereas G-codes are reportable on physician office, hospital outpatient, and ambulatory surgical center claims.

For CY 2021, we proposed to reassign HCPCS code G2170 (Ellipsys System) from APC 5194 to APC 5193 (Level 3 Endovascular Procedures) with a proposed payment rate of $10,222.32, based on the latest claims data. Specifically, based on the predecessor HCPCS code C9754, our claims data for the proposed rule showed a HCPCS geometric mean cost of approximately $10,068 based on 57 single claims (out of 57 total claims), which is comparable to the geometric mean cost of about $9,850 for APC 5193 rather than the geometric mean cost of approximately $15,753 for APC 5194. In addition, we proposed to maintain the assignment to APC 5194 for G2171 (WavelinQ System) because our claims data for the proposed rule, based on predecessor HCPCS code C9755, showed a geometric mean cost of about $13,519 based on 182 single claims (out of 186 total claims), which is consistent with the geometric mean cost of about $15,753 for APC 5194.

At the August 31, 2020 HOP Panel Meeting, a presenter requested that we maintain the assignment for the WavelinQ procedure (HCPCS code G2170) to APC 5194. The presenter stated that the number of single claims is too small to support a reassignment to APC 5193. Based on the discussion during the meeting, the HOP Panel recommended that CMS maintain the assignment of HCPCS code G2170 in APC 5194 for CY 2021.

Comment: Most commenters opposed the reassignment to APC 5193 for G2170 and suggested that we continue to assign the code to APC 5194 based on the HOP Panel recommendation at the August 31, 2020 meeting. They argued that the number of single claims on which to base the reassignment is too low, and recommended that CMS maintain the current assignment to APC 5194 until more claims data can be gathered for appropriate APC assignment. However, one commenter suggested that we reassign HCPCS code G2170 to APC 5193 based on the 1-year

claims data, and stated that the HOP Panel recommendation to maintain the assignment to APC 5194 is not supported by the hospital claims data. This same commenter suggested that the 1-year hospital claims data does support maintaining HCPCS code G2171 in APC 5194. One commenter reported that reassigning the code to APC 5193 would be insufficient to cover the cost of the procedure in the ASC setting. According to the commenter, the proposed CY 2021 ASC payment for HCPCS code G2170 is $5,887.63, which does not cover the cost of the $6,000 device used in the procedure.

Response: As noted above, HCPCS codes G2170 and G2171 are two technologies used for hemodialysis arteriovenous fistula creation. We note that these procedures are furnished to dialysis patients with chronic kidney disease, which affects thousands of Medicare beneficiaries. To ensure Medicare access to these dialysis-related procedures in both the hospital outpatient and ASC settings, which is in line with various HHS initiatives, including the HHS Initiative on ''Advancing American Kidney Health'', we believe that we should maintain both codes in APC 5194 for CY 2021. In addition, maintaining the assignment to APC 5194 for both codes is consistent with the HOP Panel's recommendation at the August 31, 2020 meeting. Moreover, given the low frequency of claims for HCPCS code G2170 (predecessor HCPCS code C9754), we also reviewed the arithmetic mean and median costs for the code, as we would do for New Technology APC services with fewer than 100 claims. We noted that HCPCS code G2170 and HCPCS code G2171 (predecessor HCPCS code C9755) have very similar median costs, and combined with the low claims data for HCPCS code G2170, the fact that this is the first year of claims data available for these services, as well as the public comments and the HOP Panel recommendation, we believe that it would be inappropriate to assign these two services to different APCs. As a result, we are using 1833(t)(2)(E) to assign HCPCS code G2170 (predecessor HCPCS code C9754) to APC 5194 because its cost is similar to HCPCS code G2171 and both procedures are performed for ESRD patients that need dialysis. Therefore, we are using our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to assign G2170 to APC 5194. We note that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS, and continue to monitor the updated claims data for these codes as they become available.

In summary, after consideration of the public comments, we are finalizing our proposal with modification. Specifically, we are finalizing our APC proposal to assign HCPCS code G2171 to APC 5194, and assigning HCPCS code G2170 to APC 5194 for CY 2021 using our equitable adjustment authority. The final CY 2021 OPPS payment rates for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

7. Health and Behavior Services (APC 5822)

For CY 2021, we proposed to revise the payment rate associated with APC 5822 (Level 2 Health and Behavior Services) from $78.54 to $75.26 based on the latest OPPS claims data.

Comment: Some commenters expressed concern with the proposed payment decrease for APC 5822. Several commenters noted that the APC includes a number of needed behavioral health services. Those services include group therapy as well as outpatient programs that are less intensive than PHPs but are still important for those who may not need a full day of treatment all week, but who still require substantial support. The commenters noted that the proposed payment rate decrease of $3.10 per group per patient equates to a reduction of approximately $9.30 per patient per day and that group psychotherapy makes up well over 95 percent of the services provided by programs under Hospital Partial Hospitalization Services. The commenters urged CMS to reexamine the data used in developing the payment for APC 5822. Other commenters requested we reconsider the proposed 4.2 percent payment rate decrease for APC 5822.

Response: The CY 2021 OPPS payment rates are based on claims submitted January 1, 2019 through December 31, 2019, processed through June 30, 2020. Based on our evaluation of the claims data for this final rule with comment period, the geometric mean cost of APC 5822 is approximately $72.94 based on 1,069,622 single claims (out of 1,085,044 total claims).

Based on our review, we have no reason to believe that the services are miscoded. In addition, based on our analysis of the CY 2021 claims data used for this final rule with comment period, we are unable to determine whether facilities are misreporting the services. It is generally not our policy to judge the accuracy of provider coding and charging for purposes of ratesetting. We rely on providers to accurately report the use of HCPCS codes in accordance with their code descriptors and CPT and CMS instructions, and to report services on claims and charges and costs for the services on their Medicare hospital cost report appropriately. Also, we generally do not specify the methodologies that providers use to set charges for this or any other service. Furthermore, we state in Chapter 4 of the Medicare Claims Processing Manual that it is extremely important that facilities report all HCPCS codes consistent with their descriptors; CPT and/or CMS instructions; and correct coding principles, and that all charges for services they furnish, whether payment for the services is made separately paid or is packaged, are reported to enable CMS to establish future ratesetting for OPPS services. Therefore, we are finalizing our proposal, without modification, for APC 5822.

8. High-Density Lipoprotein (HDL) Therapy (APC 5243)

For CY 2021, we proposed to continue to assign CPT code 0342T (Therapeutic apheresis with selective hdl delipidation and plasma reinfusion) to APC 5243 (Level 3 Blood Product Exchange and Related Services) with a proposed payment of $4,074.81.

Comment: One commenter reported that their company expects FDA Humanitarian Device Exemption approval in Q4 of 2020 for its ''PDS–2 System,'' an HDL Therapy system that is designed to reduce plaque in coronary arteries and increase HDL levels in patients diagnosed with homozygous familial hypercholesterolemia (HoFH). The commenter indicated that the code associated with their device is CPT code 0342T. The commenter stated that they intend to apply to CMS for a new technology APC in early 2021. According to the commenter, the cost of the therapy described by CPT code 0342T is $77,100. The commenter suggested that the proposed payment of $4,074.81 for APC 5243 (Level 3 Blood Product Exchange and Related Services) and $37,470.54 for APC 5244 (Level 4 Blood Product Exchange and Related Services) does not capture the cost of providing the therapy, and

consequently, the company intends to submit an application for a new technology APC in 2021.

Response: We thank the commenter for making us aware of their intent to submit a new technology APC application. Once we receive the application, we will review it and make the appropriate determination.

9. Imaging With and Without Contrast (APCs 5523, 5524, 5571, 5572, and 5573)

a. Cardiac Computed Tomography (CT) (APC 5571)

For CY 2021, we proposed to continue to assign the following cardiac CT exam codes to APC 5571 (Level 1 Imaging with Contrast) with a proposed payment rate of $181.41.

- 75572 (Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3d image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed))
- 75573 (Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3d image postprocessing, assessment of lv cardiac function, rv structure and function and evaluation of venous structures, if performed))
- 75574 (Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3d image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed))

We received many comments related to our proposed payment for the cardiac CT codes. Below is a summary of the public comments and our responses to the comments.

Comment: Many commenters opposed the assignment of CPT codes 75572, 75573, and 75574, which are the codes that describe cardiac CT exams, to APC 5571. They stated that the proposed CY 2021 OPPS payment rate of $181.41 for APC 5571 is inadequate to cover the total cost of providing the service. They also indicated that the proposed payment will result in decreased reimbursement for cardiac CT for the fourth consecutive year. Commenters were particularly concerned with the proposed payment for CPT code 75574, for which, according to the commenters, the payment rate has decreased by 30 percent over the past 3 years. They reported that the cardiac CT exam is a complex exam and more time-consuming to perform and interpret than any other type of contrast CT scan. They also believe that the resource costs required to perform cardiac CT scans are similar to the tests that are assigned to APC 5573 rather than APC 5571. They noted that the low payment for the test limits patient access, and requested that CMS take action to increase reimbursement to levels in line with the actual testing costs. The commenters requested an APC reassignment for all three codes. Specifically, the commenters suggested reassigning CPT codes 75572 and 75573 to APC 5572 and CPT code 75574 to APC 5573. Most of the commenters reported that cardiac CT scans are more resource intensive than other CT and x-ray scans and are similar to other cardiac stress imaging modalities like nuclear stress testing; therefore, cardiac CT scans should be reimbursed accordingly.

Another commenter reported that the test described by CPT code 75574 generally takes about four times longer to perform than a CT scan of the thorax with contrast that is described by CPT code 71260 (Computed tomography, thorax; with contrast material(s)) and also assigned to APC 5571. The commenters noted that based on clinical indications and performance/interpretation, CPT code 75574 is very much like a SPECT nuclear scan, which is described by CPT code 78452 (Myocardial perfusion imaging, tomographic (spect) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection) and assigned to APC 5593 (Level 3 Nuclear Medicine and Related Services) with a proposed payment rate of $1,336.28, rather than a CT scan of the thorax. The commenters further asserted that cardiac CT scans prior to invasive angiography lead to lower utilization of cardiac catheterization, PCI, and costs.

Response: Payments under the OPPS are based on our analysis of the latest available claims and cost report data submitted to Medicare. We have many years of claims data for CPT codes 75572, 75573, and 75574. The AMA established specific CPT codes for cardiac CT services beginning in 2006 when they were first described by Category III codes. The Category III CPT codes were subsequently deleted on December 31, 2009, and replaced with Category I CPT codes 75572, 75573, and 75574, which were effective on January 1, 2010. Because OPPS payments are updated every year based on our analysis of the latest claims data, the payment rates have varied each year based on that data.

For CY 2021, OPPS payments are based on claims submitted between January 1, 2019 through December 31, 2019, that were processed on or before June 30, 2020. Based on our evaluation of the claims data for this final rule, the geometric mean costs for the cardiac CT scan codes range between $157 and $196. Specifically, as shown in Table 21, our analysis show a geometric mean cost of approximately $157 for CPT code 75572 based on 14,262 single claims, approximately $194 for CPT code 75573 based on 317 single claims, and approximately $196 for CPT code 75574 based on 32,556 single claims. Based on the geometric mean costs for these codes, we do not believe that CPT codes 75572, 75573, and 75574 utilize similar resources as the exams assigned to APC 5572 or APC 5573. The geometric mean costs for the tests placed in APC 5571 range between $157 and $196, while the tests in APC 5572 range between $265 and $510, and for APC 5573, between $534 and $961.

In addition, our data shows that the resources associated with cardiac CT exams are unlike those of single photon emission CT (SPECT) nuclear scans (CPT code 78452). As listed in Table 21, our data shows that SPECT nuclear scans are more often performed on Medicare patients than cardiac CT exams. Specifically, CPT code 78452 shows a geometric mean cost of approximately $1,288 based on 591,344 single claims compared to 47,135 single claims for cardiac CT (CPT codes 75572, 75573, and 75574). Although the commenters have indicated that the resource costs associated with cardiac CT exams are similar to SPECT nuclear scans, our analysis of the latest OPPS claims data reveal otherwise. Similarly, we found the same results for nuclear stress tests (CPT codes 93350 and 93351). That is, that the estimated resource costs to perform nuclear stress tests are higher than for cardiac CT. As noted in Table 21, the geometric mean costs for nuclear stress test range between $529 and $671 based on 92,670 single claims for CPT codes 93350 and 93351, while the geometric mean costs for the cardiac CT codes range between $157 and $196.

TABLE 21.—GEOMETRIC MEAN COSTS FOR CARDIAC CT, SPECT, AND STRESS TESTS

Exam	CPT Code	Short Descriptor	APC	Final Rule 2021 Single Claims Frequency	Final Rule 2021 Geometric Mean Cost
Cardiac CT	75572	Ct hrt w/3d image	5571	14,262	$157.27
Cardiac CT	75573	Ct hrt w/3d image congen	5571	317	$193.52
Cardiac CT	75574	Ct angio hrt w/3d image	5571	32,556	$195.72
SPECT	78452	Ht muscle image spect mult	5593	591,344	$1,287.68
Stress Echocardiogram	93350	Stress tte only	5524	44,048	$670.93
Stress Echocardiogram	93351	Stress tte complete	5524	48,622	$528.91

We believe our claims data accurately reflects the resources associated with providing cardiac CT exams in the HOPD setting. Because CPT codes 75572, 75573, and 5574 have been active for some time now, we have no reason to believe that HOPDs have issues with coding or reporting these exams correctly. We believe that HOPDs have had sufficient time to learn how to code and report these services accurately using the Category I CPT codes that were established in 2010.

Moreover, we believe that we have substantial claims data for the cardiac CT services upon which to base the CY 2021 final OPPS payment rates. As noted in Table 22, the total number of claims for these codes has increased each year. The historical OPPS payments for cardiac CT services does not appear to have affected Medicare beneficiaries' access to these services. Given that these services have been paid under the OPPS for many years, with payments based on the latest hospital claims and Medicare cost report data, we believe we are providing a stable and consistent payment methodology that appropriately reflects the hospital resources required for cardiac CT.

TABLE 22.—VOLUME FOR CARDIAC CT EXAMS FROM CY 2014 THROUGH CY 2021

CPT Code	CY 2014 OPPS Single Claims Frequency	CY 2015 OPPS Single Claims Frequency	CY 2016 OPPS Single Claims Frequency	CY 2017 OPPS Single Claims Frequency	CY 2018 OPPS Single Claims Frequency	CY 2019 OPPS Single Claims Frequency	CY 2020 OPPS Single Claims Frequency	CY 2021 OPPS Single Claims Frequency
75572	3,090	3,855	4,188	4,905	5,703	7,256	12,299	14,262
75573	225	164	275	256	177	143	323	317
75574	11,418	10,820	10,481	11,154	12,848	14,785	25,434	32,556

Further, reassigning CPT codes 75572 and 75573 from APC 5571 to APC 5572, and CPT code 75574 from APC 5571 to APC 5573 would potentially significantly overpay for the exams. As noted in Table 23, which shows the percent change for each code, reassigning the codes to APC 5572 and APC 5573 would pay at a rate that is two and three times the estimated cost of the service as reflected in the hospital outpatient claims data, and we do not believe that overpaying for the exams is appropriate. We note that we monitor our claims data every year to assess the appropriateness of the APC assignments for all services under the hospital OPPS.

TABLE 23.—PERCENT CHANGE FOR THE CARDIAC CT EXAM CODES BASED ON COMMENTERS SUGGESTED APC ASSIGNMENTS

CPT Code	Proposed CY 2021 OPPS APC	Proposed CY 2021 OPPS APC Title	Proposed CY 2021 OPPS Payment Rate	Commenters Suggested Proposed CY 2021 OPPS APC	Commenters Suggested Proposed CY 2021 OPPS APC Title	Commenters Suggested Proposed CY 2021 OPPS Payment Rate	**Percent Change**
75572	5571	Level 1 Imaging with Contrast	$181.41	5572	Level 2 Imaging with Contrast	$375.33	**107%**
75573	5571	Level 1 Imaging with Contrast	$181.41	5572	Level 2 Imaging with Contrast	$375.33	**107%**
75574	5571	Level 1 Imaging with Contrast	$181.41	5573	Level 3 Imaging with Contrast	$722.74	**298%**

Every year, since the implementation of the OPPS on August 1, 2000, we receive many requests from specialty associations, device manufacturers, drug manufacturers, and consultants to increase the payments for codes associated with specific drugs, devices, services, and surgical procedures. Under the OPPS, one of our goals is to make payments that are appropriate for the items and services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is budget neutral and increases are generally limited to the annual payment update factor. As a budget neutral payment system, the OPPS does not pay the full hospital costs of services, however, we believe that our payment rates generally reflect the costs that are associated with providing care to Medicare beneficiaries. Furthermore, we believe that our payment rates are adequate to ensure access to services.

Comment: Commenters stated that the current methodology for determining OPPS payments disadvantages cardiac CT exams disproportionately and requested that CMS exercise its authority to create an exception to the current payment methodology for the three cardiac CT codes. As an alternative to the current methodology for establishing OPPS payment rates, the commenters suggested using the general cardiology revenue code to set the payment rates for CPT codes 75572, 75573, and 75574. They stated that based on their study that used claims data from CY 2021 OPPS proposed rulemaking, the use of a general cardiology revenue code to set the payment rates matches the actual cost of cardiac exams. Specifically, their results reveal a geometric mean cost of about $400.55 for CPT code 75572, $479.74 for CPT code 75573, and $505.89 for CPT code 75574. Based on their analysis, the commenters contended that the geometric mean costs for CPT codes 75572 and 75573 justify their assignment to APC 5572, and CPT code 75574 to APC 5573.

Response: It is our standard ratesetting methodology to rely on hospital cost and charge information as it is reported to us through the claims and cost report data. We believe that the assignment to APC 5571 for the cardiac CT codes is fully consistent with our standard ratesetting methodology, which provides appropriate incentives for efficiency. The OPPS is a prospective payment system that relies on hospital charges on the claims and cost report data from the hospitals that furnish the services in order to determine relative costs for OPPS ratesetting. We believe that the prospective payment rates for CPT codes 75572, 75573, and 75574, calculated based on the costs of those providers that furnished the services in CY 2019, provide appropriate payment to the providers who will furnish the services in CY 2021. We continue to believe that this standard ratesetting methodology accurately provides payment for cardiac CT exams furnished to hospital outpatients.

Comment: One commenter recommended that we decrease the payment for CPT code 78452 because the commenter believes SPECT is an outdated test for chest pain evaluation. The commenter also stated that the test is overutilized with no evidence of improvement in patient outcomes.

Response: As stated above, we review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our analysis of the latest claims data. For CY 2021, OPPS payments are based on claims data submitted between January 1, 2019 through December 30, 2019, that were processed on or before June 30, 2020. Based on our analysis, and as shown in Table 21 above, the claims data for CPT code 78452 show a geometric mean cost of approximately $1,288 based on 591,344 single claims, which is consistent with the geometric mean cost of about $1,272 for APC 5593 (Level 3 Nuclear Medicine and Related Services). We believe that CPT code 78452 is appropriately assigned to APC 5593. Therefore, based on the latest claims data, we have no basis to reassign the SPECT exam CPT code 78452 to another APC with a lower payment rate.

Comment: Some commenters recommended that CMS allow facilities to submit charges for cardiac CT using revenue codes that they believe would more accurately estimate costs. They added that CMS should provide explicit permission via a line item to allow hospitals to submit charges for cardiac

CT tests under the cardiology stress testing revenue/cost centers. They noted that CMS guidance for all non-CT and MR CPT codes is for hospitals to submit claims utilizing revenue codes that most accurately reflect clinical and resource homogeneity. They believe that making an exception to the current policy and allowing HOPDs to submit charges for cardiac CT tests under the cardiology stress testing revenue/cost centers would provide better data in the future that reflects actual resource costs for cardiac CT.

Response: Hospital outpatient facilities make the final determination for reporting the appropriate cost centers and revenue codes. As stated in section 20.5 in Chapter 4 (Part B Hospital) of the Medicare Claims Processing, CMS ''does not instruct hospitals on the assignment of HCPCS codes to revenue codes for services provided under OPPS since hospitals' assignment of cost vary. Where explicit instructions are not provided, providers should report their charges under the revenue code that will result in the charges being assigned to the same cost center to which the cost of those services are assigned in the cost report.'' Therefore, HOPDs must determine the most appropriate cost center and revenue code for the cardiac CT exams.

In summary, after consideration of the public comments, we are finalizing our proposal, without modification, to assign the cardiac CT exam codes, specifically, CPT codes 75572, 75573, and 75574 to APC 5571. The final CY 2021 OPPS payment rates for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

b. Cardiac Magnetic Resonance (CMR) Imaging (APC 5523, 5524, 5572, and 5573)

For CY 2021, we proposed to continue to assign the following cardiac magnetic resonance imaging (MRI) CPT codes to APC 5523, 5524, 5572, and 5573, respectively:

- CPT code 75557 (Cardiac magnetic resonance imaging for morphology and function without contrast material) to APC 5523 (Level 3 Imaging without Contrast) with a proposed payment of $235.05;
- CPT code 75559 (Cardiac magnetic resonance imaging for morphology and function without contrast material; with stress imaging) to APC 5524 (Level 3 Imaging without Contrast) with a proposed payment of $490.52;
- CPT code 75561 (Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences) to APC 5572 (Level 2 Imaging with Contrast) with a proposed payment of $375.33; and
- CPT code 75563 (Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences; with stress imaging) to APC 5573 (Level 3 Imaging with Contrast) with a proposed payment of $722.74.

Comment: Some commenters expressed concern with the lack of payment stability for cardiac MRI services, specifically, those described by CPT codes 75557, 75559, 75561, and 75563. They indicated that the payments for these codes have decreased in the last several years, and prior to CY 2017, the codes were placed in appropriate APCs. Of significant concern are the payment rates for CPT codes 75561 and 75563, which, according to the commenters, are grouped with services that are not clinically similar. The commenters stated that CPT code 75561 is unlike CT of the abdomen or pelvis or MRI of the neck and spine in APC 5572, and instead, the code should be placed in APC 5573 with comparable services. The commenters further added that CPT code 75563 is labor-intensive and should be assigned to APC 5593 (Level 3 Nuclear Medicine and Related Services).

Response: Payment changes from one year to the next are unavoidable in a relative weight payment system that depends on updated hospital charges and costs and in which reassignment of HCPCS codes from one APC to another is required by law in cases of 2 times rule violations. The statutory design of the OPPS and the evolution in the delivery of outpatient hospital services include elements that are responsible for some of the fluctuation in payment rates from year to year. The OPPS is based on HCPCS coding for which there are hundreds of changes each year. In addition, the entry of new technology into a budget neutral payment system results in a shift of funds away from previously existing services to provide payments for new services. These factors are reflections of the changes in services in the outpatient department, and shifts in payment mirror those changes.

Moreover, section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the APC groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Consequently, we review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our analysis of the latest claims data. For CY 2021, OPPS payments are based on claims data submitted between January 1, 2019 through December 30, 2019, that were processed on or before June 30, 2020. Based on our analysis, and as shown in Table 24, the claims data for CPT code 75557 show a geometric mean cost of approximately $250 based on 1,941 single claims, which is consistent with the geometric mean cost of about $224 for APC 5523 (Level 3 Imaging Without Contrast). Similarly, the geometric mean cost for CPT code 75559 is approximately $403 based on 57 single claims, which is in line with the geometric mean cost of about $470 for APC 5524. For CPT code 75561, the geometric mean cost is approximately $426 based on 17,216 single claims, which is in line with the geometric mean cost of approximately $359 for APC 5572. We note that the geometric mean cost of approximately $426 for CPT code 75561 is within the range of the significant geometric mean cost for APC 5572, which is between approximately $265 (for CPT code 74174) and about $510 (for CPT code 73525). For CPT code 75563, the geometric mean cost is about $761 based on 2,370 single claims, which is close to the geometric mean cost of approximately $697 for APC 5573. The geometric cost of approximately $761 for CPT code 75563 is within the range of the significant geometric mean cost for APC 5573, which is approximately between $534 (for CPT code C8923) and about $961 (for HCPCS code C8928). Based on the latest claims data, we believe that the cardiac MRI codes are appropriately assigned to APCs 5523, 5524, 5572, and 5573.

TABLE 24.—GEOMETRIC MEAN COSTS (GMC) FOR CARDIAC MRI

HCPCS	Short Descriptor	SI	APC	Final Rule 2021 Single Claims Frequency	Final Rule 2021 HCPCS Geometric Mean Cost
75557	Cardiac mri for morph	S	5523	1,941	$249.73
75559	Cardiac mri w/stress img	S	5524	57	$403.20
75561	Cardiac mri for morph w/dye	S	5572	17,216	$425.66
75563	Card mri w/stress img & dye	S	5573	2,370	$760.81

In addition, based on the commenters' belief that the APC assignments for the cardiac MRI codes were appropriately placed prior to CY 2017 and not currently, we reviewed the OPPS payment rates from CY 2016 through CY 2021. Based on our evaluation, we believe that the payments for the cardiac MRI codes are appropriate. The OPPS, like other Medicare payment systems, is a prospective payment system based on averages. In some individual cases payment exceeds the average cost and in other cases payment is less than the average cost. Based on our review, we believe that the historical and current payment rates for CPT codes 75557, 75559, 75561, and 75563, reflect the geometric mean costs associated with the service that are consistent with providing cardiac MRI to Medicare beneficiaries in cost efficient settings.

Comment: Some commenters expressed concern with the clinical homogeneity in the Imaging APCs and requested more transparency. They also questioned the criteria for assigning HCPCS codes to specific APCs and as well as why the Imaging APCs were reduced from 17 to 7 APCs.

Response: Every year we publish an OPPS/ASC proposed rule that informs the public of our proposed policies, which include payment rates for specific HCPCS codes, for the upcoming year that will become effective on January 1. The proposed rules are subject to a 60-day public comment period, and comments received by the due dates are addressed in the final rules. In the April 7, 2000 OPPS final rule, we defined the term ''clinical homogeneity.'' As stated in the April 7, 2000 final rule, ''The definition of each APC group should be 'clinically meaningful,' that is, the procedures or services included within the APC group relate generally to a common organ system or etiology, have the same degree of extensiveness, and utilize the same method of treatment, for example, surgical, endoscopic, etc. The definition of clinical meaningfulness is, of course, dependent on the goal of the classification system. For APCs, the definition of clinical meaningfulness relates to the medical rationale for differences in resource use. If, on the other hand, classifying patient prognosis were the goal, the definition of patient characteristics that were clinically meaningful might be different.'' (68 FR 18457).

In addition, we believe that the combined annual proposed and final rules with their accompanying addenda and cost statistics files, as well as the quarterly OPPS and ASC update change request documents that are issued by CMS provide substantial transparency on APCs and, overall, the OPPS payment system.

With regard to the reduction from 17 to 7 APCs for the Imaging APCs, we discussed the issue in the CY 2017 OPPS/ASC final rule (81 FR 79628 through 79631) and stated that the change was based on stakeholder recommendations. As a part of our CY 2016 (80 FR 70392 through 70397) and CY 2017 (81 FR 79628 through 79631) comprehensive review of the structure of the imaging APCs and procedure code assignments, we examined the APCs that contained imaging services. For CY 2017, we proposed and updated the restructuring of the OPPS APC groupings for imaging services to more appropriately reflect the costs and clinical characteristics of the procedures within each APC grouping in the context of the OPPS. We believe that the updated restructuring and reconfiguration of the Imaging APCs appropriately reflect the similar resource costs and clinical characteristics of the procedures within each APC. We also believe that the current broader categories of Imaging APCs are appropriate for ratesetting under the OPPS because they support greater similarities in clinical characteristics and resource use of procedures assigned to the APCs, while improving the homogeneity of the APC structure.

In summary, after consideration of the public comments, we are finalizing our proposal, without modification, to assign CPT code 75557 to APC 5523, CPT code 75559 to APC 5524, CPT code 75561 to APC 5572, and CPT code 75563 to APC 5573. The final CY 2021 payment rates for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

10. IDx–DR: Artificial Intelligence System To Detect Diabetic Retinopathy (APC 5733)

As stated in a press release issued by the FDA on April 11, 2018, the IDx–DR is the ''first medical device to use artificial intelligence (AI) to detect greater than a mild level of the eye disease diabetic retinopathy in adults who have diabetes'' (*https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-artificial-intelligence-based-device-detect-certain-diabetes-related-eye*). Approved for marketing by the FDA in April 2018, the artificial intelligence

algorithm provides a clinical decision without the need for a clinician to also interpret the image. A provider uploads the digital images of the patient's retinas to a cloud server on which the IDx–DR software is installed, and once analysis is completed, the provider is given one of the following two results:

- More than mild diabetic retinopathy detected: Refer to an eye care professional; or
- negative for more than mild diabetic retinopathy; rescreen in 12 months.

The test itself generally takes about 5 minutes to complete and does not need to be performed by a clinician. The test associated with the IDx–DR technology received a new CPT code effective January 1, 2021, specifically, CPT code 92229. With the establishment of the new code, the CPT Editorial Panel also revised the descriptors associated with existing CPT codes 92227 and 92228 to appropriately differentiate them from the IDx–DR test. Below are the complete descriptors for CPT codes 92227, 92228, and 92229 for CY 2021. We note that CPT code 92229 was listed as placeholder 9225X in Addendum B of the CY 2021 OPPS/ASC proposed rule:

- 92227 (Imaging of retina for detection or monitoring of disease; with remote clinical staff review and report, unilateral or bilateral);
- 92228 (Imaging of retina for detection or monitoring of disease; with remote physician or other qualified health care professional interpretation and report, unilateral or bilateral); and
- 92229 (Imaging of retina for detection or monitoring of disease; point-of-care automated analysis and report, unilateral or bilateral).

As stated in the CY 2021 OPPS/ASC proposed rule (85 FR 48839), based on our evaluation of the service, we believe that IDx–DR is a diagnostic test that should be payable under the hospital OPPS, similar to existing CPT codes 92227 and 92228, which are assigned to APC 5732 (Level 2 Minor Procedures) and status indicator ''Q1.'' Based on its clinical similarity to CPT codes 92227 and 92228, we believe that the IDx–DR test should also be assigned to APC 5732. Consequently, for CY 2021, we proposed to assign the new IDx–DR CPT code to APC 5732 with a proposed payment rate of $33.16. We also proposed to assign the code to status indicator ''Q1'' to indicate that the code is conditionally packaged when performed with another service on the same day. Because the IDx–DR test will most often be performed as part of a visit, we believed that packaging the cost into the primary service is appropriate. We note that under the OPPS, the HOPD E&M visit code (G0463; CY 2021 OPPS proposed payment rate of $120.88) is paid separately when not billed with a C–APC, and we believed that payment would include the cost of providing the IDx–DR test. Generally, our policy for tests with minimal costs is to package the cost into the primary service.

Comment: Some commenters disagreed with the proposed payment amount and requested a revision in the assignment from APC 5732 to APC 5734 (Level 4 Minor Procedures) with a proposed payment rate of $113.23 and assignment to status indicator ''Q1''. The commenters reported that the service described by new CPT code 92229, which was listed as placeholder CPT code 9225X in Addendum B to the CY 2021 OPPS/ASC proposed rule), is similar to the technical components described by existing CPT code 92250 (Fundus photography with interpretation and report), which was proposed for assignment to APC 5734 and status indicator ''Q1''. They stated that providers are currently billing on an interim basis under CPT code 92250 for the same service. The commenters further disagreed with the comparison to CPT code 92227 and 92228, which are assigned to APC 5732 with a status indicator ''Q1'' and stated that the tests described by these codes involve human readers while the service described by CPT code 92229 is artificial (AI) intelligence-related. The commenters indicated that APC 5734, which is the APC assigned to the predecessor CPT code 92250, is the more appropriate assignment for new CPT code 92229 until sufficient Medicare claims data can be collected by CMS to either retain that assignment or reassign to another APC.

Response: We stated in the CY 2021 OPPS/ASC proposed rule with comment period (85 FR 48839) that the CPT Editorial Panel revised the descriptors associated with existing CPT codes 92227 and 92228 to appropriately differentiate them from the IDx–DR test, which is described by new CPT code 92229. We note that the descriptors for all three codes involve tests that use imaging of the retina for detection or monitoring of disease. Based on the revisions to CPT code 92227 and 92228 and placement of the new code, we believe that the IDx–DR test is similar to CPT code 92227 and 92228. We do not believe that CPT code 92250, which the commenters reported to be the predecessor code, is similar to the IDx–DR test; otherwise, the placement of the new IDx–DR code would have been close to CPT code 92250. However, after further review and consideration of the issue, we believe that CPT code 92229 should be assigned to APC 5733 (Level 3 Minor Procedures) rather than APC 5732 (Level 2 Minor Procedures).

We note that under the OPPS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is a prospective payment system. The payment rates that are established reflect the geometric mean costs associated with items and services assigned to an APC and we believe that our payment rates generally reflect the costs that are associated with providing care to Medicare beneficiaries in cost efficient settings. Moreover, we strive to establish rates that are adequate to ensure access to medically necessary services for Medicare beneficiaries.

For many emerging technologies there is a transitional period during which utilization may be low, often because providers are first learning about the techniques and their clinical utility. Quite often, the requests for higher payment amounts are for new procedures in that transitional phase. These requests, and their accompanying estimates for expected Medicare beneficiary or total patient utilization, often reflect very low rates of patient use, resulting in high per use costs for which requesters believe Medicare should make full payment. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on Medicare beneficiary projected utilization and does not set its payment rates based on initial projections of low utilization for services that require expensive capital equipment.

We note that in a budget neutral environment, payments may not fully cover hospitals' costs, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings. As the OPPS acquires claims data regarding hospital costs associated with new procedures, we annually review the claims data and any available new information regarding the clinical aspects of new procedures to confirm that OPPS payments remain appropriate for procedures as they transition into mainstream medical practice.

Comment: Several commenters requested a reassignment from proposed APC 5732 to APC 5733 (Level 3 Minor Procedures) consistent with the APC assignment for CPT codes 92285 (External ocular photography with interpretation and report for documentation of medical progress (e.g., close-up photography, slit lamp photography, goniophotography, stereo-photography) and 92134 (Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral; retina).

Response: The IDx–DR test generally takes about 5 minutes to complete and does not need to be performed by a clinician. Based on our evaluation of the service, we believe that IDx–DR is a diagnostic test that should be payable under the hospital OPPS. We do not believe that the services described by CPT code 92285 or 92134 are appropriate comparisons for the IDx–DR test because these tests generally involve physician work and require approximately 10 minutes to perform. However, after further review and deliberation of the issue, we believe that CPT code 92229 should be assigned to APC 5733 (Level 3 Minor Procedures) rather than APC 5732 (Level 2 Minor Procedures).

Comment: Some commenters requested a change in the proposed status indicator assignment for CPT code 92229 from ''Q1'' to ''S'' to ensure that the test is separately reimbursed when provided with an outpatient clinic visit or other service. The commenters indicated that assigning the code to ''Q1'' will not support patient access in the outpatient setting and will encourage less efficient care. They suggested that HOPDs would likely schedule patients to receive only the IDx–DR test during an outpatient visit, instead of performing the test during a clinic visit, and could discourage hospitals from offering the test altogether. They further suggested that diabetic patients receiving diabetic care in the outpatient setting would likely be asked to make separate appointments as a result of the status indicator ''Q1'' assignment.

Response: With regard to HOPDs potentially scheduling the IDx–DR test on a separate day from the clinic visit to receive separate payment, we have concerns about this kind of manipulation of patient scheduling because such a practice could create an undue burden for Medicare beneficiaries. We expect HOPDs to furnish services in the most efficient way that meets the needs of the patient. After further review and deliberation on the issue, we are revising the status indicator to ''S'' to ensure patient access to the test.

In summary, after consideration of the public comments, we are finalizing our proposal, with modification. Specifically, we are assigning CPT code 92229 to APC 5733 with status indicator ''S.'' The final CY 2021 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

11. Implantable Interstitial Glucose Sensor System (APC 5051 and 5054)

For CY 2021, we proposed to assign CPT code 0447T to APC 5051 (Level 1 Skin Procedures) with a proposed OPPS payment of $182.38. In addition, we proposed to assign CPT codes 0446T and 0448T to APC 5053 (Level 3 Skin Procedures) with a proposed OPPS payment of $530.98. We note that the long descriptors for these codes can be found in Table 25 below.

Comment: A commenter agreed with the proposed APC assignment for CPT code 0447T to APC 5051 but opposed the proposed assignment for CPT codes 0446T and 0448T to APC 5053. The commenter stated that the payment for APC 5053 does not include the provision of the service associated with the Eversense Implantable Continuous Glucose System (CGS), which is a technology that provides real-time glucose monitoring. Specifically, the payment for APC 5053 does not account for providing the glucose sensor and wireless transmitter, as well as implanting, removing, and replacing the glucose sensor. In contrast, the commenter believed that CPT codes 0446T and 0448T include those costs, referring to the discussion in the CY 2020 PFS final rule (84 FR 62627). The commenter added that assignment to APC 5053 is inappropriate based on clinical homogeneity and resource cost, and suggested reassigning CPT codes 0446T and 0448T to either APC 5054 (Level 4 Skin Procedures) with a proposed OPPS payment of $1,733.06 or New Technology APC 1523 (New Technology—Level 23 ($2501–$3000)) with a proposed OPPS payment of $2,750.50.

Response: Although CPT codes 0446T, 0447T, and 0448T were effective January 1, 2017, the Eversense CGM technology was only recently approved for marketing by the FDA on June 6, 2019. For CY 2021, OPPS payments are developed based on claims submitted between January 1, 2019 through December 31, 2019, and processed through June 30, 2020. For this final rule with comment period, we have no claims data for CPT codes 0446T, 0447T, or 0448T for OPPS ratesetting purposes. However, based on our review of the issue, and feedback from our medical advisors, as well as the expected device costs associated with CPT codes 0446T and 0448T as discussed in the CY 2021 PFS proposed rule (85 FR 50174), we believe that these codes should be reassigned to APC 5054 (Level 4 Skin Procedures) rather than New Technology APC 1523 (New Technology—Level 23 ($2501–$3000)). Because we have neither claims data nor specific HOPD costs, including the cost to perform each exam (other than the supply cost discussed in the CY 2021 PFS proposed rule), we believe that APC 5054 is the most appropriate assignment at this time for CPT codes 0446T and 0448T.

Therefore, after consideration of the public comment, we are finalizing our proposal, with modification. Specifically, we are finalizing our proposal for CPT code 0447T and assigning the code to APC 5051, however, we are reassigning CPT codes 0446T and 0448T to APC 5054. Table 25 list the long descriptors and final SI and APC assignments for the codes. The final CY 2021 payment rate for the codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

TABLE 25.—FINAL SI AND APC ASSIGNMENTS FOR CPT CODES 0446T, 0447T, and 0448T FOR CY 2021

CY 2021 CPT Code	Long Descriptor	Proposed CY 2021 OPPS SI	Proposed CY 2021 OPPS APC	Final CY 2021 OPPS SI	Final CY 2021 OPPS APC
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training	T	5053	T	5054
0447T	Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision	Q2	5051	Q2	5051
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation	T	5053	T	5054

12. Intervertebral Disc Allogeneic Cellular and/or Tissue-Based Product Percutaneous Injection (APC 5115)

In the CY 2021 OPPS/ASC Proposed Rule, we proposed to assign the procedures described by CPT codes 0627T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level) and 0629T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; first level) to status indicator ''T'', APC 5443 (Level 3 Nerve Injections) with a proposed OPPS payment rate of $836.26 based on the estimated costs of these procedures.

We proposed to assign the procedures described by CPT codes 0628T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; each additional level (List separately in addition to code for primary procedure) and 0630T (Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; each additional level (List separately in addition to code for primary procedure) to status indicator ''N'' to indicate that they are packaged under OPPS since they are add-on codes. These codes were listed as 0X32T, 0X33T, 0X34T, and 0X37T (the 5-digit CMS placeholder codes) in Addendum B with the short descriptor and also in Addendum O with the long descriptor, to the CY 2021 OPPS/ASC proposed rule.

We also proposed to assign these codes to comment indicator ''NP'' in Addendum B to indicate that the codes are new for CY 2021 and that public comments would be accepted on the proposed status indicator assignment. We note that these codes will be effective January 1, 2021.

Comment: Some commenters disagreed with the assignment of codes 0627T and 0629T to APC 5443 based on what the commenters believed was a lack of clinical and resource coherence with other procedures in this APC. They stated that CPT codes 0627T and 0629T involve percutaneous placement of an allogeneic cellular and/or tissue-based biologics to supplement and support deteriorating vertebral discs in patients suffering from degenerative disc disease. They believe that these procedures are not comparable to a simple nerve injection.

One commenter explained that the cost of these procedures is significantly higher than the proposed Level 3 Nerve Injection APC payment, which is $836.26. The cost of the VIA Disc Matrix Kit used for these procedures is $8,000 per kit. Therefore, they believed that a higher APC payment level more appropriately covers both the cost of the device and the non-device costs of the procedure.

Another commenter noted that the non-device costs of procedures 0627T and 0629T are most appropriately crosswalked to CPT code 22514 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (*e.g.* kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar) that is assigned to APC 5114 (Level 4 Musculoskeletal Procedures) with the payment rate of $6,368.58.

A medical device company recently submitted a new technology APC application to CMS for VIA® Disc Allograft Supplementation described by codes 0627T and 0629T and requested that CMS assign CPT codes 0627T and 0629 to APC 1575 (New Technology APC Level 38 ($10,001–$15,000)) for CY 2021 based on total estimated non-device-related cost of APC 5114 ($4,524) plus the device-related costs ($8,000) or $12,524 which is closest to APC 1575 with a CY 2021 proposed payment rate of $12,500.50.

The same device company recommended, because 0628T and 0630T are add-on codes used in conjunction with their primary procedural codes 0627T and 0629T, that CMS uses the device-related cost for each additional VIA Disc mixing system kit of $8,000 plus an incremental thirty minute non-device cost to capture the additional operative time and costs in performing a separate intervertebral disc injection.

The commenter requested that CMS assign CPT codes 0628T and 0630T to APC 1571 (New Technology APC Level 34 ($8001–$8500)) for CY 2021 since the total estimated cost of these codes is closest to APC 1571 with a CY 2021 proposed payment rate of $8,250.50.

Response: Based on our review of the application and input from our clinical advisors, we agree that the codes would be appropriately placed in an alternative APC that might better reflect their resource costs. Our updated claims data for this final rule with comment period shows that the geometric mean cost of APC 5115 is about $11,996.45, which is more similar to the device and procedure costs associated with these codes. Therefore, we are assigning CPT codes 0627T and 0629T to comprehensive APC 5115 (Level 5 Musculoskeletal Procedures) with status indicator ''J1'' for the CY 2021 OPPS.

CPT codes 0628T and 0630T would be assigned to status indicator ''N'' under OPPS for CY 2021 because the cost of an add-on code is packaged into the primary procedure under OPPS packaging policy, as discussed in the CY 2014 OPPS/ASC final rule (78 FR 74942).

In summary, after consideration of the public comments and our analysis of updated claims data for this final rule and other additional information, we are finalizing our proposal related to codes 0627T and 0629T with modification. Specifically, we are revising the APC assignment for CPT codes 0627T and 0629T to APC 5115 and revising their status indicator to ''J1'' for the CY 2021 OPPS. For CPT codes 0628T and 0630T, we are finalizing our proposal without modification and maintaining the assignment of status indicator ''N'' to these codes.

The final CY 2021 OPPS payment rate for CPT codes 0627T and 0629T and final status indicator assignment for 0628T and 0630T can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

The final CY 2021 APC and SI assignments for 0627T through 0630T can be found in Table 26.

TABLE 26.—FINAL APC AND SI ASSIGNMENTS FOR CPT CODES 0627T-0630T FOR CY 2021

CPT Code	Long Descriptor	Final OPPS SI	Final OPPS APC
0627T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level	J1	5115
0628T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; each additional level (List separately in addition to code for primary procedure)	N	N/A
0629T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; first level	J1	5115
0630T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; each additional level (List separately in addition to code for primary procedure)	N	N/A

13. Intraocular Procedures (APCs 5491 Through 5495)

In prior years, CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis) was assigned to the APC 5495 (Level 5 Intraocular Procedures) based on its estimated costs. In addition, its relative payment weight has been based on its median cost under our payment policy for low-volume device-intensive procedures because the APC contained a low volume of claims. The low volume device-intensive procedures payment policy was discussed in more detail in section III.C.2. of the proposed rule.

In the CY 2019 OPPS, we assigned procedure code CPT code 0308T to the APC 5494 (Level 4 Intraocular Procedures) (83 FR 58917 through 58918). We made this change based on the similarity of the estimated cost for the single claim of $12,939.75 to that of the APC ($11,427.14). However, this created a discrepancy in payments between the OPPS setting and the ASC setting in which the ASC payments would be significantly lower than the OPPS payments for the same service because of the difference in estimated cost for the encounter determined under a comprehensive methodology within the OPPS and the estimated cost determined under the payment methodology for device intensive services within the ASC payment system.

In CY 2020 OPPS/ASC rulemaking, we reestablished APC 5495 (Level 5 Intraocular Procedures) because we believed that the procedure described by CPT code 0308T would be most appropriately placed in the APC based on its estimated cost (84 FR 61249 through 61250). Assignment of the procedure to the Level 5 Intraocular Procedures APC was consistent with its historical placement and would also address the large discrepancy in payment for the procedure between the OPPS and the ASC payment system. We note that we also implemented a policy where the payment for a service when performed in an ASC (84 FR 61399 through 61400), would be no higher than the OPPS payment rate for the

service when performed in the hospital outpatient setting.

In reviewing the claims data available for CY 2021 ratesetting, there was a single claim containing the code 0308T that was unable to be used for the ratesetting process. In addition, this code and its APC have historically had relatively low claims volume for ratesetting purposes. While there were no claims usable for ratesetting in the CY 2021 OPPS proposed data under our standard process, we still needed to determine a payment weight for the APC. We believed that the most recently available data that we used to set payment for this service in the CY 2020 OPPS final rule was an appropriate proxy for both the procedure's estimated cost and its relative payment weight. We note that the proposed policy to use prior year claims data in ratesetting is similar to the application of a geometric mean cost floor to the Partial Hospitalization APCs, as initially established in the CY 2020 OPPS/ASC final rule (84 FR 61339 through 61347). Therefore, we believed it was appropriate to propose to use the median cost of $20,229.78 for CPT 0308T, calculated from claims data used in the CY 2020 OPPS final rule with comment period, to establish the payment weight for the CY 2021 OPPS for CPT code 0308T. We will continue to monitor the claims available for the procedure for ratesetting purposes.

To summarize, for CY 2021, we proposed to assign 0308T a payment weight based on the most recently available data, from the CY 2020 OPPS final rule, and therefore proposed to assign CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures). Under the proposal, the proposed CY 2021 OPPS payment rate for the service would be established based on the median cost, as discussed in section V.A.5. of the proposed rule, because it is a device intensive procedure assigned to an APC with fewer than 100 total annual claims within the APC. Therefore, the proposed APC assignment for CPT code 0308T would be based on the CY 2020 OPPS final rule median cost of $20,229.78.

Comment: We received one comment supporting our proposal to continue to assign the CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures) and use the CY 2020 median cost as a proxy for use in developing the CY 2021 OPPS payment rate.

Response: We appreciate the commenter's support. While the updated final rule claims data includes two claims containing the code 0308T, those claims are unusable for OPPS ratesetting purposes. Therefore, we are finalizing our proposed policy to assign CPT code 0308T to APC 5495 and use the CY 2020 median cost in determining a CY 2021 OPPS payment rate.

After consideration of the public comment we received, we are finalizing our proposal to continue to assign CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures) for the CY 2021 OPPS and, as a device intensive procedure assigned to an APC with fewer than 100 total claims, to establish the CY 2021 OPPS payment rate for the service using its CY 2020 median cost. Therefore, the CY 2021 OPPS payment rate for CPT 0308T will be based on the CY 2020 OPPS final rule median cost of $20,229.78.

14. Irreversible Electroporation Ablation of Tumors (NanoKnife® System) (APC 5362)

Electroporation is a technique in which an electrical field is applied to cells in order to increase the permeability of the cell membranes through the formation of nanoscale defects in the lipid bilayer. The result is creation of nanopores in the cell membrane and disruption of intra-cellular homeostasis, ultimately causing cell death. After the NanoKnife® System delivers a sufficient number of high voltage pulses; the cells surrounded by the electrodes will be irreversibly damaged. This mechanism, which causes permanent cell damage, is referred to as Irreversible Electroporation (IRE). The NanoKnife® System with six outputs for the treatment of Stage III pancreatic cancer received FDA Breakthrough Device designation on January 18, 2018 and approval of an FDA investigational device exemption (IDE G180278) on March 28, 2019.

The CPT Editorial Panel established two new codes; specifically CPT codes 0600T and 0601T, to describe NanoKnife® System procedures effective July 1, 2020. The manufacturer also submitted a new technology application requesting new technology APC assignments for CPT codes 0600T and 0601T. Based on our review of the new technology APC application for the NanoKnife® System, we provided temporary APC and status indicators assignments for 0600T and 0601T. The temporary APC and SI assignments were publicly released in the July 2020 quarterly update to the OPPS (Transmittal 10224, Change Request 11814, and dated July 15, 2020). In addition, in the CY 2021 OPPS/ASC proposed rule with comment period, we proposed to assign the codes to APC 5361 (Level 1 Laparoscopy and Related Procedures) with a payment rate of $5,148.34, and status indicator 'J1'' (Hospital Part B services paid through a comprehensive APC) based on clinical and resource similarities between 0600T, 0601T and other procedures in the same APC. We also proposed to assign these codes to comment indicator (CI) ''NP'' in Addendum B to the proposed rule to indicate that the codes are new for CY 2020 and that public comments would be accepted on their proposed APC assignments.

Comment: We received one comment from the applicant on the proposed assignment to APC 5361 (Level 1 Laparoscopy and Related Procedures). According to the applicant, new Category III CPT codes 0600T and 0601T should not be assigned to APC 5361 because the clinical characteristics and resource costs associated with the procedures are significantly different from existing procedures assigned to that APC. The applicant noted that under the IPPS, the NanoKnife® System was estimated to have a technology added cost of approximately $11,086, and that the procedures for which the system would apply generally were not significantly different in the inpatient and outpatient settings. They believe that the codes would be more appropriately placed in New Technology APC 1576 (New Technology—Level 39 ($15,001–$20,000)) with a payment rate of $17,500.50, based on the estimated costs and complexity of the procedures.

Response: We thank the applicant for their comment and the additional information they have provided regarding the procedures and in particular their estimated costs. While we recognize that there are differences between the various ablation modalities, we believe that the APC levels 5361 and 5362 for ''Laparoscopy and Related Services'' appropriately describe the resource costs and clinical characteristics of these procedures. However, we agree with the commenter that an alternative APC might better reflect the resource costs of the procedures. Therefore, we are revising the CY 2021 APC assignments for these codes. Specifically, we are assigning CPT codes 0600T and 0601T to APC 5362 (Level 2 Laparoscopy and Related Procedures) with a status indicator of ''J1'' in the CY 2021 OPPS.

After consideration of the public comment for the new irreversible electroporation codes, and based on our evaluation of the new technology application which provided the estimated costs for the services and described the components and characteristics of the new codes, we are finalizing our proposal with

modification, and reassigning CPT codes 0600T and 0601T to the final CY 2021 OPPS APC 5362 (Level 2 Laparoscopy and Related Services). Table 27 lists the four Category III CPT codes for the NanoKnife® System and their APC and SI assignments for CY 2021. The final CY 2021 OPPS payment rate for the codes can be found in Addendum B to this final rule with comment period (which is available via the internet on the CMS website).

TABLE 27.—FINAL SI AND APC ASSIGNMENTS FOR CPT CODES 0600T AND 0601T FOR CY 2021

CPT Code	Long Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
0600T	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous	J1	5361	J1	5362
0601T	Ablation, irreversible electroporation; 1 or more tumors, including fluoroscopic and ultrasound guidance, when performed, open	J1	5361	J1	5362

15. Medical Physics Dose Evaluation (APC 5611)

For CY 2021, we proposed to assign CPT code 76145 (Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report (medical physicist/dosimetrist)) in APC 5611 (Level 1 Therapeutic Radiation Treatment Preparation) with a proposed payment rate of $129.86. We note this is a new code that will be effective on January 1, 2021. Because the code is new, we requested public comments on the APC assignment for CY 2021. We also note that CPT code 76145 was listed as placeholder code 7615X in Addendum B and Addendum O of the CY 2021 OPPS/ASC proposed rule.

Comment: Several commenters disagreed with the assignment to APC 5611 and requested a reassignment to APC 5724 (Level 4 Diagnostic Tests and Related Services) with a proposed payment rate of $936.70. The commenters indicated that CPT code 76145 is not a radiation oncology code, rather, it is a service that will be performed in interventional radiology or interventional cardiology. The commenters stated that the resource consumption in APC 5724 more closely aligns with the resources used to perform CPT code 76145. One commenter explained that CPT code 76145 is used to describe the medical physicist's work in performing a patient-specific peak organ dose calculation subsequent to an interventional radiology or interventional cardiology procedure. The same commenter expressed concern that the new code will be included on the Deficit Reduction Act (DRA) cap designation list.

Response: Section 5102(b) of the Deficit Reduction Act of 2005 (DRA) added section 1848(b)(4) to the statute to place a payment cap on the technical component (TC) of certain diagnostic imaging procedures and the TC portions of the global diagnostic imaging services at the amount paid under the OPPS. To implement this provision, the physician fee schedule (PFS) amount is compared to the OPPS payment amount and the lower amount is used for payment under the PFS. However, we note that the OPPS cap is a policy that applies to the PFS payment and is not applicable under the OPPS; and the list of services that are subject to the OPPS cap is published as part of the annual PFS final rules. In addition, based on our review of the service associated with CPT code 76145 and input from our medical advisors, we believe that APC code 5611 is the most appropriate assignment for the code. The code is new for CY 2021 and therefore we have no claims data available for OPPS ratesetting. However, once we have claims data, we will review the APC assignment and determine whether a change is necessary. We note that we review, on an annual basis, the APC assignments for all items and services paid under the OPPS.

In summary, after consideration of the public comments, we are finalizing our proposal, without modification, and assigning CPT code 76145 to APC 5611 for CY 2021. The final CY 2021 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

16. Musculoskeletal Procedures (APCs 5111 Through 5116)

Prior to CY 2016, OPPS payment for musculoskeletal procedures was primarily divided according to anatomy and the type of musculoskeletal procedure. As part of the CY 2016 reorganization to better structure the OPPS payments towards prospective payment packages, we consolidated those individual APCs so that they became a general Musculoskeletal APC series (80 FR 70397 through 70398).

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59300), we continued to apply a six-level structure for the Musculoskeletal APCs because doing so provided an appropriate distinction for resource costs at each level and provided clinical homogeneity. However, we indicated that we would continue to review the structure of these APCs to determine whether additional granularity would be necessary.

In the CY 2019 OPPS proposed rule (83 FR 37096), we recognized that commenters had previously expressed concerns regarding the granularity of the current APC levels and, therefore, requested comment on the establishment of additional levels. Specifically, we solicited comments on the creation of a new APC level between the current Level 5 and Level 6 within

the Musculoskeletal APC series. While some commenters suggested APC reconfigurations and requests for change to APC assignments, many commenters requested that we maintain the current six-level structure and continue to monitor the claims data as they become available. Therefore, in the CY 2019 OPPS/ASC final rule with comment period, we maintained the six-level APC structure for the Musculoskeletal Procedures APCs (83 FR 58920 through 58921).

Based on the claims data available for the CY 2021 OPPS/ASC proposed rule, we stated that we continued to believe that the six-level APC structure for the Musculoskeletal Procedures APC series is appropriate. Therefore, we proposed to maintain the APC structure for the CY 2021 OPPS update.

In the CY 2020 OPPS/ASC final rule, we discussed issues related to the APC assignment of CPT code 22869 (Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level) to APC 5115 (84 FR 61253 through 61254). Specifically, commenters believed that the code was inappropriately assigned to APC 5115 due to one hospital inaccurately reporting its costs and charges. While we recognized the concerns that the commenters described, we noted that it is generally not our policy to judge the accuracy of hospital coding and charging for purposes of ratesetting. For the proposed CY 2021 OPPS, the geometric mean cost of CPT code 22869 increased slightly relative to the prior year, from $11,023.45 to $12,788.56. However, the proposed geometric mean costs of the Level 5 and Level 6 Musculoskeletal Procedures APCs were $12,102.02 and $15,975.08, respectively, and so, based on the data that was available, we continued to believe that it is appropriate to assign CPT code 22869 to APC 5115 (Level 5 Musculoskeletal Procedures APC).

For the CY 2021 OPPS, we also proposed to eliminate the Inpatient Only (IPO) list over a three-year transition and to assign codes removed from the IPO list to clinical APCs. Many of the codes proposed to be removed from the IPO list are musculoskeletal procedures that we proposed to assign to APCs in the Musculoskeletal Procedures APC series, and so there may be effects on the geometric means as the limited claims data for those codes is included in OPPS ratesetting. For a more detailed discussion of the proposal to remove certain codes from the IPO list, please see section IX.B. of the CY 2021 OPPS/ASC proposed rule.

Table 28 displays the final CY 2021 Musculoskeletal Procedures APC series' structure and APC geometric mean costs.

TABLE 28.—FINAL MUSCULOSKELETAL PROCEDURES APCS FOR CY 2021

APC	Group Title	HCPCS Codes Assigned to APC in this CY 2021 OPPS/ASC Final Rule	CY 2020 Final APC Geometric Mean Cost	CY 2021 Final APC Geometric Mean Cost
5111	Level 1 Musculoskeletal Procedures	103	$210.99	$200.86
5112	Level 2 Musculoskeletal Procedures	136	$1,326.17	$1,356.36
5113	Level 3 Musculoskeletal Procedures	411	$2,678.42	$2,757.24
5114	Level 4 Musculoskeletal Procedures	445	$5,852.95	$6,103.01
5115	Level 5 Musculoskeletal Procedures	122	$11,644.09	$11,996.45
5116	Level 6 Musculoskeletal Procedures	50	$15,602.23	$15,457.97

Comment: One commenter recommended that CMS create a seventh Musculoskeletal APC level above APC 5116 to account for complex procedures that were proposed to be removed from the IPO list. Another commenter requested that CMS consider the development of an additional Musculoskeletal APC between current APCs 5114 and 5115.

Response: We appreciate the commenters' recommendation. We understand that the addition of codes removed from the IPO list may affect the geometric means of the Musculoskeletal Procedures APCs and we will continue to monitor the claims data as they become available. We also appreciate the goal of developing APC levels that appropriately reflect resource costs. At this time, we believe the six-level structure for the Musculoskeletal APCs continues to be appropriate. However, we will take these comments into consideration for future rulemaking

Comment: We received one comment recommending that CMS reassign CPT codes 28297 (Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method) and 28740 (Arthrodesis, midtarsal or tarsometatarsal, single joint) to APC 5115 (Level 5 Musculoskeletal Procedures) to resolve any 2 times rule violations.

Response: We appreciate the commenter's recommendation regarding the APC assignment of CPT 28297 and 28740. CPT codes 28297 and 28740 are currently assigned to APC 5114 (Level 4 Musculoskeletal Procedures). Our review did not find that APC 5114 violates the 2 times rule. We also note that for purposes of identifying significant procedure codes for examination under the 2 times rule, we only consider procedure codes that have more than 1,000 single major claims or procedure codes that both have more than 99 single major claims and

contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832). Neither of these codes met this requirement and therefore were not considered significant procedure codes for 2 times rule purposes. Therefore, we are finalizing our proposal to continue to assign CPT codes 28297 and 28740 to APC 5114 in the CY 2021 OPPS.

Comment: Commenters supported our proposal to continue to assign CPT code 22869 to APC 5115 (Level 5 Musculoskeletal Procedures). One commenter requested that CMS continue to monitor the geometric mean cost for CPT code 22869 and reestablish the code with assignment to APC 5116 (Level 6 Musculoskeletal Procedures) when appropriate.

Response: We appreciate commenters' support. We will continue to review the most recent data and update the APC assignment for CPT code 22869 as necessary.

Comment: One commenter requested that we assign CPT code 23473 (Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component) from APC 5115 to APC 5116, based on their belief that the claims data was inaccurate and that the time required to perform the procedure was not reflected in the resource costs of the proposed APC placement.

Response: We note that CPT code 23473 has been established for some time, with an effective date of January 1, 2013 and that it was the initially established with a status indicator of ''T'' in the CY 2013 OPPS. Therefore, some of the issues related to codes transitioning off the IPO list do not necessarily apply in this case and the actual data for the claims are more appropriate in ratesetting than alternative proxies. In the updated final rule claims data available for ratesetting, the estimated geometric mean cost of CPT 23473 is approximately $10,634 based on 287 claims, which is within the range of the significant procedure costs of APC 5115 from approximately $9,644 to $12,902. As a result, we believe that the code is appropriately placed in APC 5115.

Comment: For the CY 2020 OPPS/ASC final rule, HCPCS code C9757 (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar) was assigned to comment indicator ''NI'' in the OPPS Addendum B to indicate that the code was new and that we would be accepting comments on the interim APC assignment. A commenter supported the assignment to APC 5115 (Level 5 Musculoskeletal Procedures) with a CY 2020 payment rate of $11,900.71.

Response: As we stated in the CY 2020 OPPS/ASC final rule, we accepted comments on the interim OPPS payment assignment for new codes effective January 1, 2020 that are assigned to comment indicator ''NI'' in the OPPS Addendum B (84 FR 61207). We further stated that the comments would be addressed, and if applicable, the APC assignment would be finalized in the CY 2021 OPPS/ASC final rule comment period. We appreciate the feedback. We note that for CY 2021, we are finalizing the assignment to APC 5115 (Level 5 Musculoskeletal Procedures) for HCPCS code C9757. The final payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, the status indicator definitions can be found in Addendum D1 to this final rule with comment period. Both Addendum B and Addendum D1 are available via the internet on the CMS website.

After consideration of the comments, we are finalizing our proposal to maintain the six-level Musculoskeletal Procedures APC structure. We are also finalizing the proposed assignment of CPT codes 28297 and 28740 to APC 5114, and the proposed assignment of CPT codes 22869 and 23473 to APC 5115 for the CY 2021 OPPS.

17. Neurostimulator and Related Procedures (APCs 5461 Through 5465)

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66807 through 66808), we finalized a restructuring of what were previously several neurostimulator procedure-related APCs into a four-level series. Since CY 2015, the four-level APC structure for the series has remained unchanged. In addition to that restructuring, in the CY 2015 OPPS/ASC final rule, we also made the Level 2 through 4 APCs comprehensive APCs (79 FR 66807 through 66808). Later, in the CY 2020 OPPS final rule, we also established the Level 1 Neurostimulator and Related Procedure APC (APC 5461) as a comprehensive APC (84 FR 61162 through 61166).

In reviewing the claims data available for the CY 2021 OPPS proposed rule, we believed that it was appropriate to create an additional Neurostimulator and Related Procedures level, between the current Level 2 and 3 APCs. Creating this APC allows for a smoother distribution of the costs between the different levels based on their resource costs and clinical characteristics. Therefore, for the CY 2021 OPPS, we proposed to establish a five-level APC structure for the Neurostimulator and Related Procedures series. We noted that in addition to creating the new level, we also proposed to assign CPT code 0398T (Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed) to the new Level 3 APC, as discussed in further detail in section III.C.3.A of the CY 2021 OPPS/ASC proposed rule with comment period.

Comment: Multiple commenters requested that we add a Level 6 Neurostimulator and Related Procedures APC. The commenters are concerned that the payment rate for the current Level 4 APC and the proposed Level 5 APC is dominated by CPT code 63685 (Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling) which has a geometric mean of $29,123.02. The commenter indicated this means that higher cost neurostimulator services that have relatively low utilization are substantially underpaid. The commenters believe the lack of payment for these services is discouraging their use, and they want a Level 6 APC to establish a payment rate that more closely reflects the cost of these expensive, low utilization services.

Response: We appreciate the concerns of the commenters, but we reiterate that the OPPS is a prospective payment system. We group procedures with similar clinical characteristics and resource costs into APCs and establish a payment rate that reflects the geometric mean of all services in the group even though the cost of each service within the APC may be higher or lower than the APC's geometric mean. As a result, in the OPPS any individual procedure may potentially be overpaid or underpaid because the payment rate is based on the geometric mean of the entire group of services in the APC. However, the impact of these payment differences should be mitigated when distributed across a large number of APCs. If we were to establish a Level 6 APC for Neurostimulators and Related Procedures based on the commenters' request, we would find the payment rate for the APC would be closer to some of the services assigned to that APC but

other services would continue to receive payment that is substantially lower than those services' geometric mean cost. In the end, the only way to ensure each service receives payment equivalent to the cost of the service would be to establish separate APCs for each service the commenters believe is underpaid. That solution would be contrary to payment principles of the OPPS, which is based on prospective payment. Therefore, we believe it is appropriate to maintain the same five level structure as proposed in the CY 2021 OPPS.

Comment: Most commenters supported our proposal to create an additional Neurostimulator and Related Procedures level, between the current Level 2 and 3 APCs, which is described as the Level 3 Neurostimulator and Related Procedures APC in our proposal.

Response: We appreciate the support of the commenters for our proposal.

Comment: One commenter noted that our proposal to establish an additional APC level would lead to a decrease in payment for services described by CPT codes 63650 (Percutaneous implantation of neurostimulator electrode array, epidural), 63685 (Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling), and 63688 (Revision or removal of implanted spinal neurostimulator pulse generator or receiver).

Response: We did not find that there would be a substantial decrease in the payment for the procedures described by CPT codes 63650, 63685, and 63688 due to our proposal. Based on a review of our claims data, we found only a modest payment decrease for CPT code 63650 and modest payment increases for CPT codes 63685 and 63688.

In addition, for CY 2021, we proposed to continue to assign CPT code 0587T to APC 5442 (Level 2 Nerve Injections) with a proposed payment of $644.55. We also proposed to continue to assign CPT code 0588T to APC 5441 (Level 1 Nerve Injections) with a proposed payment of $267.50. We note that because both codes were effective on January 1, 2020, we have no claims data available for OPPS ratesetting, as the CY 2021 OPPS payment rates are based on claims submitted between January 1, 2019 through December 31, 2019, and processed through June 30, 2020. The long descriptors for both codes can be found in Table 29 below.

Comment: A commenter explained that in May 2019 the AMA CPT Editorial Panel approved four (4) Category III CPT codes to describe the surgical procedures associated with the PROTECT PNS Neurostimulation System, specifically, CPT codes 0587T, 0588T, 0589T, and 0590T. The PROTECT PNS device is used for the treatment of overactive bladder (OAB) symptoms. The commenter added that on October 19, 2016, CMS approved Medicare coverage for the Category B IDE study associated with the PROTECT PNS device. In addition, the commenter also stated that CMS incorrectly assigned CPT codes 0587T and 0588T to inappropriate APC assignments.

For CPT code 0587T, the commenter clarified that CPT code 0587T is not an injection; rather, the code describes an implantation or replacement of an integrated single device neurostimulation system, similar to the procedures assigned to the Neurostimulator and Related Procedures (APCs 5461 through 5465) family. The commenter recommended reassigning CPT code 0587T to one of these APCs to adequately capture the correct clinical characteristics and resource costs of the technology similar to other neurostimulation devices in APCs 5461 through 5465. The commenter specifically recommended the reassignment to APC 5464 (Level 4 Neurostimulator and Related Procedures) with a proposed payment rate of $20,789.82, since the procedure is very similar to CPT code 64590 (Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling), which is assigned to APC 5464. According to the commenter, the cost of the PROTECT implantable device and transmitter kit that is used in the procedure is about $15,820. Based on the commenter's estimated cost of approximately $20,032, which includes the non-device cost of $2,737 and the PROTECT device cost of $15,820, the appropriate assignment for the code until OPPS claims are available is APC 5464.

For CPT code 0588T, the commenter explained that the code is not an injection procedure, rather, the code describes the surgical removal of the device. The commenter suggested reassigning the code to APC 5461 (Level 1 Neurostimulator and Related Procedures) with a proposed payment of $3,498.13 because it is comparable to CPT code 64595 (Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver) based on clinical similarity and resource costs.

Response: We do not agree that CPT code 0587T is comparable to CPT code 64590. Based on our review of the clinical characteristics of the procedure and input from our medical advisors, we believe CPT code 0587T is more similar to the procedures assigned to APC 5462 (Level 2 Neurostimulator and Related Procedures). However, we agree that CPT code 0588T is similar to the procedures in APC 5461, and are therefore assigning the code to APC 5461 in the CY 2021 OPPS.

In summary, after consideration of the public comment, we are finalizing our proposal with modification, and reassigning CPT code 0587T to APC 5462 and CPT code 0588T to APC 5461. Table 29 below list the four Category III CPT codes for the PROTECT PNS System and their APC and SI assignments for CY 2021. The final CY 2021 OPPS payment rates for the codes can be found in Addendum B of this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator meanings for all codes reported under the OPPS for CY 2021. Both Addendum B and Addendum D1 are available via the internet on the CMS website.

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TABLE 29.—FINAL SI AND APC ASSIGNMENTS FOR CPT CODES 0587T THROUGH 0590T FOR CY 2021

CY 2021 HCPCS Code	Long Descriptor	Proposed OPPS SI	Proposed OPPS APC	Final OPPS SI	Final OPPS APC
0587T	Percutaneous implantation or replacement of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve	T	5442	J1	5462
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve	T	5441	J1	5461
0589T	Electronic analysis with simple programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 1-3 parameters	S	5742	S	5742
0590T	Electronic analysis with complex programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 4 or more parameters	S	5742	S	5742

Comment: Two commenters supported our proposal to change the APC assignment for CPT code 0398T (Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed) to the proposed new Level 3 Neurostimulator and Related Procedures APC.

Response: We appreciate the support of the commenters for our proposal.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to establish a five-level APC structure for the Neurostimulator and Related Procedures series. In addition to creating this new level, we also finalizing our proposal to assign CPT 0398T (Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed) to this new Level 3 APC. Table 30 displays the proposed and final CY 2021 Neurostimulator and Related Procedures APC series' structure and APC geometric mean costs.

TABLE 30. —FINAL GEOMETRIC MEAN COST FOR THE NEUROSTIMULATOR AND RELATED PROCEDURES APCS FOR CY 2021

APC	APC Descriptor	SI	CY 2020 OPPS Final Geometric Mean Cost	CY 2021 Proposed Geometric Mean Cost	CY 2021 Final Geometric Mean Cost
5461	Level 1 Neurostimulator and Related Procedures	J1	$3,080.60	$3,370.70	$3,190.64
5462	Level 2 Neurostimulator and Related Procedures	J1	$6,053.71	$6,105.05	$6,001.45
5463	Level 3 Neurostimulator and Related Procedures	J1	$18,863.68	$12,286.43	$10,945.77
5464	Level 4 Neurostimulator and Related Procedures	J1	$28,490.84	$20,032.49	$19,950.42
5465	Level 5 Neurostimulator and Related Procedures	J1	N/A	$28,876.14	$28,683.43

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18. Noncontact Real-Time Fluorescence Wound Imaging/MolecuLight (APC 5722)

For the July 2020 update, the CPT Editorial Panel established two new codes, specifically, CPT codes 0598T and 0599T, to report noncontact real-time fluorescence wound imaging for bacterial presence in chronic and acute wounds. The codes and their long descriptors were listed in Table 7 (New HCPCS Codes Effective July 1, 2020) of the CY 2021 OPPS/ASC final rule with comment period (85 FR 48815 through 48823). We note that CMS recently received a new technology application for the MolecuLight i: X procedure, which is described by CPT codes 0598T and 0599T. In determining the appropriate payment for CPT code 0598T, we considered whether there should be separate or conditionally packaged payment for the procedure since the use of the MolecuLight imaging device will most often involve another procedure or service during the same session (for example, debridement of the wound, laboratory service, or another skin-related procedure). In addition, we considered whether the code should be placed in either the Diagnostic Procedures or Minor Procedures APC group. Based on our review of the application and input from our physicians, we assigned CPT code 0598T to APC 5722 (Level 2 Diagnostic Tests and Related Services) and status indicator ''T'' with a payment rate of $253.10 effective July 1, 2020. In addition, because CPT code 0599T is an add-on code, we assigned the code to status indicator ''N'' to indicate that the payment is included in the primary procedure. We note that the new technology application indicated a higher projected cost involving care in an operating room (OR), however, based on our review of the MolecuLight service, we removed OR-associated costs because it was not clear to us that the test would routinely be performed in the OR setting. However, in the CY 2021 OPPS/ASC proposed rule we solicited public comments from hospital-based providers that have used MolecuLight on the appropriate OPPS payment, particularly with respect to the cost of providing the service in the hospital outpatient setting.

For CY 2021, we proposed to continue to assign CPT code 0598T to APC 5722 (Level 2 Diagnostic Tests and Related Services) with a proposed payment rate of $269.85. We proposed to maintain a status indicator of ''N'' for CPT code 0599T, which is an add-on code, to indicate that the payment is included in the primary procedure. The long descriptors and proposed SI and APC assignments for both codes can be found in Table 31 below.

Comment: Some commenters agreed with the APC assignment to APC 5722 for CPT code 0598T, however, they had concerns with the packaged status indicator assignment for CPT code 0599T, and suggested assigning the code to a different APC and revising the status indicator from ''N'' (packaged) to ''S'' (Procedure or Service, Not Discounted When Multiple). One commenter indicated that the payment is insufficient to cover the cost of the procedure and contended that the low reimbursement will dissuade hospitals from offering the service. The commenter reported that the procedure requires the use of a Dark Drape technology and also requires significant time because the second ulcer and subsequent ulcers typically involve different anatomical locations. Another commenter reported that hospital outpatient charges for CPT code 0598T are between $850 and $2,500 for the first wound and between $850 and $1,850 for subsequent anatomic sites. The same commenter suggested that OPPS payment is inadequate, especially in cases that involve additional wounds in different anatomic sites such as the sacrum, abdomen, toe, or leg, all of which require additional resource costs. Consequently, the commenter requested a revision in the APC assignment for both codes. Specifically, the commenter recommended reassigning CPT code 0598T from APC 5722 to APC 5723 (Level 3 Diagnostic Tests and Related Services) with a proposed payment of $497.96, and to assign CPT code 0599T to APC 5722 with a proposed payment of $269.85. In addition, the commenter recommended assigning both codes status indicator ''S''.

Response: With regard to CPT code 0598T, based on our evaluation of the new technology application submitted to CMS as well as input from our physicians, we believe that we should maintain the assignment to APC 5722 for CY 2021. In addition, because CPT code 0599T is an add-on code, we are maintaining its status indicator assignment of ''N'' (packaged). As specified in section § 419.2(b)(18), add-on codes are generally packaged under

the hospital OPPS. As explained in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74942 through 74945), we finalized a policy to unconditionally package procedures described by add-on codes. Procedures described by add-on codes represent an extension or continuation of a primary procedure, which means that they are typically supportive, dependent, or adjunctive to a primary service. The primary code defines the purpose and typical scope of the patient encounter and the add-on code describes incremental work, when the extent of the procedure encompasses a range rather than a single defined endpoint applicable to all patients. Given the dependent nature and adjunctive characteristics of procedures described by add-on codes and in light of longstanding OPPS packaging principles, we finalized a policy to unconditionally package add-on codes with the primary procedure.

In summary, after consideration of the public comments, we are finalizing our proposal, without modification, to assign CPT code 0598T to APC 5722 with status indicator ''T'' and to assign CPT code 0599T status indicator ''N'' for CY 2021. The final CY 2021 payment rate for CPT code 0598T can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

TABLE 31.—FINAL SI AND APC ASSIGNMENTS FOR CPT CODES 0598T AND 0599T FOR CY 2021

CY 2021 CPT Code	Long Descriptor	Proposed CY 2021 OPPS SI	Proposed CY 2021 OPPS APC	Final CY 2021 OPPS SI	Final CY 2021 OPPS APC
0598T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (eg, lower extremity)	T	5722	T	5722
0599T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; each additional anatomic site (for example, upper extremity) (List separately in addition to code for primary procedure)	N	N/A	N	N/A

19. Nuclear Medicine Services: Single-Photon Emission Computed Tomography (SPECT) Studies (APC 5593)

For CY 2021, we proposed to reassign CPT code 78803 (Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (spect), single area (*e.g.*, head, neck, chest, pelvis), single day imaging) from APC 5593 (Level 3 Nuclear Medicine and Related Services) with a payment rate of $1,272.19 to APC 5592 (Level 2 Nuclear Medicine and Related Services) with a proposed payment rate of $501.45.

Comment: Several commenters objected to the reassignment of CPT code 78803 to APC 5592 and requested that we not finalize our proposal but rather maintain the current placement in APC 5593. They stated that the significant payment decrease would limit patient access, affect patient care, and restrict hospitals from offering the test. One commenter reported that the Medicare payment for CPT code 78803 is insufficient, and as a result, many hospitals refuse to offer the service. This same commenter reported that lowering the payment for the test may force some hospitals that currently offer the test to stop providing it altogether. The commenter added that many patients travel hours to access a SPECT scan exam and lowering the payment for the test would not improve patient care. Some commenters reminded us that for CY 2020, CPT code 78803 replaced seven codes that were deleted on December 31, 2019. Most commenters stated that the more appropriate placement for CPT code 78803 is APC 5593, based on resource use and clinical similarity to the other procedures in the APC.

Response: We discussed the issue related to the seven deleted codes in the CY 2020 OPPS/ASC final rule (84 FR 61257 through 61258) and noted that based on the geometric mean costs for CPT code 78803 and the deleted codes, we believe it was necessary for us to maintain the APC assignment for CPT code 78803 in APC 5593. Because the CY 2021 OPPS payments are based on claims submitted between January 1, 2019 through December 31, 2019, and processed through June 30, 2020, we again reviewed the claims data for the deleted codes to determine the appropriate placement for CPT code 78803. As listed in Table 32, the range of geometric mean costs for CPT code 78803 and the seven deleted codes is between $408 and $1,508. Similar to our CY 2020 findings, we note that several of the deleted codes were assigned to APC 5593, and based on our review of these codes, we believe it would be appropriate to maintain assignment of CPT code 78803 to APC 5593 for CY 2021.

TABLE 32.--GEOMETRIC MEAN COSTS FOR CPT CODE 78803 AND ITS DELETED PREDECESSOR CPT CODES

CPT Code	Status	Long Descriptor	SI	APC	Geometric Mean Cost
78205	DELETED	Liver imaging; with vascular flow	S	5592	$541.27
78206	DELETED	Liver imaging (spect);	S	5592	$494.65
78320	DELETED	Bone and/or joint imaging; tomographic (spect)	S	5592	$408.09
78607	DELETED	Brain imaging, tomographic (spect)	S	5593	$1,508.47
78647	DELETED	Cerebrospinal fluid flow, imaging (not including introduction of material); tomographic (spect)	S	5592	$487.74
78710	DELETED	Kidney imaging morphology; tomographic (spect)	S	5592	$447.65
78803	ACTIVE	Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); tomographic (spect)	S	5593	$528.97
78807	DELETED	Radiopharmaceutical localization of inflammatory process; tomographic (spect)	S	5592	$632.56

Comment: One commenter agreed with the proposal to maintain the four levels of nuclear medicine APCs for CY 2021 but requested that CMS consider establishing additional APCs as needed to ensure that the nuclear medicine APCs do not violate the 2-times rule when the cost of packaged diagnostic radiopharmaceuticals drugs are included.

Response: We appreciate the feedback and will consider in future rulemaking whether establishing additional nuclear medicine APCs would be appropriate.

In summary, after consideration of the public comments, and after our analysis of the updated claims data for this final rule with comment period, we are finalizing a modification to our proposal. Specifically, we are revising the APC assignment for CPT code 78803 to APC 5593 for CY 2021. The final CY 2021 payment rate for the code can be found in Addendum B to this final rule with comment period (which is available via the internet on the CMS website).

As we do every year, we will reevaluate the APC assignment for CPT code 78803 for the next rulemaking cycle. We note that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS.

20. Pathogen Test for Platelets/Rapid Bacterial Testing (APC 5732)

For the July 2017 update, the HCPCS Workgroup established HCPCS code Q9987 (Pathogen(s) test for platelets) effective July 1, 2017. This new code and the OPPS APC assignment were announced in the July 2017 OPPS quarterly update CR (Transmittal 3783, Change Request 10122, dated May 26, 2017). Because HCPCS code Q9987 represented a test to identify bacterial or other pathogen contamination in blood platelets, we assigned the code to a new technology APC, specifically, New Technology APC 1493 (New Technology—Level 1C ($21–$30)) with a status indicator ''S'' and a payment rate of $25.50. We note that temporary HCPCS code Q9987 was subsequently deleted on December 31, 2017, and replaced with permanent HCPCS code P9100 (Pathogen(s) test for platelets) effective January 1, 2018. For the January 2018 update, we continued to assign the new code to the same APC and status indicator as its predecessor code. Specifically, we assigned HCPCS code P9100 to New Technology APC 1493 and status indicator ''S''. For the CY 2019 update, we made no change to the APC or status indicator assignment for P9100, however, for the CY 2020 update, we revised the APC assignment from New Technology APC 1493 to 1494 (New Technology—Level 1D ($31–$40)) based on the latest claims data used to set the payment rates for CY 2020. We discussed the revision in the CY 2020 OPPS/ASC final rule (84 FR 61219) and indicated that the reassignment to APC 1494 appropriately reflected the cost of the service.

For the CY 2021 proposed rule, we believed that we had sufficient claims data to reassign the code from a New Technology APC to a clinical APC, and noted that HCPCS code P9100 had been assigned to a New Technology APC for over 3 years. As stated in section III.D. (New Technology APCs), a service is paid under a New Technology APC until sufficient claims data have been collected to allow CMS to assign the procedure to a clinical APC group that is appropriate in clinical and resource terms. We expect this to occur within two to three years from the time a new HCPCS code becomes effective. However, if we are able to collect sufficient claims data in less than 2 years, we would consider reassigning the service to an appropriate clinical APC. Since HCPCS code P9100 has been assigned to a new technology APC since July 2017, we believed that we should reassign the code to a clinical APC. Specifically, our claims data for the proposed rule showed a geometric mean cost of approximately $30 for HCPCS code P9100 based on 70 single claims (out of 1,835 total claims). Based on resource cost and clinical homogeneity to the other services assigned to APC 5732 (Level 2 Minor Procedures), we believed that HCPCS code P9100 should be reassigned to clinical APC 5732, which had a geometric mean cost of approximately $33.

As we have stated several times since the implementation of the OPPS on August 1, 2000, we review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our analysis of the latest claims data. For the CY 2021 OPPS update, based on claims submitted between January 1, 2019, and December

30, 2019, our analysis of the latest claims data for the proposed rule supported reassigning HCPCS code P9100 to APC 5732 based on its clinical and resource similarity to the procedures and services in the APC. Therefore, we proposed to reassign HCPCS code P9100 from New Technology APC 1494 to clinical APC 5732 for CY 2021.

Comment: A commenter supported our proposal to revise the APC assignment for HCPCS code P9100 to APC 5732.

Response: We appreciate the support for our proposal. Based on our review of the updated claims data for this final rule with comment period, which is based on claims submitted between January 1, 2019, and December 30, 2019, and processed through June 30, 2020, we continue to believe that reassigning HCPCS code P9100 to APC 5732 is appropriate. Specifically, our claims data show a geometric mean cost of approximately $30.86 for HCPCS P9100 based on 75 single claims (out of 2,038 total claims), which is consistent with the geometric mean cost of about $32.97 for APC 5732.

In summary, after consideration of the public comment, and after our analysis of the updated claims data for this final rule with comment period, we are finalizing our proposal, without modification, to assign HCPCS code P9100 to APC 5732 for CY 2021. The final CY 2021 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

21. Payment for Radioisotopes Derived From Non-Highly Enriched Uranium (Non-HEU) Sources (APC 1442)

Radioisotopes are widely used in modern medical imaging, particularly for cardiac imaging and predominantly for the Medicare population. Some of the Technetium-99 (Tc-99m), the radioisotope used in the majority of such diagnostic imaging services, is produced in legacy reactors outside of the United States using highly enriched uranium (HEU).

The United States would like to eliminate domestic reliance on these reactors, and is promoting the conversion of all medical radioisotope production to non-HEU sources. Alternative methods for producing Tc-99m without HEU are technologically and economically viable, and conversion to such production has begun. We expect that this change in the supply source for the radioisotope used for modern medical imaging will introduce new costs into the payment system that are not accounted for in the historical claims data.

Therefore, beginning in CY 2013, we finalized a policy to provide an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources (77 FR 68323). Under this policy, hospitals report HCPCS code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on per study dose) once per dose along with any diagnostic scan or scans furnished using Tc-99m as long as the Tc-99m doses used can be certified by the hospital to be at least 95 percent derived from non-HEU sources (77 FR 68321).

Comment: One commenter requested that we increase the payment rate for HCPCS add-on code Q9969 from $10. The commenter noted that we have not increased the payment rate for Q9969 since the code was established in CY 2013. The commenter suggested increasing the payment for Q9969 by the annual market basket increase for CY 2021 along with a one-time increase to reflect prior increases to the market basket between CY 2013 and CY 2021. Alternatively, the commenter suggested the payment rate could be increased by the change in the drug cost threshold packaging amount between CY 2013 and CY 2021.

Response: We appreciate the information we received from the commenter supporting an increase to the payment rate of $10 for HCPCS code Q9969. As discussed in the CY 2013 OPPS/ASC final rule with comment period, we did not finalize a policy to use the usual OPPS methodologies to update the non-HEU add-on payment (77 FR 68317). The purpose of the additional payment is limited to mitigating any adverse impact of transitioning to non-HEU sources and we believe the add-on is appropriate at this time.

Comment: Multiple commenters supported the current payment amount for HCPCS code Q9969 and they requested that we finalize our proposed payment rate for the add-on.

Response: We appreciate the support of the commenters for the proposed payment rate for HCPCS code Q9969.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to continue the policy of providing an additional $10 payment for radioisotopes produced by non-HEU sources for CY 2021 and subsequent years as represented by HCPCS code Q9969.

22. Percutaneous Transcatheter Ultrasound Nerve Ablation

The Therapeutic Intra-Vascular Ultrasound System (TIVUS™) is a high intensity, non-focused, ultrasound catheter system, which enables remote, localized, controlled and repeatable thermal modulation of nerves adjacent to arterial vessel wall for performing therapeutic pulmonary artery sympathetic denervation and is used for the treatment of pulmonary arterial hypertension (PAH). In 2020, the TIVUS™ system was approved by FDA for a Category B (Nonexperimental/investigational) Investigational Device Exemption (IDE) for the device to be used in a clinical study. The study sponsors have also requested Medicare coverage of the Category B IDE study to allow for coverage of the TIVUS™ system and the routine care items and services in the clinical trial. To date, CMS has not established approval of Medicare coverage for the Category B IDE study for the TIVUS™ system.

The TIVUS™ system is used with CPT code 0632T (Percutaneous transcatheter ultrasound ablation, nerves innervating the pulmonary arteries, including right heart catheterization, radiological supervision and interpretation and pulmonary artery angiography), which will become effective January 1, 2021. In the CY 2021 OPPS/ASC proposed rule, CPT code 0632T was assigned status indicator ''E1'', which describes items, codes, and services not covered by any Medicare outpatient benefit category, statutorily excluded by Medicare, or not reasonable and necessary. These items, codes, and services are not paid by Medicare when submitted on outpatient claims.

Comment: One commenter, the manufacturer of the TIVUS™ system, requested that, in anticipation of approval of Medicare coverage for the Category B IDE study for the TIVUS™ system, CMS assign CPT code 0632T status indicator ''J1'', which describes services paid through a comprehensive APC (C–APC) instead of status indicator ''E1'' for CY 2021. The commenter also requested that CMS assign CPT code 0632T to C–APC 5213 (Level 3 Electrophysiologic Procedures) for CY 2021, stating that the procedure is similar in clinical characteristics and resource costs to CPT code 93656 (Comprehensive electrophysiologic evaluation including transseptal catheterizations, insertion and repositioning of multiple electrode catheters with induction or attempted induction of an arrhythmia including

left or right atrial pacing/recording, when necessary, right ventricular pacing/recording when necessary, and his bundle recording when necessary with intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation), which is assigned to C–APC 5213 for CY 2021.

Response: For approved Category B IDE studies, CMS allows for coverage of the Category B device and the routine care items and services in the clinical trial. To date, coverage for the Category B IDE clinical study for the TIVUS™ system has not been approved by CMS. We do not believe that it is appropriate to assign a payable status indicator under the OPPS to CPT code 0632T prior to the approval of the Category B IDE study. Therefore, for CY 2021, we are finalizing the assignment of status indicator ''E1'' to CPT code 0632T.

23. Peripheral Intravascular Lithotripsy (IVL) Procedure (APCs 5192, 5193, and 5194)

The IVL system has three components: A proprietary IVL Catheter, an IVL Generator, and an IVL Connector Cable. It is a lithotripsy-enhanced balloon catheter used to dilate lesions, including calcified lesions, in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries. The IVL catheter has integrated lithotripsy emitters and is designed to enhance percutaneous transluminal angioplasty by enabling delivery of the calcium disrupting capability of lithotripsy prior to full balloon dilatation at low pressures. The application of lithotripsy mechanical pulse waves alters the structure of an occlusive vascular deposit (stenosis) prior to low-pressure balloon dilation of the stenosis and facilitates the passage of blood and is used for the treatment of peripheral artery disease (PAD).

In 2019, FDA cleared 510(k) submission based on a determination of substantial equivalence to a legally marketed predicate device. The manufacturer also submitted a new technology application requesting new technology APC assignment for IVL procedures. Based on our review of the New Technology APC application for this service and the service's clinical similarity to existing APCs in the OPPS, we created four new HCPCS codes for these services and assigned these codes to existing clinical APCs. Specifically, CMS proposed to add HCPCS code C9764 (Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed), C9765 (Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed) C9766 (Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed), and C9767 (Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed), effective July 1, 2020. We assigned code C9764 to APC 5192 (Level 2 Endovascular Procedures) with a payment rate of $4,953.91; C9765 and C9766 to APC 5193 (Level 3 Endovascular Procedures) with a payment rate of $9,908.48; and C9767 to APC 5194 (Level 4 Endovascular Procedures) with a payment rate of $15,939.97 for CY 2020. In the CY 2021 OPPS/ASC proposed rule, we proposed to maintain these APC assignments for these codes in CY 2021.

At the August 31, 2020 HOP Panel Meeting, a presenter requested that we reassign IVL procedure C9764 to APC 5193 and procedures C9765 and C9766 to APC 5194. The presenter indicated that the APC payment associated with HCPCS code(s) C9764, C9765 and C9766 is inadequate to cover the cost of the procedures. According to the presenter, the proposed CY 2021 geometric mean cost for the procedures range from $6,619.26 to $22,305.36, not including the additional cost of the IVL catheter. The presenter reported that the cost of one catheter is $2,800 but each procedure requires an average of 1.2 catheters, bringing the total cost of catheters to $3,360 per procedure. The presenter stated that the payment rate for the IVL procedures on tibial and peroneal vessels was lower than the payment rate for similar procedures without IVL. The presenter believed that hospitals will limit access to IVL, reducing patient access, because payment for the procedure is inadequate. They argued that limiting IVL access to patients suffering from critical limb ischemia in tibial and peroneal arteries could lead to higher complications associated with current treatment modalities. They believe that traditional treatments are associated with higher risk of distal embolization, perforation and possible amputation. Based on the information presented at the meeting, the HOP Panel recommended CMS reassign HCPCS code C9764 to APC 5193 and HCPCS codes C9765 and C9766 to APC 5194, as long as the cost of the IVL device is within 10 percent of other devices currently available. However, we are unable to identify devices that are similar to IVL and therefore cannot complete the data analysis recommended by the HOP Panel.

Comment: Several commenters disagreed with CMS' proposed APC assignments for the peripheral intravascular lithotripsy service described by HCPCS codes C9764, C9765 and C9766. They reported that, based on the resource cost of the service described by HCPCS code C9764, APC 5192 does not provide adequate reimbursement for the service, and recommended reassignment to APC 5193 (Level 3 Endovascular Procedures) with a proposed payment rate of $10,222.32. Similarly, for HCPCS codes C9765 and C9766, the commenters indicated that APC 5193 would not adequately cover the resource costs associated with these procedures, and recommended their reassignment to APC 5194 (Level 4 Endovascular Procedures) with a proposed payment rate of $16,348.66.

Response: APC assignment for a code is based on similarity to other codes within an APC in terms of clinical homogeneity and resource costs. As specified in 42 CFR 419.31(a)(1), CMS classifies outpatient services and procedures that are comparable clinically and in terms of resource use into APC groups. As we stated in the CY 2012 OPPS/ASC final rule (76 FR 74224), the OPPS is a prospective payment system that provides payment for groups of services that share clinical and resource use characteristics. For all new codes, our policy has been to assign the service or procedure to an APC informed by a variety of sources, including but not limited to, review of the clinical similarity of the service to existing procedures; advice from CMS medical advisors; information from interested specialty societies; and review of all other information available to us, including information provided to us by the public, whether through meetings with stakeholders or additional information that is mailed or otherwise communicated to us.

Based on the comments we received, the HOP Panel recommendation, information provided in the new technology application, and advice from our medical advisors, we believe we should add new HCPCS codes to describe tibial and peroneal IVL procedures, for a total of eight IVL procedure codes, and revise the long

descriptors for HCPCS codes C9764, C9765, C9766, and C9767 by deleting the words ''any vessel(s)'' and replacing with ''lower extremity artery(ies), except tibial/peroneal'' effective January 1, 2021. We agree with commenters that the resources associated with tibial and peroneal IVL procedures are higher than iliac, femoral and popliteal procedures. Therefore, we are creating new HCPCS codes C9772, C9773, C9774, and C9775 to describe tibial and peroneal procedures and assigning these codes to APCs as listed in the Table 33 below.

In summary, after consideration of public comments, we are finalizing our proposal with modification, to provide new HCPCS codes C9772, C9773, C9774 and C9775 and assign these codes to APCs listed in Table 33. Table 33 also lists revised long descriptors for HCPCS codes C9764, C9765, C9766, and C9767, and final SI and APC assignments for all eight codes. The final CY 2021 payment rate for these codes can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

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TABLE 33.—FINAL SI AND APC ASSIGNMENTS FOR HCPCS CODES C9764 THROUGH C9767 AND C9772 THROUGH C9775 FOR CY 2021

CY 2021 HCPCS Code	Long Descriptor	Final OPPS SI	Final OPPS APC
C9764	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed	J1	5192
C9765	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed	J1	5193
C9766	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed	J1	5193
C9767	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel (s), when performed	J1	5194
C9772	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies), with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed	J1	5193
C9773	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed	J1	5194
C9774	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed	J1	5194
C9775	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel (s), when performed	J1	5194

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24. Remote Physiological Monitoring (APC 5741)

a. Initial Remote Monitoring of Physiologic Parameters (APC 5741)

For the CY 2019 update, the CPT Editorial Panel established a new code, specifically, CPT code 99454, to describe initial remote monitoring of physiological parameters effective January 1, 2019. In the CY 2019 update, we assigned this code to APC 5741 (Level 1 Electronic Analysis of Devices) with status indicator ''Q1'' (conditionally packaged) and a payment rate of $37.16 effective January 1, 2019, based on the clinical and resource similarity with CPT code 93270 (External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; recording (includes connection, recording, and disconnection)). The new code appeared in the OPPS Addendum B of the CY 2019 OPPS/ASC final rule.

For CY 2020 OPPS/ASC final rule, we maintained the assignment of CPT code 99454 to APC 5741 with a payment rate of $36.25. We note that we had no claims data for CPT code 99454 for the CY 2020 final rule since the code was established on January 1, 2019. For the CY 2021 OPPS/ASC proposed rule, we proposed to maintain the assignment of CPT code 99454 to APC 5741 with the proposed payment rate of $37.76.

Comment: One commenter was concerned that the current reimbursement rate is too low, which the commenter believes discourages providers from using much-needed equipment and services. The commenter stated that CMS must ensure that life-saving RPM technology would be available to Medicare beneficiaries by updating the status indicator and increasing reimbursement rate for CPT code 99454. The commenter requested: (1) A change in the status indicator for CPT code 99454 from ''Q1'' to ''S,'' so that it will be paid when used in conjunction with other services; and (2) reassignment of CPT code 99454 from APC 5741 (Level 1 Electronic Analysis of Devices) to APC 5742 (Level 2 Electronic Analysis of Devices).

Response: As we have stated every year since the implementation of the OPPS on August 1, 2000, we review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on our analysis of the latest claims data. For CY 2021, based on claims submitted between January 1, 2019 through December 31, 2019, that were processed on or before June 30, 2020, our analysis of the latest claims data for this final rule with comment period supports continuing to assign CPT code 99454 to APC 5741. Specifically, our claims data shows a geometric mean cost of approximately $28.06 for CPT 99454 based on 185 single claims (out of 275 total claims), which is comparable to the geometric mean cost of about $36.19 for APC 5741, rather than the geometric mean cost of approximately $97.72 for APC 5742.

We proposed to assign code 99454 to status indicator ''Q1'' for CY 2021 to indicate that the payment for CPT code 99454 is packaged when the code is billed on the same claim as a HCPCS code assigned to OPPS status indicator ''S'', ''T'', or ''V'', but is paid separately when it is the only major service on the claim. Because the service described by CPT code 99454 will most often be performed as part of another significant procedure, we believe that packaging the cost associated with CPT code 99454 into the primary service is appropriate. Therefore, assignment of status indicator ''Q1'' to CPT 99454 is appropriate.

In summary, after consideration of the public comments and after evaluation of our claims data for this final rule with comment period, we are finalizing our proposal, without modification, for CPT code 99454. The final CY 2021 payment rate for the CPT code 99454 can be found in Addendum B to this final rule with comment period (which is available via the internet on the CMS website).

As we do every year, we will reevaluate the APC assignment for CPT code 99454 for the next rulemaking cycle. We remind hospitals that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on the latest claims data.

b. Remote Physiological Monitoring Services, Virtual Check-In, E-Visits, Telephone E/M, and Medication Management Services

For CY 2021, we proposed to continue to assign CPT code 99091 (Collection and interpretation of physiologic data (*e.g.*, ecg, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days) to status indicator ''N'' (packaged) to indicate that the payment for the service is included in the primary service reported with the code. We also proposed to continue to assign CPT codes 99457 (Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes) and 99458 (Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (list separately in addition to code for primary procedure)) to status indicator ''B'' (not recognized under OPPS) to indicate that the codes are not paid under the hospital OPPS but may be paid under a different Medicare payment system other than the OPPS. However, if the services described by either CPT code 99457 or 99458 are performed in the hospital outpatient facility, the facility should report an alternate code. These codes are listed in Table 34 along with the descriptors and status indicator assignments. In addition, the definitions for all the OPPS status indicators can be found in Addendum D1.

We note that for CY 2020, we revised the status indicator for CPT code 99457 from ''M'' (Items and Services Not Billable to the MAC. Not paid under OPPS) to ''B,'' and for CPT code 99458, which is an add-on code, from ''N'' (packaged) to ''B'' effective March 1, 2020. We made the changes to enable Critical Access Hospitals (CAHs) to bill under CAH's Method II for these waiver services so that claims with these codes would process appropriately in the Integrated Outpatient Code Editor (IOCE). We announced the revisions in the July 2020 OPPS Quarterly Update CR (Transmittal 10224, Change Request 11814, dated July 15, 2020).

At the August 31, 2020 HOP Panel Meeting, a presenter requested that we revise the status indicators for these codes. Specifically, the presenter suggested that CPT codes 99091 and 99457 should be treated similar to HCPCS G0463 (Hospital outpatient clinic visit for assessment and management of a patient), which is assigned to status indicator ''V'' (Clinic or Emergency Department Visit) and APC 5012 (Clinic Visits and Related Services) which has a CY 2021 proposed payment rate of $120.88. Based on the discussion at the Panel Meeting, the HOP Panel recommended that the status indicator for CPT codes 99091 and 99457 be revised to ''V'' and the status indicator for CPT code 99458 be revised

to ''N''. We note that we are not accepting the Panel's recommendation because we believe that we need further review to determine whether these type of services (*i.e.,* remote physiologic monitoring) should be paid separately under the OPPS. We appreciate the HOP Panel's recommendations on the status indicator revisions for CPT codes 99091, 99457, and 99458, and will consider them in future rulemaking.

Comment: For CPT code 99091, one commenter disagreed with the status indicator assignment of ''N,'' and stated the code should not be packaged because the service may be the only OPPS service furnished during a month for a registered hospital outpatient. The commenter recommended assigning the code to either status indicator ''V'' or treating it similar to CPT code 99454 (Remote monitoring of physiologic parameter(s) (*e.g.,* weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days), which has a payable status indicator of ''Q1'' (STV-Packaged Codes) and assigned to APC 5741 (Level 1 Electronic Analysis of Devices) with a CY 2021 proposed payment of $37.76.

Response: Although we are sensitive to the concern raised by the commenter, we do not believe that revising the status indicator for CPT code 99091 would be appropriate at this time. We believe we need further review of this code, along with all the remote physiological monitoring (PRM) service codes, to determine whether these types of services should be separately payable under the OPPS. Therefore, for CY 2021, we are finalizing our proposal, without modification and will continue to assign CPT code 99091 to status indicator ''N,'' and consider the suggestion to revise the status indicator in future rulemaking. The final CY 2021 status indicator for CPT code 99091 can also be found in Table 34 below.

Comment: For CPT code 99457, several commenters suggested reassigning the code to status indicator ''V,'' similar to CPT code 99453 (Remote monitoring of physiologic parameter(s) (*e.g.,* weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment), which has a payable status indicator of ''V'' and assigned to APC 5012 with a CY 2021 proposed payment of $120.88. The commenters stated that in the CY 2020 Physician Fee Schedule (PFS), CMS clarified that ''CPT codes 99457 and 99458 can be furnished by clinical staff under the general supervision of the physician or NPP.'' Based on this statement, the commenters believe that CPT code 99457 should be paid separately under the OPPS. The commenters reported that because the code is currently assigned to status indicator ''B,'' hospital outpatient facilities do not receive any reimbursement when the service is provided by clinical staff in a hospital outpatient setting. One commenter stated that the status indicator should be revised to ''V'' to support the service being provided to Medicare beneficiaries under the order of a physician.

Response: We appreciate the commenters' suggestions, however, we believe we need further evaluation of this code, along with the rest of the RPM service codes, to determine whether this type of service should be separately payable under the OPPS. Therefore, for CY 2021, we are finalizing our proposal, without modification, to assign CPT code 99457 to status indicator ''B.'' We will consider the commenters' suggestion to revise the status indicator for future rulemaking. The final CY 2021 status indicator for CPT code 99457 can also be found in Table 34 below. Also, as noted above, we revised the status indicator for CPT code 99457 from ''M'' to ''B'' effective March 1, 2020, to enable Critical Access Hospitals (CAHs) to bill under CAH's Method II for these waiver services so that claims with this code would process appropriately in the Integrated Outpatient Code Editor (IOCE). We announced the revisions in the July 2020 OPPS Quarterly Update CR (Transmittal 10224, Change Request 11814, dated July 15, 2020).

Comment: For CPT code 99458, the commenters suggested the reassignment to status indicator ''N'' because this is an add-on code.

Response: As noted above, similar to CPT code 99457, we revised the status indicator for CPT code 99458 to ''B'' effective March 1, 2020, to enable Critical Access Hospitals (CAHs) to bill under CAH's Method II for the service so that claims with this code would process appropriately in the Integrated Outpatient Code Editor (IOCE). We announced the revisions in the July 2020 OPPS Quarterly Update CR (Transmittal 10224, Change Request 11814, dated July 15, 2020). We appreciate the commenters' suggestions, however, we believe we need further evaluation of this code, along with the rest of the RPM service codes, to determine whether this type of service should be separately payable under the OPPS. Therefore, for CY 2021, we are finalizing our proposal, without modification, to assign CPT code 99458 to status indicator ''B,'' and we will consider the suggestion to revise the status indicator in future rulemaking. The final CY 2021 status indicator for CPT code 99458 can be found in Table 34 below.

Comment: One commenter indicated that CMS is currently paying separately for certain RPM services and have assigned the codes to separately payable status indicator ''V,'' ''S,'' or ''Q1,'' however, some other RPM codes are assigned to non-payable status indicators such as ''B'' and ''M''. The commenter added that the status indicator assignments for the RPM codes are inconsistent and confusing to providers. The same commenter suggested that CMS recognize each distinct RPM CPT code that require hospital resources and assign the codes consistently to payable status indicators. The commenter recommended reassigning CPT codes 93264, 93268, 93297, 93298 from status indicator ''M'' to ''S'' and assigning the code to either APC 5741 (Level 1 Electronic Analysis of Devices) with a proposed CY 2021 payment rate of $37.76, APC 5742 (Level 2 Electronic Analysis of Devices) with a proposed CY 2021 payment rate of $101.76, or APC 5743 (Level 3 Electronic Analysis of Devices) with a proposed CY 2021 payment rate of $272.91. The commenter stated that CPT codes 93264, 93268, 93297, 93298 should be covered and payable, similar to CPT code 93296 (Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system, leadless pacemaker system, or implantable defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results), which is assigned to APC 5741 with a proposed CY 2021 payment rate of $37.76. The same commenter suggested reassigning CPT code 99474 from status indicator ''B'' to ''V'' and assigning it to APC 5012, similar to CPT code 99453 (Remote monitoring of physiologic parameter(s) (*e.g.,* weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment).

Response: We appreciate the commenter's suggestions, however, we believe that we need further evaluation of the codes to determine whether all RPM CPT codes should be paid separately under the OPPS. Therefore, for CY 2021, we are finalizing our proposal, without modification, to assign CPT codes 93264, 93268, 93297, and 93298 to status indicator ''M,'' and consider the suggestions to revise the status indicator and assign appropriate APCs to the codes in future rulemaking. Similarly, we are finalizing our

proposal, without modification, to assign CPT code 99474 to status indicator B'' for CY 2021. The final status indicators for CPT codes 93264, 93268, 93297, 93298, and 99474 can be found in Table 34 below.

Commenter: One commenter suggested revising the status indicator for 19 CPT codes that describe virtual check-ins, e-visits, and telephone evaluation and management services from non-payable to separately payable under the OPPS. The 19 codes, along with the proposed status indicator assignments and descriptors, can be found in Table 34 below. The commenter explained that when clinicians furnish virtual check-ins, e-visits, and telephone E/M services to hospital outpatients, hospital resources are used to support the clinician. The commenter stated that while the codes are separately payable under the PFS, the hospital resources are not paid separately under the OPPS. The commenter believes that under 42 CFR 419.22, virtual or remote services are not excluded from OPPS and, therefore, the facility expense should be paid separately under the OPPS.

Response: We appreciate the commenter's suggestions, however, we believe that we need further evaluation of the 19 codes to determine whether the services should be paid separately under the OPPS. Therefore, for CY 2021, we are finalizing our proposal, without modification, to assign the codes to either status indicator ''A'' or ''B'' for the 19 codes listed in Table 34 as virtual check-in, e-visit, and telephone E/M services.

Comment: One commenter suggested revising the status indicator for two medication therapy management (MTM) codes from ''E1'' to ''B,'' and indicated that the codes should be assigned to the same status indicator as genetic counseling code CPT 96040 (Medical genetics and genetic counseling services, each 30 minutes face-to-face with patient/family), which is assigned to status indicator ''B'' under the OPPS. Specifically, the commenter recommended reassigning CPT codes 99605 (Medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided; initial 15 minutes, new patient) and 99606 (Medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided; initial 15 minutes, established patient) from ''E1'' to ''B.'' The commenter explained that the CY 2021 PFS proposed rule clarified that genetic counseling and pharmacist services can be considered ''incident to'' a professional service in the office setting. Specifically, the commenter noted that the 2021 PFS proposed rule (85 FR 50146) states ''Medication management is covered under both Medicare Part B and Part D. We are reiterating the clarification we provided in the May 1st COVID–19 IFC (85 FR 27550 through 27629), that pharmacists fall within the regulatory definition of auxiliary personnel under our regulations at § 410.26. As such, pharmacists may provide services incident to the services, and under the appropriate level of supervision, of the billing physician or NPP, if payment for the services is not made under the Medicare Part D benefit.'' In light of the statements, the commenter believes that when MTM services are furnished in the HOPD setting, the hospital outpatient facility is reporting for the pharmacists' services, which the commenter believes meet the definition of outpatient services at 42 CFR 410.27 and the definition of OPPS services at 42 CFR 419.21. Consequently, the commenter believes that MTM services should be paid separately under the OPPS.

Response: We appreciate the commenter's suggestions, however, we believe that we need further evaluation of the two MTM codes to determine whether the services should be paid separately under the OPPS. We note that policies discussed in the PFS proposed rules typically do not apply to OPPS policies; however, we will review the issue. Therefore, for CY 2021, we are finalizing our proposal, without modification, to assign the codes to status indicator ''E1'' for the 2 MTM codes listed in Table 34.

Comment: One commenter suggested that CMS treat all telehealth and communication technology-based services (CTBS) consistently with OPPS payable status indicators and ambulatory payment classification (APC) assignments. The commenter explained that these issues were discussed in the 2021 PFS proposed rule.

Response: We appreciate the commenter's suggestion, however, we believe that we need further evaluation of the issue to determine whether all the codes that describe telehealth and communication technology-based services (CTBS) should be paid separately under the OPPS. In addition, we made no proposals regarding these issues in the CY 2021 OPPS/ASC proposed rule. As stated above, the proposed policies discussed in the PFS proposed rules typically do not apply to OPPS policies because they are two different Medicare payment systems. However, we will review the issue for potential future rulemaking.

In summary, after consideration of the public comments, we are finalizing our proposal, without modification, for the 29 codes listed in Table 34 for CY 2021. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

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TABLE 34.—FINAL SI ASSIGNMENTS FOR THE REMOTE PHYSIOLOGICAL MONITORING, VIRTUAL CHECK-INS, E-VISITS, TELEPHONE E/M, AND MEDICATION THERAPY MANAGEMENT CODES

HCPCS Code	Short Descriptor	Proposed CY 2021 OPPS SI	Commenters Suggested SI	Commenters Suggested APC	Category	Final CY 2021 OPPS SI
93264	Rem mntr wrls p-art prs snr	M	S	5741, 5742 or 5743	Remote Physiological Monitoring (RPM)	M
93268	Ecg record/review	M	S	5741, 5742 or 5743	Remote Physiological Monitoring (RPM)	M
93297	Rem interrog dev eval icpms	M	S	5741, 5742 or 5743	Remote Physiological Monitoring (RPM)	M
93298	Rem interrog dev eval scrms	M	S	5741, 5742 or 5743	Remote Physiological Monitoring (RPM)	M
99091	Collj & interpj data ea 30 d	N	V	5012	Remote Physiological Monitoring (RPM)	N
99457	Rem physiol mntr 1st 20 min	B	V	5012	Remote Physiological Monitoring (RPM)	B
99458	Rem physiol mntr ea addl 20	B	N	N/A	Remote Physiological Monitoring (RPM)	B
99474	Self-meas bp 2 readg bid 30d	B	V	5012	Remote Physiological Monitoring (RPM)	B
98966	Hc pro phone call 5-10 min	A	V	5012	Telephone E/M	A

HCPCS Code	Short Descriptor	Proposed CY 2021 OPPS SI	Commenters Suggested SI	Commenters Suggested APC	Category	Final CY 2021 OPPS SI
98967	Hc pro phone call 11-20 min	A	V	5012	Telephone E/M	A
98968	Hc pro phone call 21-30 min	A	V	5012	Telephone E/M	A
99441	Phone e/m phys/qhp 5-10 min	B	V	5012	Telephone E/M	B
99442	Phone e/m phys/qhp 11-20 min	B	V	5012	Telephone E/M	B
99443	Phone e/m phys/qhp 21-30 min	B	V	5012	Telephone E/M	B
98970	Qnhp ol dig e/m svc 5-10min	B	V	5012	E-visit	B
98971	Qnhp ol dig em svc 11-20min	B	V	5012	E-visit	B
98972	Qnhp ol dig e/m svc 21+ min	B	V	5012	E-visit	B
99421	Ol dig e/m svc 5-10 min	B	V	5012	E-visit	B
99422	Ol dig e/m svc 11-20 min	B	V	5012	E-visit	B
99423	Ol dig e/m svc 21+ min	B	V	5012	E-visit	B
G2061	Qual nonmd est pt 5-10m	A	V	5012	E-visit	A
G2062	Qual nonmd est pt 11-20m	A	V	5012	E-visit	A
G2063	Qual nonmd est pt 21>min	A	V	5012	E-visit	A

HCPCS Code	Short Descriptor	Proposed CY 2021 OPPS SI	Commenters Suggested SI	Commenters Suggested APC	Category	Final CY 2021 OPPS SI
G2010	Remot image submit by pt	A	V	5012	Virtual Check-in	A
G2012	Brief check in by MD/QHP	A	V	5012	Virtual Check-in	A
Placeholder code G20X2	Placeholder code G20X2	in PFS	V	5012	Virtual Check-in	A
Placeholder code G20X0	Placeholder code G20X0	in PFS	V	5012	Virtual Check-in	A
99605	Mtms by pharm np 15 min	E1	B	N/A	Medication Therapy Management (MTM)	E1
99606	Mtms by pharm est 15 min	E1	B	N/A	Medication Therapy Management (MTM)	E1

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25. Review of Electrocorticograms From an Implanted Brain Neurostimulator (APC 5741)

For CY 2021, we proposed to continue to assign CPT code 95836 (Electrocorticogram from an implanted brain neurostimulator pulse generator/transmitter, including recording, with interpretation and written report, up to 30 days) to APC 5741 (Level 1 Electronic Analysis of Devices) with a proposed payment of $37.76.

Comment: A commenter urged CMS to reassign CPT code 95836 from APC 5741 to APC 5742 (Level 2 Electronic Analysis of Devices) with a proposed payment rate of $101.76, and stated that the payment for APC 5741 does not adequately reflect the resources used by HOPDs in performing this procedure.

Response: Based on our analysis of the hospital outpatient claims data for this final rule, we disagree that the resource cost to perform the service is inappropriate. Our evaluation of the latest claims data show a geometric mean cost of about $14 based on 21 single claims (out of 213 total claims). We believe that reassigning the code to APC 5742, whose geometric mean cost is approximately $98, would significantly overpay for the service. Additionally, we believe that the payment for CPT code 95836 is sufficient to cover the hospital cost of performing the service.

In summary, after consideration of the public comment, we are finalizing our proposal, without modification, to continue to assign CPT code 95836 to APC 5741 for CY 2021. The final CY 2021 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

As we do every year, we will reevaluate the APC assignment for CPT code 95836 in the next rulemaking cycle. We remind hospitals that we review, on an annual basis, the APC assignments for all services and items paid under the OPPS based on the latest claims data available to us.

26. Therapeutic Apheresis

The LIXELLE® β2-microglobulin Apheresis Column is indicated for use in the treatment of dialysis-related amyloidosis (DRA), a disease that affects people with end-stage renal disease (ESRD) who have been receiving dialysis for five or more years. The LIXELLE® device is used in an apheresis procedure that selectively removes β2-microglobulin (''β2m'') from the circulating blood of patients with DRA. LIXELLE® is used pursuant to a physician prescription in conjunction with hemodialysis and is intended to be used at each hemodialysis session (*i.e.,* frequency of treatment is expected to be three times per week).

In March 2015, FDA approved LIXELLE® as a Class III Humanitarian Use Device (HUD) with an approved Humanitarian Device Exemption (HDE). FDA regulations require the manufacturer to conduct a post-approval study (PAS) to evaluate the safety of the LIXELLE® Apheresis procedure in U.S. patients on chronic hemodialysis with clinically-diagnosed DRA, and assess the probable benefit of LIXELLE® Apheresis to increase the β2m reduction rate in these patients in successive dialysis sessions (compared to dialysis without LIXELLE®). Currently, there is no payment under the OPPS for the apheresis procedure used with the LIXELLE® device.

Comment: One commenter, the manufacturer of the LIXELLE® device,

requested that CMS provide payment for the apheresis procedure used with the device under the OPPS. The commenter stated that the LIXELLE® apheresis procedure may be administered in either a dialysis facility or the hospital outpatient department and that the HOPD was the more clinically appropriate setting. Specifically, the commenter requested that CMS provide payment through the OPPS via one of three potential pathways: (1) Allow payment for the apheresis procedure used with the LIXELLE® device through CPT code 36516 (Therapeutic apheresis with extracorporeal immunoadsorption, selective adsorption or selective filtration and plasma reinfusion), which was proposed to be assigned to APC 5243 (Level 3 Blood Product Exchange and Related Services) for CY 2021, and require the use of a modifier or add-on code when the LIXELLE® apheresis procedure is billed to reduce the payment for the procedure to the payment rate for APC 5242 (Level 2 Blood Product Exchange and Related Services); (2) allow payment for the dialysis performed as part of LIXELLE® apheresis procedure through HCPCS code G0257 (Unscheduled or emergency dialysis treatment for an ESRD patient in a hospital outpatient department that is not certified as an ESRD facility), which is assigned to APC 5401 (Dialysis) for CY 2021, and require the use of a modifier or add-on code to provide additional payment beyond that provided by APC 5401; or (3) create a HCPCS C code or G code for the LIXELLE® apheresis procedure and assign the code to APC 5242 (Level 2 Blood Product Exchange and Related Services). Finally, the commenter also noted that they have been unable to complete the FDA-required post-approval study as a condition of the HDE, due to difficulty in securing patient enrollment because of lack of CMS payment for the LIXELLE® apheresis procedure.

Response: We appreciate these comments and understand the various issues related to coverage and payment for the LIXELLE® apheresis procedure. We will consider these comments for future rulemaking.

27. Tympanostomy Using an Automated Tube Delivery System (APC 5163)

As displayed in Addendum B to the CY 2021 OPPS/ASC proposed rule, we proposed to assign CPT code 0583T (Tympanostomy (requiring insertion of ventilating tube), using an automated tube delivery system, iontophoresis local anesthesia) to status indicator (SI) ''E1'' to indicate that the code is not payable by Medicare when submitted on outpatient claims (any outpatient bill type) because the services associated with these codes are either not covered by any Medicare outpatient benefit category, are statutorily excluded from Medicare payment, or are not reasonable and necessary.

Comment: Some commenters reported that the device associated with CPT code 0583T received FDA approval in November 2019 and requested separate payment for the code. They specifically requested assignment to APC 5164 (Level 4 ENT Procedures), with a proposed payment of $2,776.63, and also requested assignment to either status indicator ''S'' (Procedure or Service, Not Discounted When Multiple) or ''T'' (Procedure or Service, Multiple Procedure Reduction Applies). They reported that assignment to APC 5164 would match the resources furnished when providing this service. The manufacturer for the device associated with the code explained that while the surgical procedure described by CPT code 0583T is primarily performed on children, the device is approved for all ages above 6 months. The manufacturer also indicated that the procedure will be extremely important for the Medicaid population and Medicaid programs who often refer to Medicare to establish coverage and payment. One commenter reported that the total cost for the complete procedure is approximately $2,776, while the device manufacturer reported a cost of about $1,400 for the device.

Response: Based on our review of the procedure and input from our medical advisors, we believe that the surgical procedure described by CPT code 0583T is most similar, in terms of clinical homogeneity and resource cost, to CPT code 69436 (Tympanostomy (requiring insertion of ventilating tube), local or topical anesthesia), which is assigned to APC 5163 (Level 3 ENT Procedures) with a proposed payment of about $1,395. Both procedures (as described by CPT codes 0583T and 69436) require ventilating tubes that require anesthesia. Therefore, we believe that the most appropriate APC assignment for CPT code 0583T is APC 5163, which is associated with status indicator ''J1'' (Hospital Part B services paid through a comprehensive APC).

In summary, after consideration of the public comments, we are finalizing our proposal with modification, and assigning CPT code 0583T to APC 5163 with a status indicator of ''J1'' for CY 2021. The final CY 2021 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

28. Unlisted Dental Procedure (APC 5161)

For CY 2021, we proposed to continue to assign CPT code 41899 (Unlisted procedure, dentoalveolar structures) to APC 5161 (Level 1 ENT Procedures) with a payment rate of $213.59.

Comment: Two dental specialty societies expressed concern with the payment rate for CPT code 41899. They explained that this is the only CPT code available for dental surgery and its low reimbursement is insufficient to cover the facility costs. The commenters added that the low payment rate has resulted in many dentists, especially pediatric dentists, experiencing difficulty in obtaining operating room (OR) time to perform surgical procedures under general anesthesia. They stated that the problem has been exacerbated by the COVID–19 pandemic, with further limited access to ORs to address patient dental needs.

Response: CPT code 41899 is designated as an unlisted code. Some HCPCS codes are used to report items, services, and procedures that do not define the exact item, service, or surgical procedure furnished. They are commonly called ''unlisted'' codes. The code descriptors often contain phrases such as: ''unlisted procedure,'' ''not otherwise classified,'' or ''not otherwise specified.'' The unlisted codes typically fall within a clinical or procedural category, but they lack the specificity needed to describe the resources used. Until a more specific HCPCS code is established, as an interim, the unlisted code provides a way for providers to report items, services, and procedures furnished. In general, unlisted codes are reported when no other specific CPT or Level II HCPCS code accurately describes the item, procedure, or service. Because of the lack of specificity, unlisted codes are assigned to the lowest level, clinically appropriate APC group under the OPPS. The assignment of the unlisted codes to the lowest level APC in the clinical category specified in the code provides a reasonable means for interim payment until such time as there is a code that specifically describes what is being paid. It also encourages the creation of codes where appropriate and protects against overpayment of services that are not clearly identified on the claim. As a reminder, unlisted codes are not used in establishing the percent of claims contributing to the APC, nor are their

costs used in the calculation of the APC geometric mean (80 FR 70321), because, by the code's definition, we do not know what service or combination of services is reflected in the claims billed with the unlisted code. Currently, we have five levels of ENT Procedure APCs, Levels 1 through 5, with Level 1 assigned to the lowest paying of the five APCs. Because the code is designated as an unlisted code, we believe that CPT 41899 code is appropriately assigned to APC 5161, which is the lowest level ENT APC.

In addition, because unlisted codes are non-specific, HOPDs are reminded that Medicare Administrative Contractors (MACs) may have additional documentation requirements for how the codes should be reported to receive payment. Refer to section 180.3 (Unlisted Service or Procedure) in Chapter 4 (Part B Hospital) of the Medicare Claims Processing Manual for information on how MACs review claims with unlisted codes.

We note that AMA establishes new CPT codes, depending on the code type, quarterly and annually. Interested parties that desire more specific codes for unlisted codes should consult the AMA. Information on CPT codes and the process for requesting new codes can be found on the AMA website: *https://www.ama-assn.org/about/cpt-editorial-panel/cpt-code-process*.

In summary, after consideration of the public comments, we are finalizing our proposal, without modification, to assign CPT code 41899 to APC 5161 for CY 2021. The final CY 2021 payment rate for the code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

29. Urology and Related Services (APCs 5371 Through 5378)

We received comments on the CY 2020 OPPS/ASC proposed rule suggesting we revise the APC assignments for the services assigned to the Urology & Related Services APCs. The commenter specifically noted that a reorganization for APCs 5374 through 5376 would be appropriate, but added that there were other adjustments across services within the Urology APCs that could improve the structure of these APCs. In response to this comment, we stated in the CY 2020 OPPS/ASC final rule with comment period that we would consider revisions to the urology APCs in future rulemaking.

Currently, for CY 2020, there are seven levels of APCs for urology services. We reviewed the geometric mean cost for APCs 5371 through 5377 and, after our analysis of the claims data for the CY 2021 OPPS/ASC proposed rule, we believed that a modification to the urology APCs would be appropriate.

For the CY 2021 OPPS/ASC proposed rule, we evaluated the claims data and noted the large difference in geometric mean cost between APC 5376 (level 6) and APC 5377 (level 7) has continued to grow. This difference in the geometric mean cost from APC 5376 to APC 5377 would have been about $9,700, with the geometric mean cost for APC 5377 at approximately 220 percent of the geometric mean cost of APC 5376. Based on the proposed rule claims data, which showed an unusually large difference between the geometric mean costs of the Level 6 Urology APC and the Level 7 Urology APC on both a dollar and percentage basis, we believed that creating an additional APC in the urology and related series would provide an appropriate structure, distinguishing between clinical and cost similarity for the procedures in the different levels. Therefore, for CY 2021, we proposed to establish an additional level for the urology and related services APCs, specifically, APC 5378 (Level 8 Urology and Related Services) and to re-organize the current APCs 5376 (Level 6 Urology and Related Services) and 5377 (Level 7 Urology and Related Services). We believed this re-organization would address the lack of an appropriate level for procedures with geometric mean costs that fall between current APC 5376 and current APC 5377.

As we stated in the proposed rule (85 FR 48842), the proposed reorganization would reassign CPT 53440 (Male sling procedure) and CPT 0548T (Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy) from the current APC 5376 to APC 5377.

In addition, the proposed revision would reassign the following services from APC 5377 to APC 5378:

- CPT 54416 (Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session).
- CPT 53444 (Insert tandem cuff).
- CPT 54410 (Removal and replacement of all component(s) of a multi-component, inflatable penile prosthesis at the same operative session).
- CPT 54411 (Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue).
- CPT 54401 (Insertion of penile prosthesis; inflatable (self-contained)).
- CPT 54405 (Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir).
- CPT 53447 (Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff at the same operative session).
- CPT 53445 (Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff).

As further stated in the proposed rule, the proposed APC reassignment for these 10 codes results in geometric mean costs for Levels 6, 7, and 8 of the Urology APCs that we believe more appropriately align with the geometric mean costs for services in these APCs than the current structure. Specifically, as listed in Table 19 of the proposed rule, and reprinted below, the geometric mean cost of $8,089.78 for APC 5376, $11,275.15 for APC 5377, and $18,015.54 for APC 5378 reduces the unusually large gaps on both a dollar and percentage basis in geometric mean costs between each APC level.

TABLE 19*. —PROPOSED CY 2021 GEOMETRIC MEAN COST FOR THE UROLOGY AND RELATED APCS 5371 THROUGH 5378

APC	Group Title	SI	CY 2020 OPPS Geometric Mean Cost	Proposed CY 2021 OPPS Geometric Mean Cost
5371	Level 1 Urology and Related Services	T	$229.83	$262.04
5372	Level 2 Urology and Related Services	T	$544.53	$565.10
5373	Level 3 Urology and Related Services	J1	$1,733.35	$1,758.24
5374	Level 4 Urology and Related Services	J1	$2,953.45	$3,010.01
5375	Level 5 Urology and Related Services	J1	$4,140.38	$4,324.38
5376	Level 6 Urology and Related Services	J1	$7,893.96	$8,089.78
5377	Level 7 Urology and Related Services	J1	$17,195.00	$11,275.15
5378	Level 8 Urology and Related Services	J1	N/A	$18,015.54

* Table19 of the CY 2021 OPPS/ASC proposed rule

We received many comments on our proposal. Below are the comments and our responses.

Comment: Several commenters supported our proposal to establish an additional Urology and Related Services APC, specifically, APC 5378 (Level 8 Urology and Related Services), and re-organize the current APCs 5376 (Level 6 Urology and Related Services) and 5377 (Level 7 Urology and Related Services). These commenters agreed that the addition of APC 5378 within the Urology APCs would better align procedures based on their resource cost and clinical homogeneity.

Response: We appreciate the commenters' support for our proposal to establish new APC 5378 and to re-organize the procedures in the Urology APCs. We note that each year, under the OPPS, we revise and make changes to the APC groupings based on the latest hospital outpatient claims data to appropriately place procedures and services in APCs based on clinical characteristics and resource similarity. We note that based on our review of the claims data for the final rule, we are also finalizing our proposal without modification to reassign CPT codes 53440 and 0548T to APC 5377. Similarly, we are finalizing our proposal without modification to reassign CPT codes 54416, 53444, 54410, 54411, 54401, 54405, 53447, and 53445 to APC 5378.

Comment: A commenter supported the continued assignment of HCPCS code C9739 (Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants) to APC 5375 and HCPCS C9740 (Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants) to APC 5376.

Response: We appreciate the commenter's support for our APC assignments, which are based on our review of the latest claims data. We are finalizing our proposal and assigning these codes to the proposed APCs in this final rule.

Comment: Several commenters also recommended additional changes within APCs 5371 to APC 5376. Specifically, for APCs 5371 and 5372, the commenters recommended the following reassignments from APC 5371 to APC 5372:

- CPT 51720 (Bladder instillation of anticarcinogenic agent (including retention time);
- CPT 43763 (lacement of gastrostomy tube, percutaneous, includes removal, when performed, without imaging or endoscopic guidance; requiring revision of gastrostomy tract);
- 51725 Simple cystometrogram (cmg) (*e.g.,* spinal manometer);
- 51726 Complex cystometrogram (*i.e.,* calibrated electronic equipment); and
- 51040 Cystostomy, cystotomy with drainage.

Also, the commenters suggested the reassignment of the following codes from APC 5373 to APC 5374:

- 52287 Cystourethroscopy, with injection(s) for chemodenervation of the bladder
- 52276 Cystourethroscopy with direct vision internal urethrotomy
- 54840 Excision of spermatocele, with or without epididymectomy
- 53854 Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy

In addition, the commenters recommended reassigning the following codes from APC 5375 to APC 5376:

- 53420 Urethroplasty, 2-stage reconstruction or repair of prostatic or membranous urethra; first stage;
- C9747 Ablation of prostate, transrectal, high intensity focused ultrasound (hifu), including imaging guidance;
- 53410 Urethroplasty, 1-stage reconstruction of male anterior urethra;
- 50553 Renal endoscopy through established nephrostomy or pyelostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with ureteral catheterization, with or without dilation of ureter;
- 54111 Excision of penile plaque (peyronie disease); with graft to 5 cm in length;
- 55875 Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy;
- 54660 Insertion of testicular prosthesis (separate procedure);
- 50576 Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with fulguration and/or incision, with or without biopsy; and
- 0549T Transperineal periurethral balloon continence device; unilateral placement, including cystoscopy and fluoroscopy;

Further, the commenters suggested revising the assignment for these codes from APC 5376 to APC 5377:

- 55873 Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring);
- 50081 Percutaneous nephrostolithotomy or pyelostolithotomy, with or without dilation, endoscopy, lithotripsy, stenting, or basket extraction; over 2 cm; and
- 50562 Renal endoscopy through established nephrostomy or pyelostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with resection of tumor.

Response: Based on our review of the claims data for the final rule, we do not believe that reassigning these 21 urology procedures to the suggested APCs is appropriate. Our review of the claims data for this CY 2021 OPPS/ASC final rule with comment period show that the procedures are appropriately placed in the proposed APCs based on clinical homogeneity and resource costs. Consequently, we are finalizing our proposal without modification for the 21 urology procedures discussed above.

In summary, after consideration of the public comments, and after our analysis of the updated claims data for this final rule with comment period, we are finalizing our proposal, without modification, to reorganize the Urology and Related Services APCs. The final CY 2021 payment rate for the codes for all the codes discussed above can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

a. High-Intensity Focused Ultrasound of the Prostate (HIFU) Procedure (APC 5375)

In 2017, CMS received a new technology application for the prostate HIFU procedure and established a new code, specifically, HCPCS code C9747 (Ablation of prostate, transrectal, high intensity focused ultrasound (hifu), including imaging guidance). Based on the estimated cost provided in the new technology application, we assigned the new code to APC 5376 (Level 6 Urology and Related Services) with a payment rate of $7,452.66 effective July 1, 2017. We announced the SI and APC assignment in the July 2017 OPPS quarterly update CR (Transmittal 3783, Change Request 10122, dated May 26, 2017).

For the CY 2018 update, we maintained the assignment of HCPCS code C9747 to APC 5376 with a payment rate of $7,596.26. We note that the payment rates for the CY 2018 OPPS update were based on claims submitted between January 1, 2016 through December 30, 2016, that were processed on or before June 30, 2017. Since HCPCS code C9747 was established on July 1, 2017, we had no claims data for the procedure for use in ratesetting for CY 2018.

However, for the CY 2019 update, based on the latest claims data for the final rule, we revised the APC assignment for HCPCS code C9747 from APC 5376 to APC 5375 with a payment rate of $4,020.54. We note that the payment rates for CY 2019 were based on claims submitted between January 1, 2017 through December 30, 2017, that were processed on or before June 30, 2018. Our claims data showed a geometric mean cost of approximately $5,000 for HCPCS code C9747 based on 64 single claims (out of 64 total claims), which was significantly lower than the geometric mean cost of about $7,717 for APC 5376. We believed that the geometric mean cost for HCPCS code C9747 was more comparable to the geometric mean cost of approximately $4,055 for APC 5375. Consequently, we reassigned the code from APC 5376 to APC 5375 (Level 5 Urology and Related Services) for CY 2019 and C9747 remained in APC 5376 for CY 2020.

For CY 2021, we proposed to continue to assign HCPCS code C9747 to APC 5375 with a proposed payment rate $4,487.87. In addition, we noted that HCPCS C9747 will be replaced with CPT 55880 beginning January 2021.

Comment: Many commenters stated that the APC 5375 payment rate does not cover the hospital facility cost for this procedure, and thus, discourages hospitals from providing this procedure for Medicare patients. Some commenters argued that HIFU is a device-intensive procedure, believed that the average cost of the HIFU procedure is closer to the APC 5376 proposed payment rate of $8,395.87, and requested a reassignment to enable Medicare beneficiaries to receive the treatment. They projected that maintaining the assignment in APC 5375 will deter HOPD facilities from offering the HIFU treatment to Medicare beneficiaries because the payment is insufficient to cover the cost of the procedure. Several commenters recommended we assign this procedure to APC 5376 because they believe the service is clinically similar and comparable in terms of resources to cryoablation of the prostate, which is described by CPT code 55873 (Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring) and assigned to APC 5376 (Level 6 Urology and Related Services), with a proposed payment rate of $8,395.62.

Response: As we have stated every year since the implementation of the OPPS on August 1, 2000, we review, on an annual basis, the APC assignments for all services and items (including devices) paid under the OPPS based on our analysis of the latest claims data. For CY 2021, based on claims submitted between January 1, 2019 through December 30, 2019, that were processed on or before June 30, 2020, our analysis of the latest claims data for this final rule supports maintaining HCPCS code C9747 in APC 5375. Specifically, our claims data shows a geometric mean cost of approximately $5,744 for HCPCS code C9747 based on 279 single claims, which is more comparable to the geometric mean cost of about $4,300 for APC 5375, rather than the geometric mean cost of approximately $8,045 for APC 5376. Furthermore, the claims data do not indicate that HCPCS code C9747 meets the device-intensive threshold of 30 percent. Therefore, we are not designating HCPCS code C9747 as a device-intensive procedure.

With regard to the issue of similarity to CPT code 55873, while we agree both procedures are intended to treat prostate cancer, we disagree that the resource costs associated with the prostate HIFU procedure are necessarily similar to those of cryoablation of the prostate. Specifically, our claims data for cryoablation of the prostate shows a geometric mean cost of about $8,423 based on 1,226 single claims. The geometric mean cost for CPT code 55873 is reasonably consistent with APC 5376, which has a geometric mean cost of approximately $8,045.

In summary, after careful consideration of the public comments and after our analysis of the updated claims data for this final rule with comment period, we are maintaining the APC assignment for HCPCS code C9747 in APC 5375. We note that for the CY 2021 update, the CPT Editorial Panel established CPT code 55880 (Ablation of malignant prostate tissue, transrectal, with high intensity—focused ultrasound (HIFU), including ultrasound guidance) to describe HIFU effective January 1, 2021. Therefore, we are deleting HCPCS code C9747 on December 31, 2020 because it will be replaced with CPT code 55880. The final CY 2021 payment rate for CPT code 55880 can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes

reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

b. Optilume Procedure—Optilume Drug Coated Balloon Catheter System (APC 5375)

For the July 2020 update, the CPT Editorial Panel established a new code, specifically, Category III CPT code 0619T (Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed), to describe the surgical procedure associated with the Optilume Drug Coated Balloon Catheter System used to treat benign prostate hyperplasia (BPH). We announced the APC assignment for CPT code 0619T in the July 2020 OPPS quarterly update CR (Transmittal 10207, Change Request 11814, dated July 2, 2020).

Specifically, we assigned CPT code 0619T to APC 5375 (Level 5 Urology and Related Services) with a payment rate of approximately $4,232 effective July 1, 2020 and also assigned the code a status indicator of ''J1'' (Hospital Part B services paid through a comprehensive APC). Based on input from our medical advisors and the nature of the procedure, we believed that the procedure described by CPT code 0619T was similar, based on clinical homogeneity and resource cost, to CPT code 52601 (Transurethral electrosurgical resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)).

Comment: A commenter asserted that CPT code 0619T should be reassigned to APC 5376 (Level 6 Urology and Related Services). The commenter reported that the CPT code 0619T is more clinically similar to HCPCS C9740 (Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants) in terms of clinical characteristics, physician work/intraoperative intensity, and resource costs including both non-device related and device related costs. Furthermore, the commenter also indicated that CPT code 0619T has additional non-device costs, including transrectal ultrasound, fluoroscopy and use of a rectal steeper device. The commenter stated that CPT code 0619T has similar resource cost to HCPCS code C9740 in terms of its device and non-device cost.

Response: We appreciate the commenter's input on this subject and we understand that this is a new procedure without a predecessor code. Based on our evaluation, we do not agree that CPT code 0619T is similar to HCPCS code C9740. Based on the nature of the procedure and input from our medical advisors, we believe CPT code 0619T is more comparable to HCPCS code C9739 (Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants), and CPT 52601 (Transurethral electrosurgical resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)), which are both currently assigned to APC 5375 (Level 5 Urology and Related Services). We believe the assignment of CPT code 0619T to APC 5375 and its device-offset of 31 percent is appropriate until CMS receives more cost data to support a reassignment to another APC or a different device offset adjustment.

In summary, after consideration of the comment, we are finalizing our proposal without modification to continue to assign CPT code 0619T to APC 5375 for CY 2021. The final CY 2021 payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

30. Venous Mechanical Thrombectomy (APC 5193)

For CY 2020, CPT code 37187 (Percutaneous transluminal mechanical thrombectomy, vein(s), including intraprocedural pharmacological thrombolytic injections and fluoroscopic guidance) is assigned to APC 5192 (Level 2 Endovascular Procedures) with a payment of $4,953.91. For CY 2021, we proposed to reassign CPT code 37187 from APC 5192 to APC 5193 (Level 3 Endovascular Procedures) with a proposed payment of $10,222.32.

Comment: A commenter approved of our proposal to reassign CPT code 37187 to APC 5193 and requested that CMS finalize the proposal. The commenter noted that the geometric mean cost of CPT code 37187 is well aligned with APC 5193, and stated that the cost of the venous mechanical thrombectomy procedure is comparable to other clinically similar procedures within the APC.

Response: We appreciate the support for our proposal to reassign CPT code 37187 from APC 5192 to APC 5193. The claims data for the final rule, which is based on claims submitted between January 1, 2019, through December 31, 2019, processed through June 30, 2020, show that the geometric mean cost for CPT code 37187 is approximately $10,385, which is within the range of procedures of significant volume within APC 5193. Procedures with significant volume in APC 5193 range between $7,278 for CPT code 36905 and $13,492 for CPT code 37225. We believe that reassigning CPT code 37187 is appropriate based on its clinical homogeneity and similarity in resource costs to the other thrombectomy procedures (*e.g.,* 36905, 37225) assigned to APC 5193.

In summary, after consideration of the public comment, we are finalizing our proposal to assign CPT code 37187 to APC 5193 for CY 2021. The final CY 2021 payment rate for this code can be found in Addendum B to this final rule with comment period. In addition, we refer readers to Addendum D1 of this final rule with comment period for the status indicator (SI) meanings for all codes reported under the OPPS. Both Addendum B and D1 are available via the internet on the CMS website.

IV. OPPS Payment for Devices

A. Pass-Through Payment for Devices

1. Beginning Eligibility Date for Device Pass-Through Status and Quarterly Expiration of Device Pass-Through Payments

a. Background

The intent of transitional device pass-through payment, as implemented at 42 CFR 419.66, is to facilitate access for beneficiaries to the advantages of new and truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure APC rate (66 FR 55861). Under section 1833(t)(6)(B)(iii) of the Act, the period for which a device category eligible for transitional pass-through payments under the OPPS can be in effect is at least 2 years but not more than 3 years. Prior to CY 2017, our regulation at 42 CFR 419.66(g) provided that this pass-through payment eligibility period began on the date CMS established a particular transitional pass-through category of devices, and we based the pass-through status expiration date for a device category on the date on which pass-through payment was effective for the category. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79654), in accordance with section 1833(t)(6)(B)(iii)(II) of the Act, we amended § 419.66(g) to provide that the

pass-through eligibility period for a device category begins on the first date on which pass-through payment is made under the OPPS for any medical device described by such category.

In addition, prior to CY 2017, our policy was to propose and finalize the dates for expiration of pass-through status for device categories as part of the OPPS annual update. This means that device pass-through status would expire at the end of a calendar year when at least 2 years of pass-through payments had been made, regardless of the quarter in which the device was approved. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79655), we changed our policy to allow for quarterly expiration of pass-through payment status for devices, beginning with pass-through devices approved in CY 2017 and subsequent calendar years, to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through payment devices.

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79648 through 79661) for a full discussion of the current device pass-through payment policy.

We also have an established policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates (67 FR 66763).

b. Expiration of Transitional Pass-Through Payments for Certain Devices

As stated earlier, section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2 years, but not more than 3 years. There currently are 7 device categories eligible for pass-through payment: C1823-Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads); C1824-Generator, cardiac contractility modulation (implantable); C1982-Catheter, pressure-generating, one-way valve, intermittently occlusive; C1839-Iris prosthesis; C1734-Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable); C2596-Probe, image-guided, robotic, waterjet ablation; and C1748-Endoscope, single-use (that is disposable), Upper GI, imaging/illumination device (insertable).

The pass-through payment status of the device category for HCPCS code C1823 will end on December 31, 2021; the pass-through payment status of the device category for HCPCS code C1748 will end on June 30, 2023; and the pass-through payment status of the device categories for HCPCS codes C1824, C1982, C1839, C1734, and C2596 will end on December 31, 2022. Table 35 shows the expiration of transitional pass-through payments for these devices. All of these HCPCS codes will have pass-through payment status and will continue to receive pass-through payments in CY 2021.

Table 35: EXPIRATION OF TRANSITIONAL PASS-THROUGH PAYMENTS FOR CERTAIN DEVICES

HCPCS Codes	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads	1/1/2019	12/31/2021
C1824	Generator, cardiac contractility modulation (implantable	1/1/2020	12/31/2022
C1982	Catheter, pressure-generating, one-way valve, intermittently occlusive	1/1/2020	12/31/2022
C1839	Iris prosthesis	1/1/2020	12/31/2022
C1734	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)	1/1/2020	12/31/2022
C2596	Probe, image-guided, robotic, waterjet ablation	1/1/2020	12/31/2022
C1748	Endoscope, single-use (that is, disposable), Upper GI, imaging/illumination device (insertable)	7/1/2020	6/30/2023

2. New Device Pass-Through Applications

a. Background

Section 1833(t)(6) of the Act provides for pass-through payments for devices, and section 1833(t)(6)(B) of the Act requires CMS to use categories in determining the eligibility of devices for pass-through payments. As part of implementing the statute through regulations, we have continued to believe that it is important for hospitals to receive pass-through payments for devices that offer substantial clinical improvement in the treatment of Medicare beneficiaries to facilitate access by beneficiaries to the advantages of the new technology. Conversely, we have noted that the need for additional payments for devices that offer little or no clinical improvement over previously existing devices is less apparent. In such cases, these devices can still be used by hospitals, and hospitals will be paid for them through appropriate APC payment. Moreover, a goal is to target pass-through payments for those devices where cost considerations might be most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629). We note that, as discussed in section IV.A.4. of this CY 2021 OPPS/ASC proposed rule, we created an alternative pathway in the CY 2020 OPPS/ASC final rule that granted fast-track device pass-through payment under the OPPS for devices approved under the FDA Breakthrough Device Program for OPPS device pass-through payment applications received on or after January 1, 2020. We refer readers to section IV.A.4. of this CY 2021 OPPS/ASC proposed rule for a complete discussion of this pathway.

As specified in regulations at 42 CFR 419.66(b)(1) through (3), to be eligible for transitional pass-through payment under the OPPS, a device must meet the following criteria:

- If required by FDA, the device must have received FDA marketing authorization (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA), or meet another appropriate FDA exemption; and the pass-through payment application must be submitted within 3 years from the date of the initial FDA marketing authorization, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA marketing authorization is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability;
- The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Act; and
- The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion.

In addition, according to § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker).

Separately, we use the following criteria, as set forth under § 419.66(c), to determine whether a new category of pass-through payment devices should be established. The device to be included in the new category must—

- Not be appropriately described by an existing category or by any category previously in effect established for transitional pass-through payments, and was not being paid for as an outpatient service as of December 31, 1996;
- Have an average cost that is not ''insignificant'' relative to the payment amount for the procedure or service with which the device is associated as determined under § 419.66(d) by demonstrating: (1) The estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices; (2) the estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent; and (3) the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service (with the exception of brachytherapy and temperature-monitored cryoablation, which are exempt from the cost requirements as specified at § 419.66(c)(3) and (e)); and
- Demonstrate a substantial clinical improvement, that is, substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

Beginning in CY 2016, we changed our device pass-through evaluation and determination process. Device pass-through applications are still submitted to CMS through the quarterly subregulatory process, but the applications will be subject to notice-and-comment rulemaking in the next applicable OPPS annual rulemaking cycle. Under this process, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle, while submitters of applications that are not approved upon quarterly review will have the option of being included in the next applicable OPPS annual rulemaking cycle or withdrawing their application from consideration. Under this notice-and-comment process, applicants may submit new evidence, such as clinical trial results published in a peer-reviewed journal or other materials for consideration during the public comment process for the proposed rule. This process allows those applications that we are able to determine meet all of the criteria for device pass-through payment under the quarterly review process to receive timely pass-through payment status, while still allowing for a transparent, public review process for all applications (80 FR 70417 through 70418).

In the CY 2020 annual rulemaking process, we finalized an alternative pathway for devices that are granted a Breakthrough Device designation (84 FR 61295) and receive Food and Drug Administration (FDA) marketing authorization. Under this alternative pathway, devices that are granted a FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2) for the purposes of determining device pass-through payment status, but do need to meet the other requirements for pass-through payment status in our regulation at § 419.66. Devices that are part of the Breakthrough Devices Program, have received FDA marketing authorization, and meet the other criteria in regulation can be approved through the quarterly process and announced through that process (81 FR 79655). Proposals regarding these devices and whether pass-through

payment status should continue to apply are included in the next applicable OPPS rulemaking cycle. This process promotes timely pass-through payment status for innovative devices, while also recognizing that such devices may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization.

More details on the requirements for device pass-through payment applications are included on the CMS website in the application form itself at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html,* in the ''Downloads'' section. In addition, CMS is amenable to meeting with applicants or potential applicants to discuss research trial design in advance of any device pass-through application or to discuss application criteria, including the substantial clinical improvement criterion.

Comment: Some commenters requested that CMS waive the criteria for establishing new device categories specified at § 419.66(c)(1), which states that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996, for devices that are granted a FDA Breakthrough Device designation. The commenters stated that these devices should automatically be considered not to be described by any of the existing (either currently active or expired) categories established for transitional device pass-through payments because the FDA Breakthrough Device designation implies that the device is a first of kind. These commenters noted that under the IPPS New Technology Add-on Payment (NTAP), devices granted a Breakthrough Device designation that have received FDA marketing authorization are considered new and not substantially similar to an existing technology for purposes of the NTAP.

Response: We continue to believe that it is necessary to evaluate whether a device that has been granted a FDA Breakthrough Device designation is already described by any of the current device pass-through categories or by any category previously in effect to ensure that no device is described by more than one category. We also remind stakeholders that the criteria for establishing a new device category described in the regulation at 42 CFR 419.66(c)(1) are unique to the OPPS device pass-through policy.

b. Applications Received for Device Pass-Through Payment for CY 2021

We received five complete applications by the March 1, 2020 quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included in the CY 2021 OPPS/ASC proposed rule. We received one of the applications in the second quarter of 2019, two of the applications in the fourth quarter of 2019, and two of the applications in the first quarter of 2020. Two of the applications were approved for device pass-through payment during the quarterly review process: CUSTOM*FLEX*® ARTIFICIAL*IRIS* and EXALT™ Model D Single-Use Duodenoscope. CUSTOM*FLEX*® ARTIFICIAL*IRIS* received fast-track approval under the alternative pathway effective January 1, 2020. EXALT™ Model D Single-Use Duodenoscope received fast-track approval under the alternative pathway effective July 1, 2020. As previously stated, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle. Therefore, CUSTOM*FLEX*® ARTIFICIAL*IRIS* and EXALT™ Model D Single-Use Duodenoscope are discussed below in section IV.2.b.1.

Applications received for the later deadlines for the remaining 2020 quarters (June 1, September 1, and December 1), if any, will be presented in the CY 2022 OPPS/ASC proposed rule. We note that the quarterly application process and requirements have not changed in light of the addition of rulemaking review. Detailed instructions on submission of a quarterly device pass-through payment application are included on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf.*

A discussion of the applications received by the March 1, 2020 deadline is presented below.

1. Alternative Pathway Device Pass-Through Applications

We received three device pass-through applications by the March 2020 quarterly application deadline for devices that have received Breakthrough Device designation from FDA and FDA marketing authorization, and therefore are eligible to apply under the alternative pathway. As stated above in section IV.2.a of this final rule with comment, under this alternative pathway, devices that are granted a FDA Breakthrough Device designation are not evaluated in terms of the substantial clinical improvement criterion at § 419.66(c)(2)(i) for purposes of determining device pass-through payment status, but will need to meet the other requirements for pass-through payment status in our regulation at § 419.66.

(1) CUSTOM*FLEX*® ARTIFICIAL*IRIS*

VEO Ophthalmics submitted an application for a new device category for transitional pass-through payment status for the CUSTOM*FLEX*® ARTIFICIAL*IRIS* by the June 2019 quarterly deadline. The CUSTOM*FLEX*® ARTIFICIAL*IRIS* device is described as a foldable iris prosthesis that is custom-made for each individual patient who requires one. The applicant stated that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* comes in two models-With Fiber or Fiber Free. The two models are identical in every respect except that the With Fiber model has a polyester meshwork layer embedded in it to provide adequate tear strength to withstand suturing.

The applicant provided that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is intended to serve as an artificial iris prosthesis, inserted at the time of cataract surgery or during a subsequent stand-alone procedure. The CUSTOM*FLEX*® ARTIFICIAL*IRIS* is indicated for use in children and adults for the treatment of full or partial aniridia resulting from congenital aniridia, acquired defects, or other conditions associated with full or partial aniridia. The conditions that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* treats are rare; congenital aniridia is present in approximately 1.8 in 100,000 live births (1 in 40,000 to 1 in 100,000),[6–2] congenital IridoCorneal Endothelial Syndrome (ICE) syndrome is even less common (incidence not available). Iris defects such as iatrogenic iridodialysis as a complication of cataract surgery has variable prevalence, ranging from 0–0.84 percent of surgeries,[3–8] and may

[6] Berlin HS, Ritch R. The treatment of glaucoma secondary to aniridia. Mt Sinai J Med. 1981;48:11.

[2] Nelson LB, Spaeth GL, Nowinski TS, et al. Aniridia. A review. Surv Ophthalmol. 1984; 28:621–642.

[3] Greenberg PB, Tseng VL, Wu WC, et.al. Prevalence and predictors of ocular complications associated with cataract surgery in United States veterans. Ophthalmology. 2011 Mar;118(3):507–14.

[4] Jaycock P, Johnston RL, Taylor H, et al., UK EPR User Group. The Cataract National Dataset electronic multi-centre audit of 55,567 operations: Updating benchmark standards of care in the United Kingdom and internationally. Eye (Lond). 2009;23:38–49.

[5] Lum F, Schein O, Schachat AP, et al. Initial two years of experience with the AAO National Eyecare Outcomes Network (NEON) cataract surgery database. Ophthalmology. 2000;107:691–697.

occur in approximately 0.2 percent of blunt orbital trauma.[9] Although rare, these conditions are cosmetically and functionally limiting. The applicant provided that in addition to a noticeably absent or irregular iris/pupil, affected patients frequently experience photophobia (light sensitivity) and glare as well as symptoms such as dry eye.[10] [11]

According to the applicant, currently available treatments for symptomatic glare, photophobia, and cosmesis are limited, and an FDA-approved, commercially available iris prosthesis fills a needed gap. Alternatives include tinted spectacles or contact lenses, iris reconstruction (for example, pupilloplasty or iridodialysis repair), and corneal tattooing.[10] Among these, tinted spectacles can provide some symptomatic relief, but the applicant stated that they do not address the underlying problem and cannot be used in all settings. Iris reconstruction requires that sufficient iris tissue be present. Tinted contact lenses and corneal tattooing are cosmetically not ideal and have an associated risk of corneal infection (corneal ulcer and infectious keratitis). According to the applicant, in addition, corneal tattooing has a risk of surface toxicity, anterior segment inflammation, and/or corneal epithelial defect. The only other artificial iris devices in the U.S. were previously available under FDA compassionate use exemption (Morcher 50F, 96F; Ophtec 311 aniridia lens).[10] However, these devices are no longer available following FDA approval of the CUSTOM*FLEX*® ARTIFICIAL*IRIS.*

With respect to the newness criterion at § 419.66(b)(1), the FDA designated the CUSTOM*FLEX*® ARTIFICIAL*IRIS* as a Breakthrough Device on December 21, 2017, and approved the premarket approval application (PMA) for CUSTOM*FLEX*® ARTIFICIAL*IRIS* (P170039) on May 30, 2018 for use in the treatment of full or partial aniridia resulting from congenital or acquired defects. The applicant provided that there was a roughly 3-month market delay after receipt of PMA approval while final labeling in its printed form was submitted to FDA and FDA completed its review and approval process. The applicant notes that commercial availability of the device commenced on September 12, 2018 after it received FDA approval for the final labeling. We received the application for a new device category for transitional pass-through payment status for the CUSTOM*FLEX*® ARTIFICIAL*IRIS* on May 31, 2019, which is within 3 years of the date of the initial FDA marketing authorization. We solicited public comment on whether the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the newness criterion.

Comment: Commenters claimed that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the newness criterion as described at § 419.66(b)(1).

Response: After consideration of the public comments and our review of the application, we agree that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the newness criterion as described at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), the applicant stated that the device is implanted via injection through a 2.75–4 mm clear corneal incision. Depending on the site of implantation (capsular bag, ciliary sulcus, sutured to sclera), the device is cut (trephined) to the correct diameter. The device can also be sutured to an intraocular lens if an intraocular lens is also implanted at the time of surgery. The applicant further provided that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically implanted. The applicant also claimed that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We solicited public comment on whether the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the eligibility criteria at § 419.66(b).

Comment: Commenters believed that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the eligibility criteria as described at § 419.66(b).

Response: After consideration of the public comments we received and our review of the application, we agree that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the eligibility criteria as described at § 419.66(b).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. Upon review, it did not appear that there were any other existing pass-through payment categories that might apply to the CUSTOMFLEX® ARTIFICIAL*IRIS* and we solicited public comments on this issue.

Comment: Commenters claimed that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the criterion for establishing new device categories specified at § 419.66(c)(1).

Response: After consideration of the public comments we received, we have determined that there are no existing pass-through categories that appropriately describe the CUSTOMFLEX® ARTIFICIAL*IRIS* and we have determined the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the criterion for establishing new device categories specified at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization. As stated in section IV.2.a above, devices that apply under the alternative pathway for devices that have a Breakthrough Device designation with a FDA marketing authorization are not subject to evaluation for substantial clinical improvement (84 FR 61295). The CUSTOM*FLEX*® ARTIFICIAL*IRIS* was designated as a Breakthrough Device by FDA on December 21, 2017.

We did not receive comments on whether the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the second criterion for establishing a device category at § 419.66(c)(2)(i). Based on its Breakthrough Device designation, we

[6] Steinberg EP, Tielsch JM, Schein OD, et.al. National study of cataract surgery outcomes: Variation in 4-month postoperative outcomes as reflected in multiple outcomes measures Ophthalmology. 1994;101:1131–1140.

[7] Schein OD, Steinberg EP, Javitt JC, et al. Variation in cataract surgery practice and clinical outcomes. Ophthalmology. 1994;101:1142–1152.

[8] Powe NR, Schein OD, Gieser SC, et al. Cataract Patient Outcome Research Team Synthesis of the literature on visual acuity and complications following cataract extraction with intraocular lens implantation. Arch Ophthalmol, 1994;112:239–252.

[9] Kreidl KO, Kim DY, Mansour SE. Prevalence of significant intraocular sequelae in blunt orbital trauma. Am J Emerg Med. 2003 Nov;21(7):525–8.

[10] Weissbart SB, Ayres BD. Management of aniridia and iris defects: An update on iris prosthesis options. Curr Opin Ophthalmol. 2016 May;27(3):244–9.

[11] Lee HJ, Colby KA. A review of the clinical and genetic aspects of aniridia. Semin Ophthalmol. 2013 Sep-Nov;28(5–6):306–12.

have determined that CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets this criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* would be reported with CPT code 66999—Unlisted procedure, anterior segment of eye, which was assigned to APC 5491 (Level 1 Intraocular Procedures) for Calendar Year (CY) 2020. To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5491, which had a CY 2019 payment rate of $1,917. Beginning in CY 2017, we calculated the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). CPT code 66999 had a device offset amount of $149.80 at the time the application was received. According to the applicant, the cost of the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is $7,700, for both the Fiber Free and with Fiber models.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $7,700 for the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is 402 percent of the applicable APC payment amount for the service related to the category of devices of $1,917 (($7,700/$1,917) × 100 = 402 percent). Therefore, we stated in the CY 2021 OPPS/ASC proposed rule that we believe the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $7,700 for the CUSTOM*FLEX*® ARTIFICIAL*IRIS* is 5,140 percent of the cost of the device-related portion of the APC payment amount for the related service of $150 (($7,700/$150) × 100 = 5,140 percent). Therefore, we stated in the CY 2021 OPPS/ASC proposed rule that we believe that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $7,700 for the CUSTOM*FLEX*® ARTIFICIAL*IRIS* and the portion of the APC payment amount for the device of $1,917 is 394 percent of the APC payment amount for the related service of $150 (($7,700 − $150)/$1,917) × 100 = 394 percent). Therefore, we stated in the CY 2021 OPPS/ASC proposed rule that we believe that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the third cost significance requirement.

We solicited public comment on whether the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the device pass-through payment criteria discussed in this section, including the cost criterion.

Comment: We received comments indicating that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the device pass-through payment criteria, including the cost criterion.

Response: After considering the public comments received and our review of the application, we have determined that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the device pass-through payment criteria, including the cost criterion.

As stated above, we received the application for the CUSTOMFLEX® ARTIFICIAL*IRIS* application by the June 1, 2019 quarterly deadline and preliminarily approved it for transitional pass-through payment under the alternative pathway for CY 2020, effective January 1, 2020. We solicited public comment on whether the CUSTOM*FLEX*® ARTIFICIAL*IRIS* should continue to receive transitional pass-through payment under the alternative pathway for devices that have FDA's Breakthrough Device designation and marketing authorization.

Comment: Commenters stated that CUSTOM*FLEX*® ARTIFICIAL*IRIS* should continue to receive transitional pass-through payment.

Response: After consideration of the public comments we received and our review of the device pass-through application, we have determined that the CUSTOM*FLEX*® ARTIFICIAL*IRIS* meets the requirements for device pass-through payment status described at § 419.66. As stated previously, devices that are granted a FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2)(i) for purposes of determining device pass-through payment status, but must meet the other criteria for device pass-through status, which we believe CUSTOM*FLEX*® ARTIFICIAL*IRIS* does. Therefore, we are finalizing approval for device pass-through payment status for CUSTOM*FLEX*® ARTIFICIAL*IRIS* under the alternative pathway for devices that have a FDA Breakthrough Device designation and are FDA market authorized. For CY 2021, we will continue the device pass-through payment status for CUSTOM*FLEX*® ARTIFICIAL*IRIS.*

(2) EXALT™ Model D Single-Use Duodenoscope

Boston Scientific Corporation submitted an application before the March 2020 quarterly deadline for a new device category for transitional pass-through payment status for the EXALT™ Model D Single-Use Duodenoscope. The EXALT™ Model D Single-Use Duodenoscope is described as a sterile, single-use, flexible duodenoscope used to examine the duodenum and perform endoscopic retrograde cholangiopancreatography (ERCP) procedures by facilitating access to the pancreaticobiliary system. The applicant stated that it has designed the technology of the EXALT™ Model D Single-Use Duodenoscope to eliminate the risk of nosocomial infections due to improper reprocessing of a reusable duodenoscope. As stated above, the EXALT™ Model D Single-Use Duodenoscope is used during ERCP procedures that are performed to examine bile and pancreatic ducts. According to the applicant, the EXALT™ Model D Single-Use Duodenoscope enables passage and manipulation of accessory devices in the pancreaticobiliary system for diagnostic and therapeutic purposes, as necessary. During the ERCP procedure, the physician inserts the duodenoscope through the patient's mouth, passes the duodenoscope through the esophagus and stomach and enters into the first part of the small intestine (duodenum). The applicant stated that during ERCP a cannula is passed through the duodenoscope via a working channel and used to cannulate a small opening on the duodenal wall. Once that step is complete, the physician injects contrast while x-rays are taken to study the bile and/or pancreatic ducts. If the physician

identifies an area that warrants further investigation, accessory devices can be inserted through the working channel of the scope and into the pancreaticobiliary system for diagnosis or treatment. According to the applicant, after the conclusion of the procedure, the single-use EXALT™ Model D Single-Use Duodenoscope device has no further medical use and is fully disposable.

With respect to the newness criterion at § 419.66(b)(1), the FDA designated the EXALT™ Model D Single-Use Duodenoscope as a Breakthrough Device on November 19, 2019, and approved the premarket approval application (K193202) for EXALT™ Model D Single-Use Duodenoscope on December 13, 2019. We received the application for a new device category for transitional pass-through payment status for the EXALT™ Model D Single-Use Duodenoscope on January 17, 2020, which is within 3 years of the date of the initial FDA premarket approval. We solicited public comment on whether the EXALT™ Model D Single-Use Duodenoscope meets the newness criterion.

Comment: The manufacturer of EXALT™ Model D Single-Use Duodenoscope believes the device meets the eligibility criteria for device pass-through payment under the regulation at § 419.66, which includes the newness criterion, based on FDA Breakthrough Device designation it received on December 13, 2019 and the 510(k) premarket approval it received on November 19, 2019.

Response: We appreciate the commenter's input. After consideration of the public comment we received and based on the fact that the EXALT™ Model D Single-Use Duodenoscope application was received January 17, 2020, within 3 years of FDA premarket approval, which was on November 19, 2019, and FDA Breakthrough Device designation on December 13, 2019, we believe that the EXALT™ Model D Single-Use Duodenoscope meets the newness criterion.

With regard to the eligibility criterion at § 419.66(b)(3), according to the applicant, the EXALT™ Model D Single-Use Duodenoscope is integral to the ERCP service provided, is used for one patient only, and is surgically inserted as it is inserted through the patient's mouth, down the esophagus, into the stomach, and then into the first part of the small intestine. The applicant also stated that the EXALT™ Model D Single-Use Duodenoscope meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

Comment: The manufacturer of EXALT™ Model D Single-Use Duodenoscope believed that the EXALT™ Model D Single-Use Duodenoscope met the eligibility criteria at § 419.66(b). They maintained that the EXALT™ Model D Single-Use Duodenoscope meets the criterion at § 419.66(b)(3) because it is integral to the ERCP service provided, is used for one patient only, and is surgically inserted through the patient's mouth, down the esophagus, into the stomach, and then into the first part of the small intestine. The commenter believes the device meets eligibility requirements at § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

Response: We appreciate the commenter's feedback. Based on the information we have received from the commenter and our review of the application, we have determined that EXALT™ Model D Single-Use Duodenoscope meets the eligibility criteria at § 419.66(b)(3) and (b)(4) because, as previously discussed, the device is integral to the service furnished, is used for one patient only, and is inserted through the patient's mouth, down the esophagus, into the stomach, and finally into the first part of the small intestine. It also is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. With respect to the existence of a previous pass-through device category that describes EXALT™ Model D Single-Use Duodenoscope, the applicant suggested a category descriptor of ''Duodenoscope, single-use.'' The applicant also provided an existing device category ''C1749, Endoscope, retrograde imaging/illumination colonoscope device (implantable),'' for pass-through payment for another endoscope and explained why they believe the category descriptor is not applicable to EXALT™ Model D Single-Use Duodenoscope. The applicant stated that HCPCS C1749 does not appropriately describe the EXALT Model D, as C1749 is intended to describe endoscopic imaging devices that are inserted through a colonoscope and into the colon. The applicant argued that EXALT Model D is the first and only single-use duodenoscope through which devices can be passed, and it is utilized in ERCP procedures. The applicant further stated that the scope that is the subject of this request provides access to a different part of the anatomy, specifically, the pancreaticobiliary system and facilitates access for diagnostic and therapeutic purposes, as opposed to the devices described by C1749, which are endoscopic imaging devices that are inserted through a colonoscope and into the colon, providing access to a different part of the anatomy. Upon review, we agreed with the applicant that it does not appear that there are any other existing pass-through payment categories that might apply and we solicited public comment on this issue.

Comment: Several commenters stated they did not believe there is an existing pass-through payment category that describes the EXALT™ Model D Single-Use Duodenoscope. They commented that the existing device category that CMS identified does not adequately describe critical aspects of the device. The commenters also noted that existing category, C1749 Endoscope, retrograde imaging/illumination colonoscope device (implantable), does not appropriately describe single-use endoscopes that provide access to a different part of the anatomy, specifically the upper gastrointestinal (GI) tract.

Response: We appreciate the commenters' input. After consideration of the public comments we received, we agree there is no existing pass-through payment category that appropriately describes the EXALT™ Model D Single-Use Duodenoscope because it is a single use endoscope with internal channel that provides access to the duodenum and the hepatopancreatic duct. Based on this information, we have determined that the EXALT™ Model D Single-Use Duodenoscope meets the eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part

compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization. As previously discussed in section IV.2.a above, we finalized the alternative pathway for devices that are granted a Breakthrough Device designation and receive FDA marketing authorization in the CY 2020 OPPS/ASC final rule (84 FR 61295). The EXALT™ Model D Single-Use Duodenoscope has a Breakthrough Device designation and marketing authorization from the FDA and therefore is not evaluated based on substantial clinical improvement.

We did not receive comments on whether EXALT™ Model D Single-Use Duodenoscope meets the second criterion for establishing a device category at § 419.66(c)(2). We have determined that the EXALT™ Model D Single-Use Duodenoscope meets this criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the EXALT™ Model D Single-Use Duodenoscope would be reported with CPT code 43274 which is associated with APC 5331 (Complex GI Procedures). To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. We used APC 5331 for our calculations, which had a CY 2020 payment rate of $4,780.30 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). CPT code 43274 had a device offset amount of $1,287.81 at the time the application was received. According to the applicant, the cost of the EXALT™ Model D Single-Use Duodenoscope is $2,930.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $2,930 for the EXALT™ Model D Single-Use Duodenoscope is 61 percent of the applicable APC payment amount for the service related to the category of devices of $4,780.30 ($2,930/$4,780.30 × 100 = 61.3 percent). Therefore, we believe the EXALT™ Model D Single-Use Duodenoscope meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $2,930 for the EXALT™ Model D Single-Use Duodenoscope is 228 percent of the cost of the device-related portion of the APC payment amount for the related service of $1,287.81 ($2,930/$1,287.81) × 100 = 227.5 percent. Therefore, we believe that the EXALT™ Model D Single-Use Duodenoscope meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $2,930 for the EXALT™ Model D Single-Use Duodenoscope and the portion of the APC payment amount for the device of $1,287.81 is 34 percent of the APC payment amount for the related service of $4,780.30 (($2,930 − $1,287.81)/$4,780.30) × 100 = 34.4 percent). Therefore, we believe that the EXALT™ Model D Single-Use Duodenoscope meets the third cost significance requirement. We solicited public comment on whether the EXALT™ Model D Single-Use Duodenoscope meets the device pass-through payment criteria discussed in this section, including the cost criterion.

As specified above, the EXALT™ Model D Single-Use Duodenoscope application was preliminarily approved for transitional pass-through payment under the alternative pathway effective July 1, 2020. We solicited public comment on whether the EXALT™ Model D Single-Use Duodenoscope should continue to receive transitional pass-through payment under the alternative pathway for devices that have a FDA Breakthrough Device designation and are FDA market authorized.

Comment: Several commenters, including the manufacturer of the EXALT™ Model D Single-Use Duodenoscope, believed that the device meets the cost criterion for device pass-through payment status. Some commenters recommended we not apply a device offset amount for EXALT™ Model D Single-Use Duodenoscope because they believed that single-use duodenscopes are not replacing devices that are packaged into the APC payment rate and thus, should not be subject to the device offset.

Response: We appreciate the commenters input. Section 1833(t)(6)(D)(ii) of the Act requires that the amount of payment for a pass-through device be the amount by which a hospital's charges, adjusted to cost, exceeds the portion of the otherwise applicable APC payment amount that the Secretary determines is associated with the device. The portion of the APC payment amount that we determine is associated with the cost of the pass-through device is referred to as the device offset. The device offset is used to reduce the otherwise applicable APC payment amount for the applicable pass-through device.

After further review, we agree with the commenters. We have determined that the costs associated with the EXALT™ Model D Single-Use Duodenoscope are not already reflected in the device portions of APCs 5303 (Level 3 Upper GI Procedures) or 5331 (Complex GI Procedures) because there were no single-use duodenoscopes on the market previously so no operating cost data associated with such devices could be included historical OPPS claims data. Therefore, we are not applying a device offset for the EXALT™ Model D Single-Use Duodenoscope.

After consideration of the public comments we received, we believe that EXALT™ Model D Single-Use Duodenoscope meets the cost criterion for device pass-through payment status.

For CY 2021, we will continue the device pass-through payment status for EXALT™ Model D Single-Use Duodenoscope. As stated previously, devices that are designated as Breakthrough Devices by the FDA are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2)(i) for purposes of determining device pass-through payment status, but must meet the other criteria for device pass-through status, which we believe EXALT™ Model D Single-Use Duodenoscope does. Therefore, we are finalizing approval for

device pass-through payment status for EXALT™ Model D Single-Use Duodenoscope under the alternative pathway for devices that have FDA Breakthrough Device designation and FDA market authorization beginning CY 2021.

(3) BAROSTIM NEO™ System

CVRx, Inc. submitted an application for the BAROSTIM NEO™ System by the December 2019 quarterly deadline. The applicant provided that the BAROSTIM NEO™ is indicated for the treatment of symptoms of patients with advanced heart failure. The applicant asserted that the BAROSTIM therapy triggers the body's main cardiovascular reflex to regulate blood pressure and address the underlying causes of the progression of heart failure. According to the applicant, increased sympathetic and decreased parasympathetic activity contribute to heart failure (HF) symptoms and disease progression. Barostim's mechanism of action is stimulating the carotid baroreceptor which results in centrally mediated reduction of sympathetic and increase in parasympathetic activity. A single 2 mm coated electrode with a 7 mm silicone backer is sutured to the carotid artery to activate the baroreceptors. It is connected to an implantable pulse generator in the chest which provides control of baroreflex activation energy. The BAROSTIM NEO™ System uses CVRx patented BAROSTIM THERAPY™ technology to trigger the body's own natural systems (baroreflex) by electrically activating the carotid baroreceptors, the body's natural cardiovascular regulation sensors.

According to the applicant, in conditions such as hypertension and heart failure, it is believed the baroreceptors, the body's natural sensors, are not functioning properly and are not sending sufficient signals to the brain. This results in the brain sending signals to other parts of the body (heart, blood vessels, kidneys) to constrict the blood vessels, retain water and salt by the kidneys and increase stress-related hormones. The applicant provided that when the baroreceptors are activated by the BAROSTIM NEO™ system, signals are sent through neural pathways to the brain. In response, the brain works to counteract this stimulation by sending signals to other parts of the body (heart, blood vessels, and kidneys) that relax the blood vessels and inhibit the production of stress-related hormones. These changes act to reduce cardiac after-load and enable the heart to increase blood output, while maintaining or reducing its workload. Parameters are programmed into the Implantable Pulse Generator (IPG) using telemetry via a wireless external programming system. The applicant stated that the BAROSTIM NEO™ System is fully programmable to adjust the therapy to each patient's needs.

With respect to the newness criterion at § 419.66(b)(1), the FDA designated the BAROSTIM NEO™ System as a Breakthrough Device and approved the premarket approval application (P180050) on August 16, 2019 based on the improvement of symptoms of heart failure—quality of life, six-minute hall walk, and functional status—for patients who remain symptomatic despite treatment with guideline-directed medical therapy, are New York Heart Association (NYHA) Class III or Class II (who had a recent history of Class III), have a left ventricular ejection fraction ≤35 percent, a NT-proBNP <1600 pg/ml and excluding patients indicated for Cardiac Resynchronization Therapy (CRT) according to AHA/ACC/ESC guidelines. We received the application for a new device category for transitional pass-through payment status for the BAROSTIM NEO™ on November 27, 2019, which is within 3 years of the date of the initial FDA premarketing approval. We solicited public comment on whether the BAROSTIM NEO™ meets the newness criterion.

Comment: The manufacturer stated that BAROSTIM NEO™ meets the newness criterion as described by § 419.66(b) because the FDA designated the BAROSTIM NEO™ System as a Breakthrough Device and approved the premarket application (P180050) on August 16, 2019 based on the improvement of symptoms of heart failure—quality of life, six-minute hall walk, and functional status—for patients who remain symptomatic despite treatment.

Response: We appreciate the commenter's input. After consideration of the public comments we received and because the BAROSTIM NEO™ application was received November 27, 2019 and received FDA premarketing approval on August 16, 2019 which is within 3 years, we agree that the BAROSTIM NEO™ meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the use of BAROSTIM NEO™ is integral to the service of providing baroreflex therapy, is used for one patient only, comes in contact with human skin and is surgically implanted or inserted. The applicant also claimed the BAROSTIM NEO™ meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We solicited public comments on whether the BAROSTIM NEO™ meets the eligibility criteria at § 419.66(b).

Comment: The manufacturer of BAROSTIM NEO™ felt that their device met the eligibility criteria at § 419.66(b) because it is used for one patient only, comes in contact with human skin and is surgically implanted or inserted. The applicant claimed the BAROSTIM NEO™ meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

Response: Based on the information we have received and our review of the application, we agree with the commenter that the device is used for one patient only, comes in contact with human skin and is surgically implanted or inserted. We also agree with the commenter that BAROSTIM NEO™ meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. Based on this assessment we have determined that BAROSTIM NEO™ meets the eligibility criterion at § 419.66(b)(3) and (4).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. With respect to the existence of a previous pass-through device category that described BAROSTIM NEO™, the applicant suggested a category descriptor of ''Generator, neurostimulator (implantable), non-rechargeable with carotid sinus stimulation lead.'' The applicant also provided a list of current and expired device categories for pass-through payment for other neurostimulation systems and their rationale for why they believed the category descriptors are not applicable to BAROSTIM NEO™.

The applicant stated that BAROSTIM NEO™ is not described by existing device category C1767, Generator, neurostimulator (implantable), non-

rechargeable. The applicant stated that similar to the traditional spinal cord stimulation (SCS) systems included in this category, the BAROSTIM NEO™ System is not rechargeable; however, it is the only system that works to deliver CVRx's proprietary baroreflex activation therapy (BAT). The applicant provided that BAT uses afferent signaling to the brain by stimulating the carotid artery to reduce the sympathetic signal and increase the parasympathetic signal. The applicant stated that this unique therapy works to rebalance the autonomic input to the heart to improve heart failure symptoms.

Additionally, the applicant stated that traditional devices provide pain relief by disrupting the pain signals traveling between the spinal cord's nervous system and the brain, but the BAROSTIM NEO System uses the generator to stimulate the baroreceptors in the carotid artery to treat the symptoms of patients with advanced heart failure. The applicant stated that the BAROSTIM NEO generator is unique in its capability to drive electricity up to 20 mA/100 Hz with sufficient battery capacity to provide the required therapy through the BAROSTIM NEO™ carotid sinus lead. The applicant described that the BAROSTIM NEO™ carotid sinus lead is sutured to the carotid wall, where the baroreceptors (stretch fibers) are located. Electrical current radiating from the carotid sinus lead activates the baroreceptors. When activated, the baroreceptors send afferent signals through the Carotid Sinus Nerve to the brain. The brain interprets these afferent signals and reacts by reducing the sympathetic tone and increasing the parasympathetic tone. The applicant stated that the BAROSTIM NEO™ System is the only device currently approved by FDA that leverages this mechanism of action to treat the symptoms of patients with advanced heart failure.

The applicant stated that BAROSTIM NEO™ is not described by existing device category C1823, Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads. They contended that existing device category C1823 is exclusively used to describe a complete system comprised of a generator implanted in the chest, a stimulation lead attached to the phrenic nerve and a sensing lead to control the function of the diaphragm for the treatment of moderate to severe central sleep apnea. The applicant also stated that the BAROSTIM NEO™ System utilizes a single stimulation lead positioned on the carotid artery to stimulate baroreceptors. The stimulation of the baroreceptors creates afferent nerve traffic through the Carotid Sinus Nerve, and results in the activation of the baroreflex. The applicant again stated that the BAROSTIM NEO™ System is the only device currently approved by FDA that leverages this mechanism of action to improve quality of life and functional status in heart failure.

The applicant also provided that BAROSTIM NEO™ is not described by existing device category C1778, Lead, neurostimulator (implantable). The applicant stated that leads used in traditional neurostimulation are implanted on nerves (for example, spinal cord, peripheral nerves). The applicant contended that in contrast, the BAROSTIM NEO carotid sinus lead is sutured onto the carotid artery and is the only lead that is designed to be secured on an arterial wall to stimulate sensors located inside the arterial wall (baroreceptors). The applicant provided that stimulation is delivered to the arterial wall, where the baroreceptors (stretch fibers) are located. The applicant stated that the BAROSTIM NEO™ generator is uniquely designed to send electric current via the BAROSTIM NEO™ carotid sinus lead and that the BAROSTIM NEO™ carotid sinus lead is uniquely designed to only interface with the BAROSTIM NEO generator. Again, the applicant provided that the BAROSTIM NEO™ System is the only device currently approved by FDA that leverages this mechanism of action to treat the symptoms of patients with advanced heart failure.

We stated in the CY 2021 OPPS/ASC proposed rule that we were concerned that the BAROSTIM NEO™ System may be appropriately described by existing pass-through payment categories. For example, we believed that the BAROSTIM NEO™ System may be appropriately described by C1767 as the BAROSTIM NEO™ device consists of a generator, a neurostimulator, and a lead. We solicited public comment on this issue.

Comment: The manufacturer of the device stated that it does not believe there is an existing pass-through payment category that describes the BAROSTIM NEO™ System, commenting that the existing device categories that CMS identified do not adequately describe critical aspects of the device. The manufacturer noted that existing categories, such as C1767, Generator, neurostimulator (implantable), non-rechargeable, C1823, Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads, and C1778, Lead, neurostimulator (implantable), do not appropriately describe systems that activate special receptors in the carotid artery known as baroreceptors, which are in a different anatomical location than nerves. The manufacturer stated that baroreceptors are sensory cells that respond to mechanical pressure. They have ion channels that open to allow ions to pass through when they are stretched. Baroreceptors are mechanosensitive ion channels, which according to the manufacturer, are functionally very different from the voltage gate ion channels of nerves. In addition, the manufacturer continued, BAROSTIM NEO stimulates baroreceptors deep within the arterial wall of the carotid sinus, as opposed to direct activation of the carotid sinus nerve. The manufacturer explained that the carotid sinus nerve contains afferent nerve fibers leading from baroreceptors, but also contains afferent nerve fibers leading from the chemoreceptors, which can cause unwanted side effects. The manufacturer stated that BAROSTIM NEO™ uses electricity to activate the baroreceptors and stimulate the baroreflex and does not directly stimulate neurons and therefore, is not appropriately described by existing categories.

Response: We appreciate the commenter's input. After consideration of the public comments we received, we agree that there is no existing pass-through payment category that appropriately describes BAROSTIM NEO™ because it is an implantable generator with surgically placed lead providing selective stimulation of carotid sinus baroreceptors and activation of baroreflex, which then stimulates the autonomic nervous system. Based on this information, we have determined that BAROSTIM NEO™ meets the eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device has received FDA marketing authorization and is part of the FDA's Breakthrough Devices Program. As stated in section IV.2.a above, devices

that apply under the alternative pathway for devices with FDA premarketing approval and a Breakthrough Device designation are not subject to evaluation for substantial clinical improvement (84 FR 61295). The BAROSTIM NEO™ System has Breakthrough Device designation and FDA premarketing approval, and therefore is not evaluated based on substantial clinical improvement.

We did not receive comments on whether BAROSTIM NEO™ meets the second criterion for establishing a device category at § 419.66(c)(2). We have determined that the BAROSTIM NEO™ meets this criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the BAROSTIM NEO™ would be reported with CPT code 0266T, which they consider to be a total system code. CPT code 0266T is assigned to APC 5464 (Level 4 Neurostimulator and Related Procedures). To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5464, which has a CY 2020 payment rate of $29,115.50. Beginning in CY 2017, we calculated the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). CPT code 0266T had a device offset amount of $24,253 at the time the application was received. According to the applicant, the cost of the BAROSTIM NEO™ is $35,000.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $35,000 for the BAROSTIM NEO™ is 120 percent of the applicable APC payment amount for the service related to the category of devices of $29,116 (($35,000/29,116) × 100 = 120.2 percent). Therefore, we believe the BAROSTIM NEO™ meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $35,000 for the BAROSTIM NEO™ is 144 percent of the cost of the device-related portion of the APC payment amount for the related service of $24,253 (($35,000/$24,253) × 100 = 144.3 percent). Therefore, we believe that the BAROSTIM NEO™ meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $35,000 for BAROSTIM NEO™ and the portion of the APC payment amount for the device of $24,253 is 37 percent of the APC payment amount for the related service of $29,116 (($35,000 − $24,253)/$29,116) × 100 = 36.9 percent). Therefore, we believe that the BAROSTIM NEO™ System meets the third cost significance requirement.

We solicited public comment on whether the BAROSTIM NEO™ System meets the device pass-through payment criteria discussed in this section, including the cost criterion.

Comment: The manufacturer of the BAROSTIM NEO™ System believed that the device meets the cost criterion for device pass-through payment status.

Response: We appreciate the manufacturer's input. After consideration of the public comments we received and our cost threshold calculations, we agree that BAROSTIM NEO™ meets the cost criterion for device pass-through payment status.

After consideration of the public comments we received and our review of the device pass-through application, we have determined that the BAROSTIM NEO™ qualifies for device pass-through payment. As stated previously, devices that receive FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2)(i) for purposes of determining device pass-through payment status, but must meet the other criteria for device pass-through status, which we believe BAROSTIM NEO™ does. Therefore, we are finalizing approval for device pass-through payment status beginning CY 2021 for BAROSTIM NEO™ under the alternative pathway for devices that receive FDA Breakthrough Device designation and FDA premarket approval. Please refer to section IV.B.1.b of this final rule with comment for more information on the device offset for BAROSTIM NEO™ device.

2. Traditional Device Pass-Through Applications

(1) Hemospray® Endoscopic Hemostat

Cook Medical submitted an application for a new device category for transitional pass-through payment status for the Hemospray® Endoscopic Hemostat (Hemospray) for CY 2021. Hemospray® Endoscopic Hemostat is a prescription use device consisting of a hemostatic agent and a delivery system. The hemostatic agent is an inert, bentonite powder, naturally sourced from aluminum phyllosilicate clay, developed for endoscopic hemostasis. According to the applicant, Hemospray® is indicated by the FDA for hemostasis of nonvariceal gastrointestinal bleeding. Using an endoscope to access the gastrointestinal tract, the Hemospray delivery system is passed through the accessory channel of the endoscope and positioned just above the bleeding site without making contact with the GI tract wall. The Hemospray® powder is propelled through the application catheter, either a 7 or 10 French polyethylene catheter, by release of CO_2 from the cartridge located in the device handle and sprayed onto the bleeding site. Bentonite can absorb five to ten times its weight in water and swell up to 15 times its dry volume. Bentonite rapidly absorbs water and becomes cohesive to itself and adhesive to tissue, forming a physical barrier to aqueous fluid (for example, blood). Hemospray® is not absorbed by the body and does not require removal as it passes through the GI tract within 72 hours. Hemospray® is single-use and disposable.

With respect to the newness criterion at § 419.66(b)(1), the FDA granted a *de novo* request classifying the Hemospray® Endoscopic Hemostat (Hemospray®) as a Class II device under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act on May 7, 2018. We received the application for a new device category for transitional pass-through payment status for the Hemospray® Endoscopic Hemostat on December 2, 2019, which is within 3 years of the date of the initial FDA marketing authorization. We solicited public comments on whether Hemospray® meets the newness criterion.

Comment: The manufacturer of Hemospray® believed this device meets

the newness eligibility criteria for device pass-through payment under the regulation at § 419.66(b)(1) since Hemospray® was granted de novo marketing authorization and classified as a Class II device on May 7, 2018.

Response: We appreciate the commenter's input. After consideration of the public comments we received and based on the fact that the Hemospray® application was received on May 7, 2018, within 3 years of FDA approval, we agree that the Hemospray® System meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, Hemospray® is integral to the service provided, is used for one patient only, comes in contact with human skin, and is applied in or on a wound or other skin lesion. The applicant also claimed that Hemospray® meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We solicited public comments on whether Hemospray® meets the eligibility criteria at § 419.66(b).

Comment: Three commenters, including the manufacturer of Hemospray®, believed that the Hemospray® meets the eligibility criteria at § 419.66(b)(3) stating that Hemospray® is a prescription single use device consisting of a hemostatic agent and a delivery system that is integral to the service provided.

Response: We appreciate the commenters' input. Based on the public comments we have received and our review of the application, we have determined that Hemospray® meets the eligibility criterion at § 419.66(b)(3) and (4).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. We stated in the CY 2021 OPPS/ASC proposed rule that we have not identified an existing pass-through payment category that describes Hemospray®. We solicited public comment on whether Hemospray® meets the device category criterion.

Comment: Two commenters, including the manufacturer of the Hemospray®, indicated that there is not an existing pass-through payment category that describes the device.

Response: We appreciate the commenters' input. After consideration of the public comments we received, we continue to believe that there is not an existing pass-through payment category that describes Hemospray®, and therefore, Hemospray® meets the device category eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization. The applicant stated that Hemospray® represents a substantial clinical improvement over existing technologies. With respect to this criterion, the applicant submitted studies that examined the impact of Hemospray® on endoscopic hemostasis outcomes, rebleeding occurrence, and mortality.

According to the applicant, Hemospray® is a topically applied mineral powder that offers a novel primary treatment option for endoscopic bleeding management, serves as an option for patients who fail conventional endoscopic treatments, and serves as an alternative to interventional radiology hemostasis (IRH) and surgery. Broadly, the applicant outlined two treatment areas in which it stated Hemospray® would provide a substantial clinical improvement: (1) As a primary treatment or a rescue treatment after the failure of a conventional method, and (2) in use for the treatment of malignant lesions. The applicant provided seven articles specifically for the purpose of addressing the substantial clinical improvement criterion.

The first article provided by the applicant was a prospective, single-armed, multicenter Phase 2 safety and efficacy study performed in France.[7] From March 2013 to January 2015, 64 endoscopists in 20 centers enrolled 202 patients in the study in which Hemospray® was used as either a first line treatment (46.5 percent) or salvage therapy (53.5 percent) following unsuccessful treatment with another method. The indication for Hemospray® as a first-line therapy or salvage therapy was at the discretion of the endoscopist. Of the 202 patients, the mean age was 68.9, 69.3 percent were male, and all patients were classified into four primary etiologic groups: Ulcers (37.1 percent), malignant lesions (30.2 percent), post-endoscopic bleeding (17.3 percent), and other (15.3 percent). Patients were further classified by the American Society of Anesthesiologist (ASA) physical status scores with 4.5 percent as a normal healthy patient, 24.3 percent as a patient with mild systemic disease, 46 percent as a patient with severe systemic disease, 22.8 percent as a patient with severe systemic disease that is a constant threat to life, and 2.5 percent as a moribund patient who is not expected to survive without an operation.[8] [9] Immediate hemostasis was achieved in 96.5 percent across all patients; among treatment subtypes, immediate hemostasis was achieved in 96.8 percent of first-line treated patients and 96.3 percent of salvage therapy patients. At day 30, the overall rebleeding was 33.5 percent of 185 patients with cumulative incidences of 41.4 percent for ulcers, 37.7 percent for malignant lesions, 17.6 percent for post-endoscopic bleedings, and 25 percent for others. When Hemospray® was used as a first-line treatment, rebleeding at day 30 occurred in 26.5 percent (22/83) of overall lesions, 30.8 percent of ulcers, 33.3 percent of malignant lesions, 13.6 percent of post-endoscopic bleedings, and 22.2 percent of other. When Hemospray® was used as a salvage therapy, rebleeding at day 30 occurred in 39.2 percent (40/102) of overall lesions, 43.9 percent of ulcers, 50.0 percent of malignant lesions, 25.0 percent of post-endoscopic bleedings, and 26.3 percent for others. According to the article, the favorable hemostatic results seen from Hemospray® are due to its threefold mechanism of action: Formation of a mechanical barrier; concentration of clotting factors at the bleeding site; and enhancement of clot formation.[10] No severe adverse events

[7] Haddara S, Jacques J, Lecleire S et al. A novel hemostatic powder for upper gastrointestinal bleeding: A multicenter study (the GRAPHE registry). Endoscopy 2016; 48: 1084–95.

[8] Ibid.

[9] ASA House of Delegates/Executive Committee. (2014, October 15). *ASA Physical Status Classification System*. Retrieved from American Society of Anesthesiologists: *https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system*.

[10] Haddara S, Jacques J, Lecleire S et al. A novel hemostatic powder for upper gastrointestinal

were noted, however the authors note the potential for pain exists due to the use of carbon dioxide. Lastly, the authors stated that while Hemospray® was found to reduce the need for radiological embolization and surgery as salvage therapies, it was not found to be better than other hemostatic methods in terms of preventing rebleeding of ulcers.

The applicant provided a second article consisting of an abstract from another systematic review article.[11] The abstract purports to cover a review of prospective, retrospective, and randomized control trials evaluating Hemospray® as a rescue therapy. Eighty-five articles were initially identified and 23 were selected for review. Of those, 5 studies were selected which met the inclusion criteria of the analysis. The median age of patients was 69; 68 percent were male. The abstract concludes that when used as a rescue therapy after the failure of conventional endoscopic modalities in nonvariceal gastrointestinal bleeding, Hemospray® seems to have significantly higher rates of immediate hemostasis.

A third article provided by the applicant described a single-arm retrospective analytical study of 261 enrolled patients conducted at 21 hospitals in Spain.[12] The mean age was 67 years old, 69 percent of patients were male, and the overall technical success, defined as correct assembled and delivery of Hemospray® to a bleeding lesion, was 97.7 percent (95.1 percent–99.2 percent). The most common causes of bleeding in patients were peptic ulcer (28 percent), malignancy (18.4 percent), therapeutic endoscopy-related (17.6 percent), and surgical anastomosis (8.8 percent). Overall, 93.5 percent (89.5 percent to 96 percent) of procedures achieved hemostasis. Recurrent bleeding, defined as (1) a new episode of bleeding symptoms, (2) a decrease in hemoglobin of >2 g/dL within 48 hours of an index endoscopy or >3g/dL in 24 hours, or (3) direct visualization of active bleeding at the previously treated lesion on repeat endoscopy, had a cumulative incidence at 3 and 30 days of 16.1 percent (11.9 percent–21 percent) and 22.9 percent (17.8 percent–28.3 percent) respectively. The overall risk of Hemospray® failure at 3 and 30 days was 21.1 percent (16.4 percent–26.2 percent) and 27.4 percent (22.1 percent–32.9 percent) respectively with no statistically significant differences (p=0.07) between causes at 30 days (for example, peptic ulcer, malignancy, anastomosis, therapeutic endoscopy-related, and other causes). With the use of multivariate analysis, spurting bleeding vs. nonspurting bleeding (subdistribution hazard ratio [sHR] 1.97 (1.24–3.13)), hypotension vs. normotensive (sHR 2.14 (1.22–3.75)), and the use of vasoactive drugs (sHR 1.80 (1.10–2.95)) were independently associated with Hemospray® failure. The overall 30-day survival was 81.9 percent (76.5 percent–86.1 percent) with 46 patients dying during follow-up and 22 experiencing bleeding related deaths; twenty patients (7.6 percent) with intraprocedural hemostasis died before day 30. The authors indicated the majority of Hemospray® failures occurred within the first 3 days and the rate of immediate hemostasis was similar to literature reports of intraprocedural success rates of over 90 percent. The authors stated that the hemostatic powder of Hemospray® is eliminated from the GI tract as early as 24 hours after use, which could explain the wide ranging recurrent bleeding percentage. The authors reported that importantly, adverse events are rare, but cases of abdominal distension, visceral perforation, transient biliary obstruction, and splenic infarct have been reported; one patient involved in this study experienced an esophageal perforation without a definitive causal relationship.

A fourth article provided by the applicant described a single-arm multicenter prospective registry involving 314 patients in Europe which collected data on days 0, 1, 3, 7, 14, and 30 after endotherapy with Hemospray®.[13] The outcomes of interest in this study were immediate endoscopic hemostasis (observed cessation of bleeding within 5 minutes post Hemospray® application) with secondary outcomes of rebleeding immediately following treatment and during follow-up, 7 and 30 day all-cause mortality, and adverse events. The sample was 74 percent male with a median age of 71 with the most common pathologies of peptic ulcer (53 percent), malignancy (16 percent), post-endoscopic bleeding (16 percent), bleeding from severe inflammation (11 percent), esophageal variceal bleeding (2.5 percent), and cases with no obvious cause (1.6 percent). The median baseline Blatchford score (BS) and RS were 11 and 7 respectively. The BS ranges from 0 to 23 with higher scores indicating increasing risk for required endoscopic intervention and is based upon the blood urea nitrogen, hemoglobin, systolic blood pressure, pulse, presence of melena, syncope, hepatic disease, and/or cardiac failure.[14] The RS ranges from 0 to 11 with higher scores indicating worse potential outcomes and is based upon age, presence of shock, comorbidity, diagnosis, and endoscopic stigmata of recent hemorrhage.[15] Immediate hemostasis was achieved in 89.5 percent of patients following the use of Hemospray®; only the BS was found to have a positive correlation with treatment failure in multivariate analysis (OR 1.21 (1.10–1.34)). Rebleeding occurred in 10.3 percent of patients who achieved immediate hemostasis again with only the BS having a positive correlation with rebleeding (OR: 1.13 (1.03–1.25)). At 30 days, the all-cause mortality was 20.1 percent; 78 percent of these patients had achieved immediate endoscopic hemostasis and had a cause of death resulting from the progression of other comorbidities. A subgroup analysis of treatment type (monotherapy, combination therapy, and rescue therapy groups) was performed showing no statistically significant difference in immediate hemostasis across groups (92.4 percent, 88.7 percent, and 85.5 percent respectively). Higher all-cause mortality rates at 30 days were highest in the monotherapy group (25.4 percent, p=0.04) as compared to all other groups. According to the authors, in comparison to major recent studies, they were able to show lower rebleeding rates overall and in all subgroups despite the high-risk population.[16] The authors further note limitations in that the inclusion of patients was nonconsecutive and at the discretion of the endoscopist at the time of the endoscopy, which allows for the potential introduction of selection bias,

bleeding: A multicenter study (the GRAPHE registry). Endoscopy 2016; 48: 1084–95.

[11] Moole, V., Chatterjee, T., Saca, D., Uppu, A., Poosala, A., & Duvvuri, A. A Systematic review and meta-analysis: Analyzing the efficacy of hemostatic nanopowder (TC–325) as rescue therapy in patients with nonvariceal upper gastrointestinal bleeding. Gastroenterology 2019; 156(6), S–741

[12] Rodriguez de Santiago E, Burgos-Santamaria D, Perez-Carazo L, et al. Hemostatic spray TC–325 for GI bleeding in a nationwide study: Survival analysis and predictors of failure via competing risks analysis. Gastrointest Endosc 2019; 90(4), 581–590.

[13] Alzoubaidi D, Hussein M, Rusu R, et al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. Digestive Endoscopy 2019.

[14] Saltzman, J. (2019, October). Approach to acute upper gastrointestinal bleeding in adults. (M. Feldman, Editor) Retrieved from UpToDate: *https://www.uptodate.com/contents/approach-to-acute-upper-gastrointestinal-bleeding-in-adults.*

[15] Ibid.

[16] Alzoubaidi D, Hussein M, Rusu R, et al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. Digestive Endoscopy 2019.

which may have affected these study results.

The fourth article also described the utility of Hemospray® in the treatment of malignant lesions. According to the applicant, malignant lesions pose a significant clinical challenge as successful hemostasis rates are as low as 40 percent with high recurrent bleeding over 50 percent within 1 month following standard treatments.[17] [18] The applicant added that bleeding from tumors is often diffuse and consists of friable mucosa decreasing the utility of traditional treatments (for example, ligation, cautery). From the fourth article, the applicant noted that 50 patients were treated for malignant bleeding with an overall immediate hemostasis in 94 percent of patients.[19] Of the 50 patients, 33 were treated with Hemospray® alone, 11 were treated with Hemospray® as the final treatment, and 4 were treated with Hemospray® as a rescue therapy of which 100 percent, 84.6 percent and 75 percent experienced immediate hemostasis respectively.[20] Similarly, from the first discussed article, the applicant noted that among malignant bleeding patients, 95.1 percent achieved immediate hemostasis with lower rebleeding rates at 8 days when Hemospray® was used as a primary treatment compared to when used as a rescue therapy (17.1 percent vs. 46.7 percent respectively).[21] The applicant concluded that Hemospray® may provide an advantage as a primary treatment to patients with malignant bleeding.

The applicant provided a fifth article, which consisted of a journal pre-proof article detailing a 1:1 randomized control trial of 20 patients treated with Hemospray® versus the standard of care (for example, thermal and injection therapies) in the treatment of malignant gastrointestinal bleeding.[22] The goals of this pilot study were to determine the feasibility of a definitive trial. The primary outcome of the study was immediate hemostasis (absence of bleeding after 3 minutes) with secondary outcomes of recurrent bleeding at days 1, 3, 30, 90, and 180 and adverse events at days 1, 30, and 180. The mean age of patients was 67.2, 75 percent were male, and on average patients presented with 2.9 ± 1.7 comorbidities. All patients had active bleeding at endoscopy and the majority of patients had an ASA score of 2 (45 percent) or 3 (40 percent). Immediate hemostasis was achieved in 90 percent of Hemospray® patients and 40 percent of standard of care patients (5 injection alone, 3 thermal, 1 injection with clips, and 1 unknown). Of those patients in the control group, 83.3 percent crossed over to the Hemospray® treatment. One patient died while being treated with Hemospray® from exsanguination; post-mortem examination demonstrated that bleeding was caused by rupture of a malignant inferior mesenteric artery aneurysm. Overall, 86.7 percent of patients treated with Hemospray® initially or as crossover treatment achieved hemostasis. Recurrent bleeding was lower in the Hemospray® group (20 percent) as compared to the control group (60 percent) at 180 days. Forty percent of the treated group received blood transfusions as compared to 70 percent of the control group. The overall length of stay was 14.6 days among treated patients as compared to 9.4 in the control group. Mortality at 180 days was 80 percent in both the treated and control groups. The authors noted the potential for operator bias in the use of Hemospray® prior to switching to another method when persistent bleeding exists. Lastly, the authors noted that while they did not occur during this study, there are concerns around the risks of perforation, obstruction, and systemic embolization with the use of Hemospray®.

A sixth article provided by the applicant was a case-controlled study with 10 patients with active upper gastrointestinal bleeding from tumor compared with 10 conventional therapy patients selected as historical controls, matched by type of tumor.[23] The study evaluated efficacy for tumor-related bleeding and compared Hemospray® to conventional therapies, specifically examining 14-day rebleeding rates, lengths of hospital stay (LOS), and mortality rate at 30-day follow up. Historical controls were selected from patient medical records from 2010 to 2014. Among the patients who received Hemospray®, the 14-day rebleeding rate (10 percent vs. 30 percent; P=0.60) and the 30-day mortality rates (10 percent vs. 30 percent, P=0.7) were three times lower compared to the control group; neither rate was statistically significant. There was no difference in LOS between the Hemospray® and conventional therapy patients.

A seventh article provided by the applicant described a single-arm multicenter retrospective study from 2011 to 2016 involving 88 patients who bled as a result of either a primary GI tumor or metastases to the GI tract.[24] In this study the authors define immediate hemostasis as no further bleeding at least one minute after treatment with Hemospray®, and recurrent bleeding was suspected if one of seven criteria were met: (1) Hematemesis or bloody nasogastric tube >6 hours after endoscopy; (2) melena after normalization of stool color; (3) hematochezia after normalization of stool color or melena; (4) development of tachycardia or hypotension after >1 hour of vital sign stability without other cause; (5) decrease in hemoglobin level greater than or equal to 3 hours apart; (6) tachycardia or hypotension that does not resolve within 8 hours after index endoscopy; or (7) persistent decreasing hemoglobin of >3 g/dL in 24 hours associated with melena or hematochezia). The sample for this study consisted of 88 patients (with a mean age of 65 years old and 70.5 percent male) of which 33.3 percent possessed no co-morbid illness, and 25 percent were on current antiplatelet/anticoagulant medication. The mean BS was 8.7 plus or minus 3.7 with a range from 0 to 18. Overall, 72.7 percent of patients had a stage 4 adenocarcinoma, squamous cell carcinoma, or lymphoma. Immediate hemostasis was achieved in 97.7 percent of patients. Recurrent bleeding occurred in 13 of 86 (15 percent) and 1 of 53 (1.9 percent) at 3 and 30 days, respectively. A total of 25 patients (28.4 percent) died during the 30-day follow up period. Overall, 27.3 percent of patients re-bled within 30 days after treatment of which half were within 3 days. Using multivariate analysis, the authors found patients

[17] Kim YI, Choi IJ, Cho SJ, et al. Outcome of endoscopic therapy for cancer bleeding in patients with unresectable gastric cancer. J Gastroenterol Hepatol 2013;28:1489–95.

[18] Roberts SE, Button LA, Williams JG. Prognosis following upper gastrointestinal bleeding. PLoS One 2012;7:e49507.

[19] Alzoubaidi D, Hussein M, Rusu R, et al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. Digestive Endoscopy 2019.

[20] Alzoubaidi D, Hussein M, Rusu R, et al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. Digestive Endoscopy 2019.

[21] Haddara S, Jacques J, Lecleire S et al. A novel hemostatic powder for upper gastrointestinal bleeding: A multicenter study (the GRAPHE registry). Endoscopy 2016; 48: 1084–95.

[22] Chen Y–I, Wyse J, Lu Y, Martel M, Barkun AN, TC–325 hemostatic powder versus current standard of care in managing malignant GI bleeding: A pilot randomized clinical trial. Gastrointestinal Endoscopy (2019), doi: *https://doi.org/10.1016/j.gie.2019.08.005*.

[23] Pittayanon, R., Prueksapanich, P., & Rerknimitr, R. (2016). The efficacy of Hemospray in patients with upper gastrointestinal bleeding from tumor. Endoscopy international open, 4(09), E933–E936.

[24] Pittayanon R, Rerknimitr R, Barkun A. Prognostic factors affecting outcomes in patients with malignant GI bleeding treated with a novel endoscopically delivered hemostatic powder. Gastrointest Endosc 2018; 87:991–1002.

with good performance status, no end-stage cancer, or receiving any combination of definitive hemostasis treatment modalities had significantly greater survival. The authors acknowledged the recurrent bleeding rate post Hemospray® treatment at 30 days of 38 percent is comparable with that seen in sole conventional hemostatic techniques and state this implies that Hemospray® does not differ from conventional techniques and remains unsatisfactory.

Ultimately, the applicant concluded nonvariceal gastrointestinal bleeding is associated with significant morbidity and mortality in older patients with multiple co-morbid conditions. Inability to achieve hemostasis and early rebleeding are associated with increased cost and greater resource utilization. According to the applicant, patients with bleeding from malignant lesions have few options that can provide immediate hemostasis without further disrupting fragile mucosal tissue and worsening the active bleed. The applicant stated Hemospray® is an effective agent that provides immediate hemostasis in patients with GI bleeding as part of multimodality treatment, as well as when used as rescue therapy in patients who have failed more conventional endoscopic modalities. Furthermore, the applicant stated that in patients with malignant bleeding in the GI tract, Hemospray® provides a high rate of immediate hemostasis and fewer recurrent bleeding episodes, which, in combination with definitive cancer treatment, may lead to improvements in long term survival. Lastly, the applicant stated Hemospray® is an important new technology that permits immediate and long-term hemostasis in GI bleeding cases where standard of care treatment with clip ligation or cautery are not effective.

In the CY 2021 OPPS/ASC proposed rule, we noted that the majority of studies provided lacked a comparator when assessing the effectiveness of Hemospray®. Three of the articles provided were systematic reviews of the literature. While we found these articles helpful in establishing a background for the use of Hemospray®, we were concerned that they may not provide strong evidence of substantial clinical improvement. Four studies appeared to be single-armed studies assessing the efficacy of Hemospray® in the patient setting. In all of these articles, comparisons were made between Hemospray® and standard of care treatments; however, without the ability to control for factors such as study design, patient characteristics, etc., it is difficult to determine if any differences seen resulted from Hemospray® or confounding variables. Furthermore, within the retrospective and prospective studies lacking a control subset, some level of selection bias appeared to potentially be introduced in that providers may have been allowed to select the manner and order in which patients were treated, thereby potentially influencing outcomes seen in these studies.

Additionally, one randomized control trial provided by the applicant appeared to be in the process of peer-review and was not yet published. Furthermore, this article was written as a feasibility study for a potentially larger randomized control trial and contained a sample of only 20 patients. This small sample size left us concerned that the results were not representative of the larger Medicare population. Lastly, as described, we were concerned the control group could receive one of multiple treatments which lacked a clear designation methodology beyond physician choice. For instance, 50 percent of the control patients received injection therapy alone, which according to the literature provided by the applicant is not an acceptable treatment for endoscopic bleeding. Accordingly, it was not clear whether performance seen in the treated group as compared to the control group was due to Hemospray® itself or due to confounding factors.

Third, we stated in the CY 2021 OPPS/ASC proposed rule that we were concerned with the samples chosen in many of the studies presented. Firstly, the Medicare population is approximately 54 percent female and 46 percent male.[25] Many of the samples provided by the applicant were overwhelmingly male. Secondly, many of the studies provided were performed in Europe and other settings outside of the U.S. We were therefore concerned that the samples chosen within the literature provided may not represent the Medicare population.

Lastly, we were concerned about the potential for adverse events resulting from Hemospray®. It was unclear from the literature provided by the applicant what the likelihood of these events is and whether or not an evaluation for the safety of Hemospray® was performed. About one-third of the articles submitted specifically addressed adverse events with Hemospray®. However, the evaluation of adverse events was limited and most of the patients in the studies died of disease progression. A few of the provided articles mentioned the potential for severe adverse reactions (for example, abdominal distension, visceral perforation, biliary obstruction, splenic infarct). Specifically, one article[26] recorded adverse events related to Hemospray®, including abdominal distention and esophageal perforation.

According to information submitted by the applicant, Cook Medical had voluntarily recalled Hemospray® Endoscopic Hemostat due to complaints received that the handle and/or activation knob on the device in some cases had cracked or broken when the device was activated and in some cases had caused the carbon dioxide cartridge to exit the handle. The applicant stated that Cook Medical had received one report of a superficial laceration to the user's hand that had required basic first aid; however, there were no reports of laceration, infection, or permanent impairment of a body structure to users or to patients due to the carbon dioxide cartridge exiting the handle. The applicant stated that Cook Medical had initiated an investigation and would determine the appropriate corrective action(s) to prevent recurrence of this issue. According to the applicant, although the recall did restrict availability of the device, they wished to continue their application as they believed the use of Hemospray® significantly improves clinical outcomes for certain patient populations compared to currently available treatments.

Based upon the evidence presented, we solicited public comments on whether the Hemospray® Endoscopic Hemostat meets the substantial clinical improvement criterion.

Comment: The manufacturer responded to several statements regarding Hemospray® and substantial clinical improvement in the CY 2021 OPPS/ASC proposed rule, and asserted that Hemospray® meets the substantial clinical improvement criterion. The manufacturer agreed the data presented is primarily from single arm and retrospective studies and may suffer from selection bias. However, the manufacturer suggested that CMS should consider that Hemospray® is commonly used when the conventional standard of care, such as injection plus clips or cautery, is inadequate to treat patients undergoing an urgent catheter-based embolization or surgery. The manufacturer stated that the selection

[25] *https://www.cms.gov/files/document/2018-mdcr-enroll-ab-5.pdf.*

[26] Rodriguez de Santiago E, Burgos-Santamaria D, Perez-Carazo L, et al. Hemostatic spray TC–325 for GI bleeding in a nationwide study: Survival analysis and predictors of failure via competing risks analysis. Gastrointest Endosc 2019; 90(4), 581–590.

bias is toward patients with the highest risk of morbidity or mortality and the high rate of successful treatment for those patients with Hemospray® represents substantial clinical improvement. They cited several studies that found that, after all other conventional treatments failed, there was overall treatment success in cases where Hemospray® was used.

In response to CMS' concerns about the unpublished randomized controlled trial presented, the manufacturer stated that the study has been published with no changes and noted that, despite the small sample size, they believe the results are representative of the general population with malignant gastrointestinal bleeding and consistent with other published retrospective studies.

The manufacturer stated that the research and studies for Hemospray® are largely international because Hemospray® was commercially available outside the U.S. for 5 to 7 years before the FDA awarded the product de Novo 510(k) status. They believed that this data is representative of the U.S. population, as the treatment strategy and patient outcomes are similar. The manufacturer acknowledged that study populations are predominantly male but noted that 60 percent of patients undergoing endoscopic control of bleeding are male, according to the 2016 Healthcare Cost and Utilization Project. The manufacturer mentioned that the mean age of study populations varied from 67–71 years, which is representative of the Medicare population.

Regarding the potential for adverse events, the manufacturer stated that FDA has determined the product is safe and effective for its intended use, has an acceptable risk/benefit ratio, and cleared Hemospray® to return to the market as of July 2020 after the issue was addressed. The manufacturer also mentioned that they understand the potential risks associated with Hemospray® and have clearly labeled the product, conducted physician training, diligently monitor reported complaints or complications, and will take appropriate steps to correct any future issues that arise.

Response: We appreciate the manufacturer's response to our questions regarding Hemospray®. After reviewing the information provided in the public comment, we agree with the applicant's statements that any potential bias introduced was toward the patients with the highest risk of negative outcomes and that this potential bias is no longer a concern. Regarding the applicant's comment on study samples, we agree with the applicant that these samples are adequately representative of the Medicare population. We also appreciate the comment response regarding the potential for adverse events and the update on the status of the Hemospray® voluntary recall. We will continue to monitor available data for Hemospray® in regard to any potential risk of adverse events.

As we noted in the FY 2021 IPPS final rule (85 FR 58672), while we acknowledge some of the data limitations, we believe that Hemospray® represents a substantial clinical improvement for the treatment of gastrointestinal bleeding for the following reasons. We believe that, given the results from the RCT trials and the single-armed studies, Hemospray® provides a treatment benefit for those with bleeding from gastrointestinal malignancies. We also see the clinical importance of Hemospray as an alternative to invasive treatments traditionally used as salvage therapy. Lastly, we note that Hemospray® provides treatment for bleeding, without requiring tissue trauma or precise targeting.

After consideration of the public comments we received, we have determined that Hemospray® meets the substantial clinical improvement criterion.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that Hemospray® would be reported with HCPCS codes 43227, 43255, 44366, 44378, 44391, 45334, and 45382. To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations in the CY 2021 OPPS/ASC proposed rule, we used APC 5312, which had a CY 2020 payment rate of $1,004.10 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 45382 had a device offset amount of $33.54 at the time the application was received. According to the applicant, the cost of the Hemospray® Endoscopic Hemostat is $2,500.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $2,500 for Hemospray® was 249 percent of the applicable APC payment amount for the service related to the category of devices of $1004.10 (($2,500/$1,004.10) × 100 = 249 percent). Therefore, we stated in the CY 2021 OPPS/ASC proposed rule that we believe Hemospray® meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $2,500 for Hemospray® was 7,454 percent of the cost of the device-related portion of the APC payment amount for the related service of $33.54 (($2,500/$33.54) × 100 = 7,453.8 percent). Therefore, we stated in the CY 2021 OPPS/ASC proposed rule that we believe that Hemospray® meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $2,500 for Hemospray® and the portion of the APC payment amount for the device of $33.54 was 246 percent of the APC payment amount for the related service of $1004.10 t ((($2,500 − $33.54)/$1004.10) × 100 = 245.6 percent). Therefore, we stated in the CY 2021 OPPS/ASC proposed rule that we believe that Hemospray® meets the third cost significance requirement.

We solicited public comment on whether the Hemospray® Endoscopic Hemostat meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

Comment: Three commenters, including the manufacturer of the Hemospray®, believe that the device meets the cost criterion for device pass-through payment status.

Response: We appreciate the manufacturer's input. After consideration of the public comments we received and consideration of the

cost criterion, we have determined that Hemospray® meets the cost criterion for device pass-through payment status.

After consideration of the public comments we received, we are approving the Hemospray® for device pass-through payment status beginning in CY 2021.

(2) The SpineJack® Expansion Kit

Stryker, Inc., submitted an application for a new device category for transitional pass-through payment status for the SpineJack® Expansion Kit (hereinafter referred to as the SpineJack® system) by the March 2020 quarterly deadline. The applicant described the SpineJack® system as an implantable fracture reduction system, which is indicated for use in the reduction of painful osteoporotic vertebral compression fractures (VCFs) and is intended to be used in combination with Stryker VertaPlex and VertaPlex High Viscosity (HV) bone cement.

The applicant described the SpineJack® system as including two cylindrical implants constructed from Titanium-6-Aluminum-4-Vanadium (Ti6Al4V) with availability in three sizes: 4.2 mm (12.5 mm expanded), 5.0 mm (17 mm expanded) and 5.8 mm (20 mm expanded). The applicant explained implant size selection is based upon the internal cortical diameter of the pedicle. According to the SpineJack® system Instructions for Use, the use of two implants is recommended to treat a fractured VB. According to the applicant, multiple VBs can also be treated in the same operative procedure as required. Additionally, the applicant explained that titanium alloy allows for plastic deformation when it encounters the hard cortical bone of the endplate yet still provides the lift force required to restore midline VB height in the fractured vertebra. The applicant stated that the SpineJack® system notably contains a self-locking security mechanism that restricts further expansion of the device when extreme load forces are concentrated on the implant. As a result, the applicant stated that this feature significantly reduces the risk of vertebral endplate breakage while it further allows functional recovery of the injured disc.[27]

The applicant stated that the implants are then progressively expanded though actuation of an implant tube that pulls the two ends of the implant towards each other in situ to mechanically restore VB height. The applicant explained that the mechanical working system of the implant allows for progressive and controlled reduction of the vertebral fracture.[28] The applicant stated that when expanded, each SpineJack® implant exerts a lifting pressure on the fracture through a mechanism that may be likened to the action of a scissor car jack, and that the longitudinal compression on the implant causes it to open in a craniocaudal direction. The applicant explained that the implant is locked into the desired expanded position as determined and controlled by the treating physician.[29]

The applicant further explained that the expansion of the SpineJack® implants creates a preferential direction of flow for the bone cement, and once the desired expansion has been obtained, polymethylmethacrylate (PMMA) bone cement is deployed from the center of the implant into the VB. The applicant stated that when two implants are symmetrically positioned in the VB, this allows for a more homogenous spread of PMMA bone cement. The applicant stated that the interdigitation of bone cement creates a broad supporting ring under the endplate, which is essential to confer stability to the VB.

According to the applicant, osteoporosis is one of the most common bone diseases worldwide that disproportionately affects aging individuals. The applicant explained that in 2010, approximately 54 million Americans aged 50 years or older had osteoporosis or low bone mass,[30] which resulted in more than 2 million osteoporotic fragility fractures in that year alone.[31] The applicant stated it has been estimated that more than 700,000 VCFs occur each year in the United States (U.S.),[32] and of these VCFs, about 70,000 result in hospital admissions with an average length of stay of 8 days per patient.[33] Furthermore, the applicant noted that in the first year after a painful vertebral fracture, patients have been found to require primary care services at a rate 14 times greater than the general population.[34] The applicant explained that medical costs attributed to VCFs in the U.S. exceeded $1 billion in 2005 and are predicted to surpass $1.6 billion by 2025.[35]

The applicant explained that osteoporotic VCFs occur when the vertebral body (VB) of the spine collapses and can result in chronic disabling pain, excessive kyphosis, loss of functional capability, decreased physical activity, and reduced quality of life. The applicant stated that as the spinal deformity progresses, it reduces the volume of the thoracic and abdominal cavities, which may lead to crowding of internal organs. The applicant noted that the crowding of internal organs may cause impaired pulmonary function, abdominal protuberance, early satiety and weight loss. The applicant indicated that other complications may include bloating, distention, constipation, bowel obstruction, and respiratory disturbances such as pneumonia, atelectasis, reduced forced vital capacity and reduced forced expiratory volume in 1 second.

The applicant explained that the SpineJack® implants provide symmetric, broad load support for osteoporotic vertebral collapse, which is based upon precise placement of bilateral ''struts'' that are encased in PMMA bone cement, whereas BKP and vertebroplasty (VP) do not provide structural support via an implanted device. The applicant explained that the inflatable balloon tamps utilized in BKP are not made from titanium and are not a permanent implant. According to the applicant, the balloon tamps are constructed from thermoplastic polyurethane, which have limited load bearing capacity. The applicant noted that although the balloon tamps are expanded within the VB to create a cavity for bone cement, they do not remain in place and are removed before the procedure is completed. The applicant explained that partial lift to the VB is obtained during inflation, resulting in kyphotic deformity

[27] Vanni D et al. ''Third-generation percutaneous vertebral augmentation systems.'' *Journal of Spine Surgery.* 2016, vol 2(1), pp. 13–20.

[28] Vanni D., et al., ''Third-generation percutaneous vertebral augmentation systems,'' *J. Spine Surg.,* 2016, vol. 2(1) pp. 13–20.

[29] Noriega D. et al., ''Clinical Performance and Safety of 108 SpineJack Implantations: 1-Year Results of a Prospective Multicentre Single-Arm Registry Study,'' *BioMed Res. Int.,* 2015, vol. 173872.

[30] National Osteoporosis Foundation. (2019). What is osteoporosis and what causes it? Available from: *https://www.nof.org/patients/what-is-osteoporosis/.*

[31] King A and Fiorentino D. ''Medicare payment cuts for osteoporosis testing reduced use despite tests' benefit in reducing fractures.'' *Health Affairs (Millwood),* 2011, vol. 30(12), pp. 2362–2370.

[32] Riggs B and Melton L. ''The worldwide problem of osteoporosis: Insights afforded by epidemiology.'' *Bone,* 1995, vol. 17(Suppl 5), pp. 505–511.

[33] Siemionow K and Lieberman I. ''Vertebral augmentation in osteoporotic and osteolytic fractures: Current Opinion in Supportive and Palliative Care.'' 2009, vol. 3(3), pp. 219–225.

[34] Wong C and McGirt M. ''Vertebral compression fractures: A review of current management and multimodal therapy.'' *Journal of Multidisciplinary Healthcare,* 2013, vol 6, pp. 205–214.

[35] Burge R et al. ''Incidence and economic burden of osteoporosis-related fractures in the United States: 2005–2025.'' *Journal of Bone and Mineral Research.* 2007, vol 22(3), pp. 465–475.

correction and partial gains in anterior VB height restoration, but inflatable balloon tamps are deflated prior to removal so some of the VB height restoration obtained is lost upon removal of the bone tamps. According to the applicant, BKP utilizes the placement of PMMA bone cement to stabilize the fracture and does not include an implant that remains within the VB to maintain fracture reduction and midline VB height restoration.

The applicant stated that if VB collapse is >50 percent of the initial height, segmental instability will ensue. As a result, the applicant explained that adjacent levels of the VB must support the additional load and this increased strain on the adjacent levels may lead to additional VCFs. Furthermore, the applicant summarized that VCFs also lead to significant increases in morbidity and mortality risk among elderly patients, as evidenced by a 2015 study by Edidin et al., in which researchers investigated the morbidity and mortality of patients with a newly diagnosed VCF (n = 1,038,956) between 2005 to 2009 in the U.S. Medicare population. For the osteoporotic VCF subgroup, the adjusted 4-year mortality was 70 percent higher in the conservatively managed group than in the balloon kyphoplasty procedures (BKP)-treated group, and 17 percent lower in the BKP group than in the vertebroplasty (VP) group. According to the applicant, when evaluating treatment options for osteoporotic VCFs, one of the main goals of treatment is to restore the load bearing bone fracture to its normal height and stabilize the mechanics of the spine by transferring the adjacent level pressure loads across the entire fractured vertebra and in this way, the intraspinal disc pressure is restored and the risk of adjacent level fractures (ALFs) is reduced.

The applicant explained that treatment of osteoporotic VCFs in older adults most often begins with conservative care, which includes bed rest, back bracing, physical therapy and/or analgesic medications for pain control. According to the applicant, for those patients that do not respond to conservative treatment and continue to have inadequate pain relief or pain that substantially impacts quality of life, vertebral augmentation (VA) procedures may be indicated. The applicant explained that VP and BKP are two minimally invasive percutaneous VA procedures that are most often used in the treatment of osteoporotic VCFs, and another VA treatment option includes the use of a spiral coiled implant made from polyetheretherketone (PEEK), which is part of the Kiva® system.

According to the applicant, among the treatment options available, BKP is the most commonly performed procedure and the current gold standard of care for VA treatment. The applicant stated that it is estimated that approximately 73 percent of all vertebral augmentation procedures performed in the U.S. between 2005 and 2010 were BKP.[36] According to the applicant, the utilization of the Kiva® system is relatively low in the U.S. and volume information was not available in current market research data.[37]

The applicant stated that VA treatment with VP may alleviate pain, but it cannot restore VB height or correct spinal deformity. The applicant stated that BKP attempts to restore VB height, but the temporary correction obtained cannot be sustained over the long term. The applicant stated that the Kiva® implant attempts to mechanically restore VB height, but it has not demonstrated superiority to BKP for this clinical outcome.[38]

The applicant provided additional detail comparing the construction and mechanism of action for other VA treatments, provided below. According to the applicant the Kiva® system is constructed of a nitinol coil and PEEK–OPTIMA sheath, with sizes including a 4-loop implant (12 mm expanded) and a 5-loop implant (15 mm expanded), and unlike the SpineJack® system, is not made of titanium and does not include a locking scissor jack design. The applicant stated that the specific mechanism of action for the Kiva® system is different from the SpineJack® system. The applicant explained that during the procedure that involves implanting the Kiva® system, nitinol coils are inserted into the VB to form a cylindrical columnar cavity. The applicant stated that the PEEK–OPTIMA is then placed over the nitinol coil. The applicant explained that the nitinol coil is removed from the VB and the PEEK material is filled with PMMA bone cement. The applicant stated that the deployment of 5 coils equates to a maximum height of 15 mm. The applicant stated that the lifting direction of the Kiva implant is caudate and unidirectional. According to the applicant, in the KAST (Kiva Safety and Effectiveness Trial) pivotal study, it was reported that osteoporotic VCF patients treated with the Kiva® system had an average of 2.6 coils deployed.[39] Additionally, in a biomechanical comparison conducted for the Kiva® system and BKP using a loading cycle of 200–500 Newtons in osteoporotic human cadaver spine segments filled with bone cement, there were no statistically significant differences observed between the two procedures for VB height restoration, stiffness at high or low loads, or displacement under compression.[40]

The applicant summarized the differences and similarities of the SpineJack®, BKP, and PEEK coiled implant as follows: (1) With respect to construction, SpineJack® is made of Titanium-6-Aluminum-4-Vanadium compared to thermoplastic polyurethanes for BKP and nitinol and PEEK for the PEEK coiled implant; (2) with respect to mechanism of action, the SpineJack® uses a locking scissor jack encapsulated in PMMA bone cement compared to hydrodynamic cavity creation and PMMA cavity filler for BKP and coil cavity creation and PEEK implant filled with PMMA bone cement for the PEEK coiled implant; (3) with respect to plastic deformation, SpineJack® and BKP allow for plastic deformation while the PEEK coiled implant does not; (4) with respect to craniocaudal expansion, SpineJack® allows for craniocaudal expansion, whereas BKP and the PEEK coiled implant do not; (5) with respect to bilateral load support, SpineJack® provides bilateral load support whereas BKP and the PEEK coiled implant do not; and (6) with respect to lift pressure of >500 N, SpineJack® provides lift pressure of >500 N whereas BKP and the PEEK coiled implant do not. The applicant summarized that the SpineJack® system is uniquely constructed and utilizes a different mechanism of action than BKP, which is the gold standard of treatment for osteoporotic VCFs, and that the construction and mechanism of action of the SpineJack® system is further differentiated when compared with the PEEK coiled implant.

With respect to the newness criterion, the SpineJack® Expansion Kit received FDA 510(k) clearance on August 30, 2018, based on a determination of substantial equivalence to a legally

[36] Goz V et al. ''Vertebroplasty and kyphoplasty: National outcomes and trends in utilization from 2005 through 2010.'' *The Spine Journal.* 2015, vol. 15(5), pp. 959–965.

[37] Lin M. ''Minimally invasive vertebral compression fracture treatments. *Medtech 360, Market Insights, Millennium Research Group.* 2019.

[38] Ibid.

[39] Tutton S et al. KAST Study: The Kiva system as a vertebral augmentation treatment—a safety and effectiveness trial: A randomized, noninferiority trial comparing the Kiva system with balloon kyphoplasty in treatment of osteoporotic vertebral compression fractures. *Spine.* 2015; 40(12):865–875.

[40] Wilson D et al. An ex vivo biomechanical comparison of a novel vertebral compression fracture treatment system to kyphoplasty. *Clinical Biomechanics.* 2012; 27(4):346–353.

marketed predicate device. The applicant explained that although the SpineJack® Expansion Kit received FDA 510(k) clearance on August 30, 2018, due to the time required to prepare for supply and distribution channels, it was not available on the U.S. market until October 2018. As we discussed previously, the SpineJack® Expansion Kit is indicated for use in the reduction of painful osteoporotic VCFs and is intended to be used in combination with Stryker VertaPlex and VertaPlex High Viscosity (HV) bone cements. We received the application for a new device category for transitional pass-through payment status for the SpineJack® Expansion Kit on February 4, 2020, which is within 3 years of the date of the initial FDA marketing authorization. We solicited public comments on whether the SpineJack® Expansion Kit meets the newness criterion.

Comment: The applicant reaffirmed that the SpineJack® system meets the newness criteria as it received FDA 510(k) clearance on August 30, 2018 and was commercially available in the United States on October 11, 2018.

Response: We appreciate the commenter's input. After consideration of the public comments we received and based on the fact that the SpineJack® Expansion Kit application was received within 3 years of FDA approval, we have determined that the SpineJack® Expansion Kit meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the use of the SpineJack® Expansion Kit is integral to the service of reducing painful osteoporotic vertebral compression fractures (VCFs), is used for one patient only, comes in contact with human skin, and is surgically implanted or inserted into the patient. Specifically, the applicant explained that the SpineJack® system is designed to be implanted into a collapsed vertebral body (VB) via a percutaneous transpedicular approach under fluoroscopic guidance. According to the applicant, the implants remain within the VB with the delivered bone cement. The applicant also claimed the SpineJack® Expansion Kit meets the device eligibility requirements of § 419.66(b)(4) because it is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. We solicited public comments on whether the SpineJack® Expansion Kit meets the eligibility criteria at § 419.66(b).

Comment: The applicant stated that the SpineJack® system meets each of the device eligibility requirements at § 419.66(b)(3) for transitional pass-through payment under the OPPS as it is integral to a service provided, and is not an instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered nor is it a material or supply furnished incident to a service.

Response: We appreciate the comment's input. Based on the information we have received and our review of the application, we have determined that the SpineJack® system meets the eligibility criteria at § 419.66(b)(3) and (4).

The criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant describes the SpineJack® Expansion Kit as an implantable fracture reduction system used to treat vertebral compression fractures (VCFs). The applicant reported that it does not believe that the SpineJack® Expansion Kit is described by an existing category and requested category descriptor ''Vertebral body height restoration device, scissor jack (implantable).'' We identified one existing pass-through payment categories that may be applicable to SpineJack® Expansion Kit. The SpineJack® Expansion Kit may be described by HCPCS code C1821 (interspinous process distraction device (implantable)). We solicited public comments on this issue.

Comment: In response to CMS' comment about whether SpineJack® is described by an existing category, the applicant stated that the SpineJack® system and implantable interspinous process distraction devices are vastly different medical devices that are distinguished by several attributes. According to the applicant, where the SpineJack® system involves the insertion of two bilateral expandable titanium implants into the vertebral body within the anterior portion of the spinal column, the interspinous spacer uses a single non-expandable device that is implanted between the spinous processes of two adjacent veterbral bodies in the posterior portion of the spinal column. The applicant further noted that the SpineJack® system differs from interspinous spacers in terms of the FDA submission type, the intended use, the mechanism of action, and whether bone cement is used as a method of fixation. The applicant reaffirmed their belief that the SpineJack® system meets the requirement at § 419.66(c)(1) that the device is not appropriately described by any of the existing categories or by any category previously in effect.

Response: We appreciate the additional information provided by the applicant. After consideration of the public comments we received, we believe there is no existing pass-through device category that appropriately describes the SpineJack® system, due to the many differences which exist between the predicate device and HCPCS code C1821—interspinous process distraction device (implantable). Based on this information, we believe that the SpineJack® system meets the eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) That a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization. With respect to the substantial clinical improvement criterion, the applicant submitted 8 studies and 19 other references to support assertions that the treatment of osteoporotic vertebral compression fracture (VCF) patients with the SpineJack® system represents a substantial clinical improvement over existing technologies because clinical research supports that it reduces future interventions, hospitalizations, and physician visits through a decrease in adjacent level fractures (ALFs), which the applicant stated are clinically significant adverse events associated with osteoporotic VCF. The applicant also stated that treatment with the SpineJack® system greatly reduces pain scores and pain medication use when compared to BKP, which the applicant stated is the current gold standard in vertebral augmentation (VA) treatment.

The applicant explained that the SpineJack® system has been available for the treatment of patients with osteoporotic VCFs for over 10 years in Europe. The applicant explained that, as

a result, the SpineJack® implant has been extensively studied, and claims from smaller studies are supported by the results from a recent, larger prospective, randomized study known as the SAKOS (SpineJack® versus Kyphoplasty in Osteoporotic Patients) study. The applicant cited the SAKOS study [41] in support of multiple substantial clinical improvement claims: Reduction in adjacent level fractures, superiority in mid-vertebral body height restoration, and pain relief. The applicant explained that the SAKOS study was the pivotal trial conducted in support of the FDA 510(k) clearance for the SpineJack® system and that the intent of the study was to compare the safety and effectiveness of the SpineJack® system with the KyphX Xpander Inflatable Bone Tamp (BKP) for treatment of patients with painful osteoporotic VCFs in order to establish a non-inferiority finding for use of the SpineJack® system versus balloon kyphoplasty procedure (BKP).

The SAKOS study is a prospective, international, randomized, non-inferiority study comparing a titanium implantable vertebral augmentation device (TIVAD), the SpineJack® system, versus BKP in the reduction of vertebral compression fractures with a 12-month follow-up. The primary endpoint was a 12-month responder rate based on a composite of three components: (1) Reduction in VCF fracture-related pain at 12 months from baseline by >20 mm as measured by a 100-mm Visual Analog Scale (VAS) measure; (2) maintenance or functional improvement of the Oswestry Disability Index (ODI) score at 12 months from baseline; and (3) absence of device-related adverse events or symptomatic cement extravasation requiring surgical reintervention or retreatment at the index level. If the primary composite endpoint was successful, a fourth component (absence of ALF) was added to the three primary components for further analysis. If the analysis of this additional composite endpoint was successful, then midline target height restoration at 6 and 12 months was assessed. According to the applicant, freedom from ALFs and midline VB height restoration were two additional superiority measures that were tested. According to the SAKOS study, secondary clinical outcomes included changes from baseline in back pain intensity, ODI score, EuroQol 5-domain (EQ–5D) index score (to evaluate quality of life), EQ–VAS score, ambulatory status, analgesic consumption, and length of hospital stay. Radiographic endpoints included restoration of vertebral body height (mm), and Cobb angle at each follow-up visit. Adverse events (AEs) were recorded throughout the study period. The applicant explained that researchers did not blind the treating physicians or patients, so each group was aware of the treatment allocation prior to the procedure; however, the three independent radiologists that performed the radiographic reviews were blinded to the personal data of the patients, study timepoints, and results of the study.

The SAKOS study recruited patients from 13 hospitals across 5 European countries and randomized 152 patients with osteoporotic vertebral compression fractures (OVCFs) (1:1) to either SpineJack® or BKP procedures. Specifically, patients were considered eligible for inclusion if they met a number of criteria, including: (1) At least 50 years of age; (2) had radiographic evidence of one or two painful VCF between T7 and L4, aged less than 3 months, due to osteoporosis; (3) fracture(s) that showed loss of height in the anterior, middle, or posterior third of the VB ≥15 percent but ≤40 percent; and (4) patient failed conservative medical therapy, defined as either having a VAS back pain score of ≥50 mm at 6 weeks after initiation of fracture care or a VAS pain score of ≥70 percent mm at 2 weeks after initiation of fracture care. Eleven of the originally recruited patients were subsequently excluded from surgery (9 randomized to SpineJack® and 2 to BKP). A total of 141 patients underwent surgery, and 126 patients completed the 12-month follow-up period (61 TIVAD and 65 BKP). The applicant contended that despite the SAKOS study being completed outside the U.S., results are applicable to the Medicare patient population, noting that 82 percent (116 of 141) of the patients in the SAKOS trial that received treatment (SpineJack® system or BKP) were age 65 or older. The applicant explained further that the FDA evaluated the applicability of the SAKOS clinical data to the U.S. population and FDA concluded that although the SAKOS study was performed in Europe, the final study demographics were very similar to what has been reported in the literature for U.S.-based studies of BKP. The applicant also explained that FDA determined that the data was acceptable for the SpineJack® system 510(k) clearance, including two clinical superiority claims versus BKP.

The SAKOS study reported that analysis on the intent to treat population using the observed case method resulted in a 12-month responder rate of 89.8 percent and 87.3 percent, for SpineJack® and BKP respectively (p=0.0016). The additional composite endpoint analyzed in observed cases resulted in a higher responder rate for SpineJack® compared to BKP at both 6 months (88.1 percent vs. 60.9 percent; p<0.0001) and 12 months (79.7 percent vs. 59.3 percent; p<0.0001). Midline VB height restoration, tested for superiority using a *t* test with one-sided 2.5 percent alpha in the ITT population, was greater with SpineJack® than BKP at 6 months (1.14 ± 2.61 mm vs 0.31 ± 2.22 mm; p=0.0246) and at 12 months (1.31 ± 2.58 mm vs. 0.10 ± 2.23 mm; p=0.0035), with similar results in the per protocol (PP) population.

Also, according to the SAKOS study, decrease in pain intensity versus baseline was more pronounced in the SpineJack® group compared to the BKP group at 1 month (p=0.029) and 6 months (p=0.021). At 12 months, the difference in pain intensity was no longer statistically significant between the groups, and pain intensity at 5 days post-surgery was not statistically different between the groups. The SAKOS study publication also reported that at each timepoint, the percentage of patients with reduction in pain intensity >20 mm was ≥90 percent in the SpineJack® group and ≥80 percent in the BKP group, with a statistically significant difference in favor of SpineJack® at 1-month post-procedure (93.8 percent vs 81.4 percent; p=0.03). The study also reported: (1) No statistically significant difference in disability (ODI score) between groups during the follow-up period, although there was a numerically greater improvement in the SpineJack® group at most time points; (2) at each time point, the percentage of patients with maintenance or improvement in functional capacity was at or close to 100 percent; and (3) in both groups, a clear and progressive improvement in quality of life was observed throughout the 1-year follow-up period without any statistically significant between-group differences.

In the SAKOS study, both groups had similar proportions of VCFs with cement extravasation outside the treated VB (47.3 percent for TIVAD, 41.0 percent for BKP; p=0.436). No symptoms of cement leakage were reported. The SAKOS study also reported that the BKP group had a rate

[41] Noriega, D., et al., ''A prospective, international, randomized, noninferiority study comparing an implantable titanium vertebral augmentation device versus balloon kyphoplasty in the reduction of vertebral compression fractures (SAKOS study),'' *The Spine Journal,* 2019, vol. 19(11), pp. 1782–1795.

of adjacent fractures more than double the SpineJack® group (27.3 percent vs. 12.9 percent; p=0.043). The SAKOS study also reported that the BKP group had a rate of non-adjacent subsequent thoracic fractures nearly 3 times higher than the SpineJack® group (21.9 percent vs. 7.4 percent) (a p-value was not reported for this result). The most common AEs reported over the study period were back pain (11.8 percent with SpineJack®, 9.6 percent with BKP), new lumbar vertebral fractures (11.8 percent with SpineJack®, 12.3 percent with BKP), and new thoracic vertebral fractures (7.4 percent with SpineJack®, 21.9 percent with BKP). The most frequent SAEs were lumbar vertebral fractures (8.8 percent with SpineJack®; 6.8 percent with BKP) and thoracic vertebral fractures (5.9 percent with SpineJack®, 9.6 percent with BKP). We also note that the length of hospital stay (in days) for osteoporotic VCF patients treated in the SAKOS trial was 3.8 ± 3.6 days for the SpineJack® group and 3.3 ± 2.4 days for the BKP group (p=0.926, Wilcoxon test).

The applicant also submitted additional studies, which are described in more detail in this section, related to the applicant's specific assertions regarding substantial clinical improvement.

As stated previously, the applicant stated that the SpineJack® system represents a substantial clinical improvement over existing technologies because it will reduce future interventions, hospitalizations, and physician visits through a decrease in ALFs. The applicant explained that ALFs are considered clinically significant adverse events associated with osteoporotic VCFs, citing studies by Lindsay et al.[42] and Ross et al.[43] The applicant explained that these studies reported, respectively, that having one or more VCFs (irrespective of bone density) led to a 5-fold increase in the patient's risk of developing another vertebral fracture, and the presence of two or more VCFs at baseline increased the risk of ALF by 12-fold. The applicant stated that analysis of the additional composite endpoint in the SAKOS study demonstrated statistical superiority of the SpineJack® system over BKP (p<0.0001) for freedom from ALFs at both 6 months (88.1 percent vs. 60.9 percent) and 12 months (79.7 percent vs. 59.3 percent) post-procedure. The applicant noted that the results were similar on both the intent to treat and PP patient populations. In addition, the applicant stated the SpineJack® system represents a substantial clinical improvement because in the SAKOS study, compared to patients treated with the SpineJack® system, BKP-treated patients had more than double the rate of ALFs (27.3 percent vs. 12.9 percent; p=0.043) and almost triple the rate of non-adjacent thoracic VCFs (21.9 percent vs. 7.4 percent).

The applicant also stated superiority with respect to mid-vertebral body height restoration with the SpineJack® system. The applicant explained that historical treatments of osteoporotic VCFs have focused on anterior VB height restoration and kyphotic Cobb angle correction; however, research indicates that the restoration of middle VB height may be as important as Cobb angle correction in the prevention of ALFs.[44] According to the applicant, the depression of the mid-vertebral endplate leads to decreased mechanics of the spinal column by transferring the person's weight to the anterior wall of the level adjacent to the fracture, and as a result the anterior wall is the most common location for ALFs. The applicant further stated that by restoring the entire fracture, including mid-VB height, the vertebral disc above the superior vertebral endplate is re-pressurized and transfers the load evenly, preventing ALFs.[45] The applicant stated that the SpineJack® system showed superiority over BKP with regard to midline VB height restoration at both 6 and 12 months, pointing to the SAKOS study results in the intent to treat population at 6 months (1.14 ± 2.61 mm vs 0.31 ± 2.22 mm; p=0.0246) and 12 months (1.31 ± 2.58 mm vs. 0.10 ± 2.23 mm; p=0.0035) post-procedure. The applicant noted that similar results were also observed in the PP population (134 patients in the intent-to-treat population without any major protocol deviations).

The applicant also provided two prospective studies, a retrospective study, and two cadaveric studies in support of its assertions regarding superior VB height restoration. The applicant stated that in a prospective comparative study by Noriega D., et al.,[46] VB height restoration outcomes utilizing the SpineJack® system were durable out to 3 years. This study was a safety and clinical performance pilot that randomized 30 patients with painful osteoporotic vertebral compression fractures to SpineJack® (n=15) or BKP (n=15).[47] Twenty-eight patients completed the 3-year study (14 in each group). The clinical endpoints of analgesic consumption, back pain intensity, ODI, and quality of life were recorded preoperatively and through 36-months post-surgery.[48] Spine X-rays were also taken 48 hours prior to the procedure and at 5 days, 6, 12, and 36 months post-surgery.[49] The applicant explained that over the 3-year follow-up period, VB height restoration and kyphosis correction was better compared to BKP, specifically that VB height restoration and kyphotic correction was still evident at 36 months with a greater mean correction of anterior VB height (10 ± 13 percent vs 2 ± 8 percent for BKP, p=0.007) and midline VB height (10 ± 11 percent vs 3 ± 7 percent for BKP, p=0.034), while there was a larger correction of the VB angle (− 4.97° ± 5.06° vs 0.42° ± 3.43°; p=0.003) for the SpineJack® group. The applicant stated that this study shows superiority with regards to VB height restoration.

The applicant stated that Arabmotlagh M., et al., also supported superiority with regard to VB height restoration. Arabmotlagh M., et al. reported an observational case series (with no comparison group) of SpineJack®. They enrolled 42 patients with osteoporotic vertebral compression fracture of the thoracolumbar, who were considered for kyphoplasty, 31 of whom completed the clinical and radiological evaluations up to 12 months after the procedure.[50] According to materials provided by the applicant, the purpose of the study was to evaluate the efficacy of kyphoplasty with the SpineJack® system to correct the kyphotic deformity and to analyze parameters affecting the restoration and maintenance of spinal alignment. The

[42] Lindsay R. et al., ''Risk of new vertebral fracture in the year following a fracture,'' *Journal of the American Medical Association,* 2001, vol. 285(3), pp. 320–323.

[43] Ross P. et al., Pre-existing fractures and bone mass predict vertebral fracture incidence in women. *Annals of Internal Medicine.* 1991, vol. 114(11), pp. 919–923.

[44] Lin J et al. Better height restoration, greater kyphosis correction, and fewer refractures of cemented vertebrae by using an intravertebral reduction device: A 1-year follow-up study. *World Neurosurgery.* 2016; 90:391–396.

[45] Tzermiadianos M., et al., ''Altered disc pressure profile after an osteoporotic vertebral fracture is a risk factor for adjacent vertebral body fracture,'' *European Spine Journal,* 2008, vol. 17(11), pp. 1522–1530.

[46] Noriega D., et al., ''Long-term safety and clinical performance of kyphoplasty and SpineJack procedures in the treatment of osteoporotic vertebral compression fractures: a pilot, monocentric, investigator-initiated study,'' *Osteoporosis International,* 2019, vol. 30, pp. 637–645.

[47] Ibid.

[48] Ibid.

[49] Ibid.

[50] Arabmotlagh M., et al., ''Radiological Evaluation of Kyphoplasty With an Intravertebral Expander After Osteoporotic Vertebral Fracture,'' *Journal of Orthopaedic Research,* 2018. Doi: 10.1002.jor.24180.

applicant explained that the mean VB height calculated prior to fracture was 2.8 cm (standard deviation (SD) of 0.47), which decreased to 1.5 cm (SD of 0.59) after the fracture. According to the applicant, following the procedure performed with the SpineJack® device, the VB height significantly increased to 1.9 cm (SD of 0.64; p<0.01), but was reduced to 1.8 cm (SD of 0.61; p<0.01) at 12 months post-procedure. We note that according to Arabmotlagh M., et al., these results were specifically for mean anterior VB height. The study does not appear to report results for midline VB height.[51] The applicant also stated that the mean kyphotic angle (KA) calculated prior to fracture was -1° (SD of 5.8), which increased to 13.4° (SD of 8.1) after the fracture. The applicant also stated that following the procedure performed with the SpineJack® device, KA significantly decreased to 10.8° (SD of 9.1; p<0.01); however, KA correction was lost at 12 months post-procedure with an increase to 13.3° (SD of 9.5; p<0.01).

The applicant provided a Lin et al., retrospective study of 75 patients that compared radiologic and clinical outcomes of kyphoplasty with the SpineJack® system to vertebroplasty (VP) in treating osteoporotic vertebral compression fractures to support its assertions regarding superiority with regard to midline VB height restoration.[52] The applicant stated that the radiologic outcomes from this study were: (1) The mean KA and mean KA restoration were more efficient after SpineJack® than VP at all time points (up to 1 year), except for mean KA observed postoperatively at 1 week; and (2) the mean middle VB heights and mean VB height restoration were more favorable after SpineJack® than VP.[53] We note that this study did not compare the SpineJack® system to BKP, which the applicant stated is the gold-standard in vertebral augmentation.

In the two cadaveric studies, Kruger A., et al. (2013) and Kruger A., et al. (2015), wedge compression fractures were created in human cadaveric vertebrae by a material testing machine and the axial load was increased until the height of the anterior edge of the VB was reduced by 40 percent.[54] The VBs were fixed in a clamp and loaded with 100 N in a custom made device. In Kruger A., et al. (2013), vertebral heights were measured at the anterior wall as well as in the center of the vertebral bodies in the medial sagittal plane in 36 human cadaveric vertebrae pre- and post-fracture as well as after treatment and loading in (27 vertebrae were treated with SpineJack® with different cement volumes (maximum, intermediate, and no cement), and 9 vertebrae were treated with BKP). In Kruger A., et al. (2015), anterior, central, and posterior height as well as the Beck index were measured in 24 vertebral bodies pre-fracture and post-fracture as well as after treatment (12 treated with SpineJack® and twelve treated with BKP). The applicant stated that Kruger A., et al. (2013) showed superiority on VB height restoration and height maintenance, and summarized that: (1) Height restoration was significantly better for the SpineJack® group compared to BKP; (2) height maintenance was dependent on the cement volume used; and (3) the group with the SpineJack® without cement nevertheless showed better results in height maintenance, yet the statistical significance could not be demonstrated.[55] The applicant stated that Kruger A., et al. (2015) showed superiority on VB height restoration, because the height restoration was significantly better in the SpineJack® group compared with the BKP group. The applicant explained that the clinical implications include a better restoration of the sagittal balance of the spine and a reduction of the kyphotic deformity, which may relate to clinical outcome and the biological healing process.[56]

The applicant also stated that use of the SpineJack® system represents a substantial clinical improvement with respect to pain relief. According to the applicant, pain is the first and most prominent symptom associated with osteoporotic VCFs, which drives many elderly patients to seek hospital treatment and negatively impacts on their quality of life. The applicant provided the SAKOS randomized controlled study, a prospective consecutive observational study, and a retrospective case series to support its assertions regarding pain relief with the SpineJack® system. The applicant cited the SAKOS trial for statistically significant greater pain relief achieved at 1 month and 6 months after surgery with the SpineJack® system. The applicant summarized that in the SAKOS trial: (1) Progressive improvement in pain relief was observed over the follow-up period in the SpineJack® system group only; (2) the decrease in pain intensity versus baseline was more pronounced in the SpineJack® system group compared to the BKP group at 1 month (p=0.029) and 6 months (p=0.021); and (3) at each time point, the percentage of patients with reduced pain intensity >20 mm was ≥90 percent in the SpineJack® system group and ≥80 percent in the BKP group, with a statistically significant difference in favor of the SpineJack® system at 1 month post-procedure (93.8 percent vs. 81.5 percent; p=0.030). The applicant also noted that although continued pain score improvements were seen out to 1 year for patients treated with the SpineJack® system, the difference between the treatment groups did not meet statistical significance (p=0.061). The applicant also explained that in the SAKOS study, at 5 days after surgery, there were significantly fewer patients taking central analgesic agent medications in the SpineJack® implant-treated group as compared to those in the BKP-treated group (SJ 7.4 percent vs. BKP 21.9 percent, p=0.015). According to the applicant, central analgesic agents included medications such as non-steroidal anti-inflammatory drugs (NSAIDS), salicylates, or opioid analgesics.

The applicant also cited a prospective consecutive observational study by Noriega D., et al. for statistically significant pain relief immediately after surgery and at both 6 and 12 months. Noriega D., et al. was a European multicenter, single-arm registry study that aimed to confirm the safety and clinical performance of the SpineJack® system for the treatment of vertebral compression fractures of traumatic origin (no comparison procedure).[57] The study enrolled 103 patients (median age: 61.6 years) with 108 VCFs due to trauma (n=81), or traumatic VCF with associated osteoporosis (n=22) who had a SpineJack® procedure. Twenty-three patients withdrew from the study before

[51] Arabmotlagh M., et al., ''Radiological Evaluation of Kyphoplasty With an Intravertebral Expander After Osteoporotic Vertebral Fracture,'' *Journal of Orthopaedic Research,* 2018. Doi: 10.1002.jor.24180.

[52] Lin J., et al., ''Better Height Restoration, Greater Kyphosis Correction, and Fewer Refractures of Cemented Vertebrae by Using an Intravertebral Reduction Device: A 1-Year Follow-up Study,'' *World Neurosurg.* 2016, vol. 60, pp. 391–396.

[53] Ibid.

[54] Kruger A., et al., ''Height restoration and maintenance after treating unstable osteoporotic vertebral compression fractures by cement augmentation is dependent on the cement volume used,'' *Clinical Biomechanics,* 2013, vol. 28, pp. 725–730; and Kruger A., et al., ''Height restoration of osteoporotic vertebral compression fractures using different intervertebral reduction devices: A cadaveric study,'' *The Spine Journal,* 2015, vol. 15, pp. 1092–1098.

[55] Ibid.

[56] Ibid.

[57] Noriega D., et al., ''Clinical performance and safety of 108 SpineJack implantations: 1-year results of a prospective multicentre single arm registry study.'' *BioMed Research International.* 2015, 173872.

the 12-month visit. The study reported a significant improvement in back pain at 48 hours after SpineJack® procedure, with the mean VAS pain score decreasing from 6.6 ± 2.6 cm at baseline to 1.4 ± 1.3 cm (mean change: −5.2 ± 2.7 cm; p<0.001) (median relative decrease in pain intensity of 81.5 percent) for the total study population. Noriega D., et al. also reported that the improvement was maintained over the 12-month follow-up period and similar results were observed with both pure traumatic VCF and traumatic VCF in patients with osteoporosis. The traumatic VCF with osteoporosis sub-group had a mean change of −5.5 (SD=1.9) (median relative change of 81.0 percent) (p<0.001) at 48 hours post-surgery (n=22), and −5.7 (SD=2.3) mean change (90.3 percent median relative change) (p<0.001) at 12 months (n=16). The applicant stated that this study supported a claim of statistically significant pain relief immediately after surgery and at both 6 and 12 months. The applicant summarized that (1) pain relief and improvements in pain scores were statistically significant immediately after treatment (48–72 hours) and at 6 and 12 months following surgery (p<0.001); and (2) the mean improvement between baseline and at 48–72 hours after the procedure (n=31) was −4.6 (2.6) (p<0.001), while the mean improvement between baseline and at the 12-month follow-up (n=22) was −6.0 (3.4) (p<0.001). We note that Noriega D., et al. did not report results for 6 months (although it does include results for 3 months versus baseline) and does not include the results of mean improvement stated by the applicant.[58] It is also unclear if the applicant intended to rely on the overall results of the study or the subgroup of traumatic VCF with osteoporosis.

The applicant also cited a retrospective case series, Renaud C., et al., for statistically significant pain relief after surgery with the SpineJack® system. Renaud C., et al., included 77 patients with a mean age of 60.9 years and 83 VCFs (51 due to trauma and 32 to osteoporosis) treated with 164 SpineJack® devices (no comparison procedure).[59] The applicant summarized that: (1) Pain relief was statistically significant (p<0.001), with a pain score decrease from 7.9 pre-operatively to 1.8 at 1 month after the procedure; (2) the pain score improvement was 77 percent at hospital discharge and gradually increased to 86 percent after 1 year following surgery; and (3) the study outcomes demonstrated that the SpineJack® system provided both immediate and long-lasting pain relief.

As we stated in the CY 2021 OPPS/ASC proposed rule (85 FR 48861), the results of the SAKOS trial did not appear to have been corroborated in any other randomized controlled study. Additionally, although the applicant stated that BKP is the gold standard in VA, there appeared to be a lack of data comparing the SpineJack® system to other existing technology, such as the PEEK coiled implant (Kiva® system), particularly since the PEEK coiled system was considered the predicate device for the SpineJack 510(k). Furthermore, there appeared to be a lack of data comparing the SpineJack® system to conservative medical therapy. We noted that there was an active study posted on *clinicaltrials.gov* comparing SpineJack® system to conservative orthopedic management consisting of brace and pain medication in acute stable traumatic vertebral fractures in subjects aged 18 to 60 years old. The *clinicaltrials.gov* entry indicated that findings should be forthcoming in 2020. Additionally, we noted that the recent systematic reviews of the management of vertebral compression fracture (Buchbinder et al. for Cochrane (2018), Ebeling et al. (2019) for the American Society for Bone and Mineral Research (ASBMR)), did not support vertebral augmentation procedures due to lack of evidence compared to conservative medical management.[60] The ASBMR recommended more rigorous study of treatment options including ''larger sample sizes, inclusion of a placebo control and more data on serious AEs (adverse events).''

We solicited public comment on whether the SpineJack® system meets the substantial clinical improvement criterion.

Comment: Many commenters expressed their support for approval of the SpineJack® system for device pass-through status. Many of these commenters shared their academic knowledge of and first-hand clinical experience with vertebral augmentation procedures, including claims of familiarity and expertise with the use of the Kiva® system, BKP and the SpineJack® system. According to many of these commenters, the SpineJack® system provides a significant benefit beyond that which is achieved by other vertebral augmentation technology. Many commenters also indicated that the price compared to the reimbursement rate has been an impediment to use of the SpineJack® system in some cases. Finally, several of these commenters expressed their belief that the SpineJack® system may reduce costs to hospitals and the U.S. health system overall by preventing the onset of additional adjacent fractures in patients.

The applicant and multiple commenters disagreed with CMS' concern that recent systematic reviews of the management of vertebral compression fracture do not support vertebral augmentation procedures according to the ASBMR, which also suggested more rigorous study of treatment options. The applicant stated that the latest clinical evidence and a policy statement from the International Society for the Advancement of Spine Surgery (ISASS) provide robust support for the use of vertebral augmentation (VA) over non-surgical management (NSM) in the treatment of osteoporotic vertebral compression fractures. Another commenter disagreed with CMS' interpretation of the ASBMR report and emphasized that the study found kyphoplasty was associated with significantly more reduction in pain, more reduction in RMDQ scale, and improvement in quality of life as compared to nonsurgical management; the commenter concluded that it is not accurate to group kyphoplasty with vertebroplasty data.

The applicant referenced a systematic review and meta-analysis of 25 prospective studies, which found that patients treated with balloon kyphoplasty and vertebroplasty had greater pain reduction that those treated with non-surgical management. Further, the applicant stated that the most compelling evidence for the use of vertebral augmentation in the treatment of osteoporotic VCF patients comes from the recently published Local Coverage Determination (LCD) on Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture by the seven regional MACs, which currently appear in either a proposed or final state.

The applicant and commenters also responded to CMS' concern that the

[58] Ibid.

[59] Renaud C., ''Treatment of vertebral compression fractures with the cranio-caudal expandable implant SpineJack: Technical note and outcomes in 77 consecutive patients.'' *Orthopaedics & Traumatology: Surgery & Research,* 2015, vol. 101, pp. 857–859.

[60] Buchbinder R., Johnston R.V., Rischin K.J., Homik J., Jones C.A., Golmohammadi K., Kallmes D.F., ''Percutaneous vertebroplasty for osteoporotic vertebral compression fracture,'' *Cochrane Database Syst Rev.* 2018 Apr 4 and Nov 6. PMID: 29618171; Ebeling P.R., Akesson K., Bauer D.C., Buchbinder R., Eastell R., Fink H.A., Giangregorio L., Guanabens N., Kado D., Kallmes D., Katzman W., Rodriguez A., Wermers R., Wilson H.A., Bouxsein M.L., ''The Efficacy and Safety of Vertebral Augmentation: A Second ASBMR Task Force Report.'' *J Bone Miner Res.,* 2019, vol. 34(1), pp. 3–21.

SAKOS trial results do not appear to be corroborated in any other randomized controlled study. Commenters stated it is unfair of CMS to require results from multiple randomized control trials (RCTs) because these studies take a large amount of time and resources to conduct, which is at odds with the characteristics inherent in applicants for device pass-through payment status given the newness criterion requiring FDA approval within three years of application. The applicant stated that multiple RCTs are often not conducted to corroborate level one evidence that has been published in journals. They added that there are a minimum of 16 journal articles that highlight the clinical benefit that the SpineJack® system provides to patients.

In response to CMS' concern that SpineJack® was not compared to the PEEK coiled implant, the applicant and multiple commenters stated that the PEEK coiled system has not demonstrated clinical superiority to BKP, which is the gold standard treatment for osteoporotic VCFs. Commenters added that the PEEK coiled implants are not widely used in the United States because of the very limited scope of use, the high price, and the difficulty of use as compared to other procedures.

In response to CMS' concern that the SpineJack® system was not compared to conservative medical therapy, many commenters and the applicant stated that this comparison would be inappropriate primarily because of the large body of research showing improvements for patients who receive treatment for VCFs with VA as opposed to NSM. One commenter stated that there is a subset of patients who suffer compression fractures for which no vertebral augmentation is advised but these patients would not currently receive balloon kyphoplasty nor would they likely receive treatment with the SpineJack® system. The applicant stated that there is clinical evidence showing improved outcomes for patients with VCFs treated with BKP as compared to NSM. The applicant concluded that based upon the body of evidence available, the use of NSM as a comparator treatment to the SpineJack® system for a new clinical study would not be in the best interest of osteoporotic VCF patients, primarily due to the increased risk of morbidity and mortality that has been reported in this patient population, particularly among the elderly. Lastly the applicant stated that the SpineJack® system is not indicated for use in the treatment of traumatic vertebral fractures in the United States.

In regard to CMS' statement that a study by Lin et al. did not compare the SpineJack® system to BKP, the applicant agreed and added that the publication provides further support of the claim for superior mid-vertebral body height restoration with the SpineJack® system as compared to other treatment options such as vertebroplasty, which the applicant asserted continue to be widely performed in Medicare patients.

In regard to CMS' statement that findings from the Arabmotlagh M. et al. study did not report results for midline VB height, the applicant stated that the publication shows that it is possible to achieve anterior VB height restoration with the SpineJack® system in addition to midline VB height restoration demonstrated in the SAKOS trial.

In response to CMS' assertion that the Noriega et al. article did not report results for six months and does not include results of mean improvement as stated by the applicant, the applicant stated that they would like to correct an error in their application attachment for the 2015 Noriega et al. publication. The data presented in their application reflects findings from another citation [61] in which the overall improvements in visual analog scale back pain scores were statistically significant at multiple time points.

Lastly, the applicant supplied minor corrections regarding the SAKOS study results. Specifically the applicant stated that for the midline VB height restoration reported at 12 months post-procedure for the SpineJack® system compared to BKP in the SAKOS trial, an error in the standard deviation value for the BKP data is reported in the CY 2021 OPPS/ASC proposed rule. The applicant stated that this value should be revised to 2.34 mm rather than the 2.23 mm reported previously.

One commenter, a manufacturer of BKP implants, criticized the evidence the applicant submitted to support its position that the SpineJack® system meets the substantial clinical improvement criterion. The commenter emphasized that although the applicant cited the SAKOS study as the basis for concluding that the SpineJack® system meets the substantial clinical improvement criterion, the SAKOS study compared the SpineJack® system to older BKP technology (KyphX), rather than to the most current BKP technology available at the time of the study (Xpander II and Express II). According to the commenter, these newer generation balloons have been available since 2011, generate lift force in excess of 1200 Newtons, and are the only BKP products indicated for the cement resistance technique, whereby one bone tamp is left in place during cement injection and curing to maximize height restoration in a collapsed vertebral body. The commenter stated that BKP does offer craniocaudal expansion while creating a void for safer cement fill. Furthermore, with respect to bilateral load support, according to the commenter, BKP has been offered since 1998 as a bilateral procedure option to maximize lift potential and reduce stress exerted on endplates. The commenter went on to explain that BKP provides bilateral symmetric load support to fractured endplates by providing a larger surface area when restoring height. The commenter suggested that if the SAKOS study had compared the SpineJack® system to these second-generation BKP implants, then the SpineJack® system might not have demonstrated superior performance on secondary outcome measures.

The commenter also offered several additional criticisms of the SAKOS study. The commenter pointed out that the SAKOS study design did not involve an even distribution of the spine levels treated across study arms, and that it is possible that a difference in the levels treated could have contributed to the reduction of ALFs in the SpineJack® system group. The commenter asserted that the vertebral levels T11–L1 are commonly known for higher number of fractures, and that these spinal segments had 14 more levels treated with BKP than with the SpineJack® system in the SAKOS study. According to the commenter, further analysis would be needed to determine if the location of fractures had an effect on the occurrence of ALFs between the two study arms in SAKOS. The commenter also pointed out that it was unclear whether there was any difference in the two treatment groups' bone density metrics, as this was not disclosed in the SAKOS study.

The commenter went on to emphasize that the clinical comparison in the SAKOS study demonstrated the SpineJack® system was non-inferior to BKP at the time of the primary endpoint (12 months); however, there was no significant difference between groups in pain intensity visual analog scale (VAS) score at the final time point, and no difference in Oswestry Disability Index (ODI) or the EQ–5D health status questionnaire at any time point during the study. The commenter acknowledged that SAKOS

[61] Noriega D et al. Long-term safety and clinical performance of kyphoplasty and SpineJack procedures in the treatment of osteoporotic vertebral compression fractures: A pilot, monocentric, investigator-initiated study. Osteoporosis International. 2019; 30:637–645.

demonstrated superiority for the SpineJack® system for mid-vertebral height restoration, but emphasized that measures of anterior height, posterior height, and cobb angle showed no difference across the study arms, within the secondary endpoints. The commenter also observed that the SAKOS study showed a similar number of adverse events between study arms, with the SpineJack® system population seeing a higher percentage of serious adverse events.

Finally, the commenter disputed the applicant's assertion that vertebral augmentation treatment with vertebroplasty may alleviate pain, but cannot restore vertebral body height or correct spinal deformity. The commenter likewise disputed the applicant's assertion that BKP attempts to restore vertebral body height, but the temporary correction obtained cannot be sustained over the long-term. In countering the applicant's assertions, the commenter referenced three published articles with empirical evidence regarding the impact of BKP on kyphotic angle and VB height restoration.[62] [63] [64] Lastly the commenter stated that any mortality benefits have only been studies for BKP and vertebroplasty and not for SpineJack®. According to the commenter, it is therefore not appropriate to use this information to demonstrate the mortality benefits from using the SpineJack® technology.

Response: We appreciate all the comments we received related to the SpineJack® system, and we have taken them into consideration in making our determination, including the applicant's submission of additional information to address the concerns presented in the CY 2021 OPPS/ASC proposed rule and the comments expressing concerns with the design and results of the SAKOS study.

After consideration of the public comments received, we believe that commenters have addressed our concerns regarding whether the SpineJack® system meets the substantial clinical improvement criterion and that the SpineJack® system represents a substantial clinical improvement over existing technologies based on the data received from commenters. The data provided from the commenters with clinical experience with vertebral augmentation procedures and the SpineJack® system, which included improved pain, VB height restoration and ALF outcomes for patients with osteoporotic VCFs when compared with existing treatments, demonstrates substantial clinical improvement.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the SpineJack® system would be reported with CPT code 22513, which is assigned to APC 5114 (Level 4 Musculoskeletal Procedures). To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. For our calculations, we used APC 5114, which has a CY 2019 payment rate of $5,891.95. Beginning in CY 2017, we calculated the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). CPT code 22513 had a device offset amount of $1,127 at the time the application was received. According to the applicant, the cost of the SpineJack® system is $5,623.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $5,622.64 for the SpineJack® system is 94 percent of the applicable APC payment amount for the service related to the category of devices of SpineJack® system (($5,622.64/$5,981.28) × 100 = 94 percent). Therefore, we believe the SpineJack® system meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $5,622.64 for the SpineJack® system is 499 percent of the cost of the device-related portion of the APC payment amount for the related service of $1,126.87(($5,622.64/$1,126.87) × 100 = 499 percent). Therefore, we believe that the SpineJack® system meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $5,622.64 for the SpineJack® system and the portion of the APC payment amount for the device of $1,126.87 is 75 percent of the APC payment amount for the related service of $5,987.28 (($5,622.64 − $1,126.87)/$5,981.28) = 75.2 percent). Therefore, we believe that the SpineJack® Expansion Kit meets the third cost significance requirement.

We solicited public comment on whether the SpineJack® Expansion Kit meets the device pass-through payment criteria discussed in this section, including the cost criterion.

Comment: The applicant agreed with CMS' conclusion that the SpineJack® system meets all three of the cost significance requirements for establishing a device pass-through category as described in § 419.66(d).

Response: We appreciate the applicant's input.

After consideration of the public comments we received, we have determined that the SpineJack® Expansion Kit qualifies for device pass-through payment status and we are approving the application for device pass-through payment status for the SpineJack® Expansion Kit beginning in CY 2021.

3. Technical Clarification to the Alternative Pathway to the OPPS Device Pass-Through Substantial Clinical Improvement Criterion for Certain Transformative New Devices

As described previously, in the CY 2020 annual rulemaking process, we finalized an alternative pathway for devices that receive Food and Drug Administration (FDA) marketing authorization and are granted a Breakthrough Device designation (84 FR 61295 through 61297). Under this alternative pathway, devices that are granted an FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2) for purposes of determining device pass-through payment status, but will need to meet the other requirements for pass-through payment status in our regulation at § 419.66. Similarly, in the FY 2020 IPPS/LTCH PPS final rule, we finalized an alternative pathway for new

[62] Van Meirhaeghe JV, et al. 2013; 38(12): 971–983.

[63] Dohm M, et al. 2014. (24 Months), Am J Neuroradiol. 2014;35:2227–2236.

[64] Bozkurt M, et al. 2014. Asian Spine J. 2014; 8(1):27–34.

technology add-on payments for certain transformative new devices. Under the existing regulations at § 412.87(c), to be eligible for approval for IPPS new technology add-on payments under this alternative pathway, the device must be part of the FDA's Breakthrough Devices Program and have received FDA marketing authorization.

We have received questions from the public regarding CMS's intent with respect to the ''marketing authorization'' required for purposes of approval under the alternative pathway for certain transformative new devices at § 412.87(c). Some of the public appear to assert that so long as a technology has received marketing authorization for any indication, even if that indication differs from the indication for which the technology was designated by FDA as part of the Breakthrough Devices Program, the technology would meet the marketing authorization requirement at § 412.87(c). Because of this potential confusion, we clarified in the FY 2021 IPPS/LTCH PPS proposed rule that an applicant cannot combine a marketing authorization for an indication that differs from the technology's indication under the Breakthrough Device Program, and for which the applicant is seeking to qualify for the new technology add-on payment, for purposes of approval under the alternative pathway for certain transformative devices (85 FR 32692).

We clarified in the CY 2021 OPPS/ASC proposed rule that the same policy applies for purposes of the OPPS alternative pathway policy. Specifically, we clarified that under the OPPS, in order to be eligible for the alternative pathway, the device must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation and we are making a conforming change to the regulations at § 419.66(c)(2). We also noted that the transitional pass-through payment application for the device must be received within 2 to 3 years of the initial FDA marketing authorization (or a verifiable market delay) for the device for the indication covered by the Breakthrough Devices Program designation.

In summary, in the CY 2021 OPPS/ASC proposed rule, we proposed to amend the regulations in § 419.66(c)(2)(ii) to state that ''A new medical device is part of the FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.''

We did not receive any comments regarding the technical clarification outlined in the CY 2021 OPPS/ASC proposed rule that in order to be eligible for the alternative pathway to the OPPS device pass-through substantial clinical improvement criterion, the device must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation. Therefore we are finalizing our proposal to amend the regulations in § 419.66(c)(2)(ii) to provide that ''a new medical device is part of the FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.''

4. Comment Solicitation on Continuing To Provide Separate Payment in CYs 2022 and Future Years for Devices With OPPS Device Pass-Through Payment Status During the COVID–19 Public Health Emergency (PHE)

In the CY 2021 OPPS/ASC proposed rule, we solicited comments on whether we should adjust future payments for devices currently eligible to receive transitional pass-through payments that may have been impacted by the PHE, and if so, how we should implement that adjustment and for how long the adjustment should apply. On January 31, 2020, HHS Secretary Azar determined that a PHE exists retroactive to January 27, 2020 [65] under section 319 of the Public Health Service Act (42 U.S.C. 247d) in response to COVID–19, and on April 21, 2020 Secretary Azar renewed, effective April 26, 2020 and again effective July 25, 2020, the determination that a PHE exists.[66] On March 13, 2020, the President of the United States declared that the COVID–19 outbreak in the U.S. constitutes a national emergency,[67] retroactive to March 1, 2020. Due to the PHE, we received multiple inquiries from stakeholders regarding potential adjustments to the pass-through payment for devices with OPPS transitional pass-through payment status that may be impacted by the PHE. According to stakeholders, healthcare resources have been triaged to assist in the COVID–19 pandemic response effort, which has reduced utilization for devices receiving transitional pass-through payment, particularly for devices used in services that could be considered elective. Stakeholders cited the CMS recommendations issued on March 18, 2020 to postpone elective surgeries due to the COVID–19 PHE.[68] Stakeholders claim that devices on pass-through status are frequently used during such elective procedures, and that CMS's ability to calculate appropriate payment for services that include these devices once the devices transition off of pass-through status could be hindered by a reduction in claims being submitted with these devices during the PHE.

Transitional pass-through payment for devices is described in section 1833(t)(6) of the Act. It is intended as an interim measure to allow for adequate payment of new innovative technology while we collect the necessary data to incorporate the costs for these items into the procedure APC rate (66 FR 55861). As previously stated, transitional pass-through payments for devices can be made for a period of at least 2 years, but not more than 3 years, beginning on the first date on which pass-through payment was made for the device.

In response to stakeholder concerns regarding reduced utilization of procedures that include pass-through devices during the PHE, we specifically requested public comment on utilizing our equitable adjustment authority under section 1833(t)(2)(E) of the Act to provide separate payment for some period of time after pass-through status ends for these devices in order to account for the period of time that utilization for the devices was reduced due to the PHE. Any rulemaking on this issue in response to this comment solicitation would be included in the CY 2022 OPPS/ASC proposed rule and would consider the impact of the PHE on devices with OPPS device pass-through payment status during the PHE. Note that OPPS device pass-through payment status generally lasts 3 years, and none of the devices with less than 3 years of pass-through payment status at the start of the PHE have pass-through payment status set to end before December 31, 2021.

The following is summary of the comments we received and our responses to those comments.

Comment: Several commenters submitted comments in support of CMS' comment solicitation on continuing to provide separate payment in CYs 2022 and future years for devices with OPPS device pass-through payment status during the COVID–19 Public Health Emergency (PHE). All commenters who supported CMS' comment solicitation stated that the COVID–19 PHE has

[65] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[66] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.aspx.*

[67] *https://www.whitehouse.gov/presidentialactions/proclamation-declaring-nationalemergency-concerning-novel-coronavirus-diseasecovid-19-outbreak/.*

[68] *https://www.cms.gov/newsroom/press-releases/cms-releases-recommendations-adult-elective-surgeries-non-essential-medical-surgical-and-dental.*

negatively affected items currently receiving pass-through payment. Two commenters stated that CMS has the authority to make an equitable adjustment to provide additional time for items to receive pass-through payments to account for reduced utilization during the PHE. Multiple commenters stated that the pass-through payment extension should be equal to the duration of the PHE with one commenter adding that it should start immediately after the later of the expiration of the item's pass-through status or the expiration of the emergency period. One commenter stated that CMS should provide, specific to each pass-through item, an adjustment to begin on January 1, 2021, and provide for a period of continued pass-through payment, rounded up to the nearest quarter, for which the item's pass-through period coincided with the PHE. Lastly, one commenter stated that CMS should allow pass-through periods for devices, drugs or biologicals adversely impacted by the PHE to be extended, if any extension does not apply to devices, drugs or biologicals that already had 3 years or more of pass-through status when the PHE began. One applicant, as well as offering support for this proposal, added a request that CMS share the operational details of its policy by the end of CY 2020 rather than waiting for the CY 2022 rulemaking cycle to facilitate planning.

Response: We appreciate the commenters' support and will take the information submitted into consideration for future rulemaking.

Comment: Some commenters stated that CMS should not limit the extension of pass-through payments to devices, but should also extend pass-through payments for drugs. One commenter stated that drugs should be subject to this policy because, like pass-through devices, the commenter believed pass-through drugs likely had reduced utilization from the PHE. A second commenter stated that there is no principled reason to limit any COVID–19 related pass-through adjustment to devices only; adding that it is a basic principle of administrative law that agencies must treat ''similarly situated'' entities ''similarly'' and there is no logical basis for treating pass-through devices used in outpatient settings differently than pass-through drugs used in outpatient settings. Two commenters stated that CMS should extend the pass-through period to radiopharmaceuticals in addition to medical devices, stating that the COVID–19 PHE has negatively affected their utilization as it has for devices.

One commenter, who supported an extension for pass-through devices, stated that most drugs, biologicals, and biosimilar biological products continue to be separately paid after their pass-through period expires such that prior year claims data do not impact their treatment under OPPS. For such products, the commenter stated that it would not be necessary or appropriate to use the equitable adjustment authority to adjust payment. A second commenter recommended that the products that received extended pass-through payments under section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018, should not receive an additional extension of pass-through status due to the PHE as these products have already had more than the required 3 years of pass-through payments. The commenter added that extending pass-through payments for these products would needlessly increase cost to taxpayers and would be contradictory to the administration's efforts to reduce the cost of prescription drugs.

Response: We did not solicit comments on extending pass-through payments for drugs, however, we will consider the commenters' points for potential future rulemaking.

We thank the commenters for their submissions and will consider their input when determining whether a change is warranted in response to the PHE as we develop the 2022 OPPS/ASC proposed rule.

B. Device-Intensive Procedures

1. Background

Under the OPPS, prior to CY 2017, device-intensive status for procedures was determined at the APC level for APCs with a device offset percentage greater than 40 percent (79 FR 66795). Beginning in CY 2017, CMS began determining device-intensive status at the HCPCS code level. In assigning device-intensive status to an APC prior to CY 2017, the device costs of all the procedures within the APC were calculated and the geometric mean device offset of all of the procedures had to exceed 40 percent. Almost all of the procedures assigned to device-intensive APCs utilized devices, and the device costs for the associated HCPCS codes exceeded the 40-percent threshold. The no cost/full credit and partial credit device policy (79 FR 66872 through 66873) applies to device-intensive APCs and is discussed in detail in section IV.B.4. of the CY 2021 OPPS/ASC proposed rule. A related device policy was the requirement that certain procedures assigned to device-intensive APCs require the reporting of a device code on the claim (80 FR 70422). For further background information on the device-intensive APC policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70421 through 70426).

a. HCPCS Code-Level Device-Intensive Determination

As stated earlier, prior to CY 2017, the device-intensive methodology assigned device-intensive status to all procedures requiring the implantation of a device that were assigned to an APC with a device offset greater than 40 percent and, beginning in CY 2015, that met the three criteria listed below. Historically, the device-intensive designation was at the APC level and applied to the applicable procedures within that APC. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we changed our methodology to assign device-intensive status at the individual HCPCS code level rather than at the APC level. Under this policy, a procedure could be assigned device-intensive status regardless of its APC assignment, and device-intensive APCs were no longer applied under the OPPS or the ASC payment system.

We believe that a HCPCS code-level device offset is, in most cases, a better representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all of the procedures assigned to an APC. Unlike a device offset calculated at the APC level, which is a weighted average offset for all devices used in all of the procedures assigned to an APC, a HCPCS code-level device offset is calculated using only claims for a single HCPCS code. We believe that this methodological change results in a more accurate representation of the cost attributable to implantation of a high-cost device, which ensures consistent device-intensive designation of procedures with a significant device cost. Further, we believe a HCPCS code-level device offset removes inappropriate device-intensive status for procedures without a significant device cost that are granted such status because of APC assignment.

Under our existing policy, procedures that meet the criteria listed in section IV.B.1.b. of the CY 2021 OPPS/ASC proposed rule are identified as device-intensive procedures and are subject to all the policies applicable to procedures assigned device-intensive status under our established methodology, including our policies on device edits and no cost/full credit and partial credit devices discussed in sections IV.B.3. and IV.B.4.

of the CY 2021 OPPS/ASC proposed rule, respectively.

b. Use of the Three Criteria To Designate Device-Intensive Procedures

We clarified our established policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52474), where we explained that device-intensive procedures require the implantation of a device and additionally are subject to the following criteria:

- All procedures must involve implantable devices that would be reported if device insertion procedures were performed;
- The required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and
- The device offset amount must be significant, which is defined as exceeding 40 percent of the procedure's mean cost.

We changed our policy to apply these three criteria to determine whether procedures qualify as device-intensive in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), where we stated that we would apply the no cost/full credit and partial credit device policy—which includes the three criteria listed previously—to all device-intensive procedures beginning in CY 2015. We reiterated this position in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), where we explained that we were finalizing our proposal to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which the CY 2016 device intensive policy will apply. Under the policies we adopted in CYs 2015, 2016, and 2017, all procedures that require the implantation of a device and meet the previously described criteria are assigned device-intensive status, regardless of their APC placement.

2. Device-Intensive Procedure Policy for CY 2019 and Subsequent Years

As part of our effort to better capture costs for procedures with significant device costs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948), for CY 2019, we modified our criteria for device-intensive procedures. We had heard from stakeholders that the criteria excluded some procedures that stakeholders believed should qualify as device-intensive procedures. Specifically, we were persuaded by stakeholder arguments that procedures requiring expensive surgically inserted or implanted devices that are not capital equipment should qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We agreed that a broader definition of device-intensive procedures was warranted, and made two modifications to the criteria for CY 2019 (83 FR 58948). First, we allowed procedures that involve surgically inserted or implanted single-use devices that meet the device offset percentage threshold to qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We established this policy because we no longer believe that whether a device remains in the patient's body should affect a procedure's designation as a device-intensive procedure, as such devices could, nonetheless, comprise a large portion of the cost of the applicable procedure. Second, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent, to allow a greater number of procedures to qualify as device-intensive. We stated that we believe allowing these additional procedures to qualify for device-intensive status will help ensure these procedures receive more appropriate payment in the ASC setting, which will help encourage the provision of these services in the ASC setting. In addition, we stated that this change would help to ensure that more procedures containing relatively high-cost devices are subject to the device edits, which leads to more correctly coded claims and greater accuracy in our claims data. Specifically, for CY 2019 and subsequent years, we finalized that device-intensive procedures will be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost (83 FR 58945).

In addition, to further align the device-intensive policy with the criteria used for device pass-through payment status, we finalized, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE), and has been classified as a Category B device by FDA in accordance with 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not either of the following:

(a) Equipment, an instrument, apparatus, implement, or item of the type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or

(b) A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker) (83 FR 58945).

In addition, for new HCPCS codes describing procedures requiring the implantation of devices that do not yet have associated claims data, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we finalized a policy for CY 2017 to apply device-intensive status with a default device offset set at 41 percent for new HCPCS codes describing procedures requiring the implantation or insertion of a device that did not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. This default device offset amount of 41 percent was not calculated from claims data; instead, it was applied as a default until claims data were available upon which to calculate an actual device offset for the new code. The purpose of applying the 41-percent default device offset to new codes that describe procedures that implant or insert devices was to ensure ASC access for new procedures until claims data become available.

As discussed in the CY 2019 OPPS/ASC proposed rule and final rule with comment period (83 FR 37108 through 37109 and 58945 through 58946, respectively), in accordance with our policy stated previously to lower the device offset percentage threshold for procedures to qualify as device-intensive from greater than 40 percent to greater than 30 percent, for CY 2019 and subsequent years, we modified this policy to apply a 31-percent default device offset to new HCPCS codes describing procedures requiring the implantation of a device that do not yet have associated claims data until claims data are available to establish the

HCPCS code-level device offset for the procedures. In conjunction with the policy to lower the default device offset from 41 percent to 31 percent, we continued our current policy of, in certain rare instances (for example, in the case of a very expensive implantable device), temporarily assigning a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer (81 FR 79658). Once claims data are available for a new procedure requiring the implantation or insertion of a device, device-intensive status is applied to the code if the HCPCS code-level device offset is greater than 30 percent, according to our policy of determining device-intensive status by calculating the HCPCS code-level device offset.

In addition, in the CY 2019 OPPS/ASC final rule with comment period, we clarified that since the adoption of our policy in effect as of CY 2018, the associated claims data used for purposes of determining whether or not to apply the default device offset are the associated claims data for either the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code. Additionally, for CY 2019 and subsequent years, in limited instances where a new HCPCS code does not have a predecessor code as defined by CPT, but describes a procedure that was previously described by an existing code, we use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining whether or not to apply the default device offset to the new HCPCS code (83 FR 58946). Clinically related and similar procedures for purposes of this policy are procedures that have little or no clinical differences and use the same devices as the new HCPCS code. In addition, clinically related and similar codes for purposes of this policy are codes that either currently or previously describe the procedure described by the new HCPCS code. Under this policy, claims data from clinically related and similar codes are included as associated claims data for a new code, and where an existing HCPCS code is found to be clinically related or similar to a new HCPCS code, we apply the device offset percentage derived from the existing clinically related or similar HCPCS code's claims data to the new HCPCS code for determining the device offset percentage. We stated that we believe that claims data for HCPCS codes describing procedures that have minor differences from the procedures described by new HCPCS codes will provide an accurate depiction of the cost relationship between the procedure and the device(s) that are used, and will be appropriate to use to set a new code's device offset percentage, in the same way that predecessor codes are used. If a new HCPCS code has multiple predecessor codes, the claims data for the predecessor code that has the highest individual HCPCS-level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status. Similarly, in the event that a new HCPCS code does not have a predecessor code but has multiple clinically related or similar codes, the claims data for the clinically related or similar code that has the highest individual HCPCS level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status.

As we indicated in the CY 2019 OPPS/ASC proposed rule and final rule with comment period, additional information for our consideration of an offset percentage higher than the default of 31 percent for new HCPCS codes describing procedures requiring the implantation (or, in some cases, the insertion) of a device that do not yet have associated claims data, such as pricing data or invoices from a device manufacturer, should be directed to the Division of Outpatient Care, Mail Stop C4–01–26, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850, or electronically at *outpatientpps@cms.hhs.gov*. Additional information can be submitted prior to issuance of an OPPS/ASC proposed rule or as a public comment in response to an issued OPPS/ASC proposed rule. Device offset percentages will be set in each year's final rule.

In response to stakeholder requests for additional detail on our device-intensive methodology, we have updated our claims accounting narrative with a description of our device offset percentage calculation. Our claims accounting narrative for the CY 2021 OPPS/ASC final rule can be found under supporting documentation on our website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

For CY 2021, we did not propose any changes to our device-intensive policy.

Comment: A number of commenters and the Advisory Panel on Hospital Outpatient Payment (HOP Panel) recommended that CMS consider lowering the device-intensive threshold from 30 percent to 25 percent to avoid excessive payment gaps when device costs do not reach the device-intensive threshold and thereby do not ''carry over'' device costs from the hospital outpatient setting to the ASC setting.

Response: We thank the commenters and the HOP Panel for their recommendation. While payment rates under the ASC payment system for a particular procedure may be subject to fluctuation if device-intensive status varies for the procedure on a year-to-year basis, we believe that the potential payment gaps that commenters note will exist for any threshold value. Further, as discussed in section XIII.G.2.a. of this final rule with comment, our established policy under the ASC payment system is to scale prospective ASC relative payment weights by comparing total payment using current year ASC scaled relative payment weights with the total payment using the prospective ASC relative payment weights, holding ASC utilization, the ASC conversion factor, and the mix of services constant from the claims year. Lowering the device-intensive threshold assigns a greater amount of device costs, which are held constant between the OPPS and ASC payment system, into the prospective year. This would put additional downward pressure on the ASC weight scalar and reduce the non-device portion of ASC payment rates for most surgical procedures. Additionally, a reduction in the device-intensive threshold to 25 percent would also be accompanied with a reduction in the default device offset percentage, from 31 percent to 26 percent. A reduction in the default device offset percentage would reduce the device portion for covered surgical procedures with device offset amounts established at the existing default offset percentage of 31 percent. In light of these concerns, we are not accepting the recommendation to lower the device-intensive threshold at this time.

Comment: Some commenters recommended that the device offset percentage for 0424T (Insertion or replacement of neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator)) be reevaluated. Commenters contend that a 99.99 percent device offset percentage appears to be erroneous and would eliminate transitional pass-through device payments for the associated device C1823 (Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads). Commenters recommended

device offset percentages of 37.76 percent which excludes the costs associated with C1823, or 74.96 percent which includes the costs associated with C1823.

Response: In reviewing our device cost calculations, we discovered an oversight related to the cost of certain devices approved for transitional pass-through payment status. Currently, our ratesetting process excludes the cost of pass-through devices from being packaged into the major procedure until those devices no longer have pass-through status. However, our device cost calculation process in developing the offsets incorporated the cost of some devices currently receiving pass-through payment status. Because the costs of these devices are not included in developing the geometric mean cost of the procedure and therefore the APC payment rate, the costs associated with these pass-through devices should not be included in a procedure's device offset percentage. For this CY 2021 OPPS/ASC final rule with comment period, we have removed the pass-through device costs at issue from the calculation of the device offsets. We have also included these changes in our claims accounting narrative for the CY 2021 OPPS/ASC final rule which can be found under supporting documentation on our website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

The change in device cost calculation from the proposed and final rule only impacted the device offset percentage associated with CPT code 0424T. Specifically, the updated calculations using final rule claims data show a device offset percentage of 27.10 percent after removing the cost of pass-through devices. Therefore, for CY 2021, we are finalizing a device offset percentage of 27.10 percent for CPT code 0424T.

Comment: Commenters contended that CPT codes 22857 (Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar), 66174 (Transluminal dilation of aqueous outflow canal; without retention of device or stent), and 55880 (Ablation of malignant prostate tissue, transrectal, with high intensity—focused ultrasound (HIFU), including ultrasound guidance) should be designated as device-intensive under the OPPS and ASC payment systems.

Response: Using the updated final rule claims data, we have determined that the device offset percentages for CPT codes 22857 and 66174 are not above the 30-percent device-intensive threshold and, therefore, these procedures are not eligible to be assigned device-intensive status. Additionally, while we do not have claims data for CPT code 55880, we have determined that the device offset percentage of C9747, the predecessor code to CPT code 55880, is also not above the 30-percent threshold based on CY 2019 claims and, therefore, CPT code 55880 is also not eligible to be assigned device-intensive status.

Comment: Commenters requested that we designate CPT code 50590 (Lithotripsy, extracorporeal shock wave) device-intensive status, or establish alternative device-intensive criteria so that the costs of capital equipment, specifically, the lithotripter, associated with CPT code 50590 would allow this procedure to receive a device-intensive designation. The commenter suggested alternative criteria that would include that: (1) The procedure cannot be performed without the equipment/device; (2) the equipment/device is typically obtained on an ''as-needed'' basis rather than purchased or leased by the entity providing the care; (3) the fair-market lease or rental cost in an HOPD or ASC setting is not materially different for either site of service; (4) the fair-market lease or rental cost of the equipment precludes performing the service at an appropriate margin in an ASC setting; and (5) the procedure is most appropriately done on an ambulatory basis for the majority of patients.

Response: Using the updated claims data for this CY 2021 OPPS/ASC final rule with comment period, we have determined that the device offset percentage for CPT code 50590 is not above the 30-percent threshold and, therefore, this procedure is not eligible to be assigned device-intensive status.

We also do not believe changes to our device-intensive criteria are necessary. We believe the existing criteria are adequate to differentiate implantable and insertable device costs from non-invasive equipment costs and other procedure-related costs. We also note that the operating resource costs associated with CPT code 50590 are captured in the geometric mean cost of the procedure used to develop the ASC relative weights, as well as the ASC payment rate. While we acknowledge that the reliance on OPPS scaled relative weights to develop the ASC payment rate may not necessarily capture the geometric mean cost of procedures with significant capital equipment costs in the ASC setting, we are not finalizing any changes to our ASC ratesetting methodology at this time.

Comment: One commenter requested that we finalize our device-intensive designation for CPT code 0275T (Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (e.g., fluoroscopic, ct), single or multiple levels, unilateral or bilateral; lumbar) but only determine the device offset percentage based on claims with a reported device code.

Response: We appreciate the commenter's recommendation; however, we do not believe it would be appropriate to exclude claims data that would otherwise be available from our ratesetting process for the purposes of modifying the final device offset percentage for 0275T in particular. We are finalizing our proposal to assign device-intensive status to CPT code 0275T with a device offset percentage of 34.16 percent, as determined based on the final rule claims data.

Comment: Some commenters recommended that we assign CPT code 0404T (Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency) device-intensive status. Commenters argue that the device was not commercially available until late 2019, which they believed explains the lack of claims data and device cost information.

Response: We agree with the commenters. While CPT code 0404T was established in 2016, which predates our policy of applying a default device offset percentage for new procedures, we have yet to receive claims information for this procedure that would allow us to determine any associated device costs. We also thank the commenters for their submission of device pricing information. After reviewing the pricing information provided by commenters, we believe a default device offset percentage of 31 percent appropriately reflects the device costs for these procedures for CY 2021.

Comment: One commenter recommended that we assign 0632T (Percutaneous transcatheter ultrasound ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance) device-intensive status.

Response: As discussed in section III.D of this CY 2021 OPPS/ASC final rule with comment period, we are finalizing our proposal to assign SI=E1 ''Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)'' to CPT code 0632T. This

procedure is not payable under the OPPS beginning in CY 2021, and therefore we are not assigning device-intensive status to 0632T at this time.

Comment: Some commenters suggested that CMS only adjust the non-device portion of the payment by the wage index, consistent with the Agency's policy for separately payable drugs and biologicals.

Response: While we did not make such a proposal in this year's proposed rule, we will take this comment into consideration for future rulemaking. We note that such a policy would increase payments to providers with a wage index value of less than 1 and be offset by a budget neutral decrease in payments to other providers.

As discussed in section IV.A. of this final rule with comment period, we are approving the BAROSTIM NEO™ system for transitional pass-through device payment status. The applicant has stated that the BAROSTIM NEO™ would be reported with CPT code 0266T (Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)). There have been no device costs reported for CPT code 0266T in CY 2019 claims or in previous calendar years. Therefore, for purposes of applying a device offset percentage for transitional pass-through device payments for CPT code 0266T, we are assigning a device offset percentage to 0266T in CY 2021 based on the clinically-similar procedure 0268T (Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)). Based on our review of CY 2019 claims data, CPT code 0268T has a device offset percentage of 95.74 percent. Therefore, for CY 2021, we are assigning device-intensive status to CPT code 0266T with a device offset percentage of 95.74 percent.

The full listing of the final CY 2021 device-intensive procedures can be found in Addendum P to the CY 2021 OPPS/ASC final rule with comment period (which is available via the internet on the CMS website).

3. Device Edit Policy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795), we finalized a policy and implemented claims processing edits that require any of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any of the APCs listed in Table 5 of the CY 2015 OPPS/ASC final rule with comment period (the CY 2015 device-dependent APCs) is reported on the claim. In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422), we modified our previously existing policy and applied the device coding requirements exclusively to procedures that require the implantation of a device that are assigned to a device-intensive APC. In the CY 2016 OPPS/ASC final rule with comment period, we also finalized our policy that the claims processing edits are such that any device code, when reported on a claim with a procedure assigned to a device-intensive APC (listed in Table 42 of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422)) will satisfy the edit.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658 through 79659), we changed our policy for CY 2017 and subsequent years to apply the CY 2016 device coding requirements to the newly defined device-intensive procedures. For CY 2017 and subsequent years, we also specified that any device code, when reported on a claim with a device-intensive procedure, will satisfy the edit. In addition, we created HCPCS code C1889 to recognize devices furnished during a device-intensive procedure that are not described by a specific Level II HCPCS Category C-code. Reporting HCPCS code C1889 with a device-intensive procedure will satisfy the edit requiring a device code to be reported on a claim with a device-intensive procedure. In the CY 2019 OPPS/ASC final rule with comment period, we revised the description of HCPCS code C1889 to remove the specific applicability to device-intensive procedures (83 FR 58950). For CY 2019 and subsequent years, the description of HCPCS code C1889 is ''Implantable/insertable device, not otherwise classified''.

We did not propose any changes to this policy for CY 2021.

Comment: Some commenters requested that CMS restore the device-to-procedure and procedure-to-device edits.

Response: As we stated in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66794), we continue to believe that the elimination of device-to-procedure edits and procedure-to-device edits is appropriate due to the experience hospitals now have in coding and reporting these claims fully. More specifically, for the most costly devices, we believe the C–APCs reliably reflect the cost of the device if charges for the device are included anywhere on the claim. We note that, under our current policy, hospitals are still expected to adhere to the guidelines of correct coding and append the correct device code to the claim when applicable. We also note that, as with all other items and services recognized under the OPPS, we expect hospitals to code and report their costs appropriately, regardless of whether there are claims processing edits in place.

4. Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

a. Background

To ensure equitable OPPS payment when a hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device offset) when the hospital receives a specified device at no cost or with full credit (71 FR 68071 through 68077). Hospitals were instructed to report no cost/full credit device cases on the claim using the ''FB'' modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without cost or with full credit, hospitals were instructed to report a token device charge of less than $1.01. In cases in which the device being inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, hospitals were instructed to report as the device charge the difference between the hospital's usual charge for the device being implanted and the hospital's usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals were instructed to append the ''FC'' modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the ''FB'' and ''FC'' modifiers payment adjustment policies (72 FR 66743 through 66749).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), beginning in CY 2014, we modified our policy of reducing

OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy had been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we reduced OPPS payment, for the applicable APCs, by the full or partial credit a hospital receives for a replaced device. Specifically, under this modified policy, hospitals are required to report on the claim the amount of the credit in the amount portion for value code ''FD'' (Credit Received from the Manufacturer for a Replaced Device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. For CY 2014, we also limited the OPPS payment deduction for the applicable APCs to the total amount of the device offset when the ''FD'' value code appears on a claim. For CY 2015, we continued our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit and to use the three criteria established in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68072 through 68077) for determining the APCs to which our CY 2015 policy will apply (79 FR 66872 through 66873). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), we finalized our policy to no longer specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices would apply and instead apply this APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device.

b. Policy for No Cost/Full Credit and Partial Credit Devices

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79659 through 79660), for CY 2017 and subsequent years, we finalized a policy to reduce OPPS payment for device-intensive procedures, by the full or partial credit a provider receives for a replaced device, when a hospital furnishes a specified device without cost or with a full or partial credit. Under our current policy, hospitals continue to be required to report on the claim the amount of the credit in the amount portion for value code ''FD'' when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), we adopted a policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit by the lesser of the device offset amount for the APC or the amount of the credit. Although we adopted this change in policy in the preamble of the CY 2014 OPPS/ASC final rule with comment period and discussed it in subregulatory guidance, including Chapter 4, Section 61.3.6 of the Medicare Claims Processing Manual, we inadvertently did not make conforming changes to the regulation text. In particular, we did not change our regulation at 42 CFR 419.45(b)(1) and (2), which describes the amount of the reduction in the APC payment in situations where the beneficiary receives an implanted device that is replaced without cost to the provider or the beneficiary or where the provider receives a full or partial credit for the cost of a replaced device and which continues to state that the amount of the reduction is the device offset amount. Therefore, in the CY 2021 OPPS/ASC proposed rule, we proposed to change our regulation at § 419.45(b)(1) and (2) to conform with the policy we adopted in CY 2014. In particular, we proposed revising our regulations at § 419.45(b)(1) to state that, for situations in which a beneficiary has received an implanted device that is replaced without cost to the provider or the beneficiary, or where the provider receives full credit for the cost of a replaced device, the amount of reduction to the APC payment is calculated by reducing the APC payment amount by the lesser of the amount of the credit or the device offset amount that would otherwise apply if the procedure assigned to the APC had transitional pass-through status under § 419.66. Additionally, we proposed to revise our regulation at § 419.45(b)(2) to state that, for situations in which the provider receives partial credit for the cost of a replaced device, but only where the amount of the device credit is greater than or equal to 50 percent of the cost of the replacement device being implanted, the amount of the reduction to the APC payment is calculated by reducing the APC payment amount by the lesser of the amount of the credit or the device offset amount that would otherwise apply if the procedure assigned to the APC had transitional-pass through status under § 419.66. The proposed revisions to § 419.45(b)(1) and (2) appear in section XXVII. of the CY 2021 OPPS/ASC proposed rule.

We did not receive any comments on our proposal and are finalizing, without modification, our revisions to § 419.45(b)(1) and (2).

5. Payment Policy for Low-Volume Device-Intensive Procedures

In CY 2016, we used our equitable adjustment authority under section 1833(t)(2)(E) of the Act and used the median cost (instead of the geometric mean cost per our standard methodology) to calculate the payment rate for the implantable miniature telescope procedure described by CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis), which is the only code assigned to APC 5494 (Level 4 Intraocular Procedures) (80 FR 70388). We noted that, as stated in the CY 2017 OPPS/ASC proposed rule (81 FR 45656), we proposed to reassign the procedure described by CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures) for CY 2017, but it would be the only procedure code assigned to APC 5495. The payment rates for a procedure described by CPT code 0308T (including the predecessor HCPCS code C9732) were $15,551 in CY 2014, $23,084 in CY 2015, and $17,551 in CY 2016. The procedure described by CPT code 0308T is a high-cost device-intensive surgical procedure that has a very low volume of claims (in part because most of the procedures described by CPT code 0308T are performed in ASCs). We believe that the median cost is a more appropriate measure of the central tendency for purposes of calculating the cost and the payment rate for this procedure because the median cost is impacted to a lesser degree than the geometric mean cost by more extreme observations. We stated that, in future rulemaking, we would consider proposing a general policy for the payment rate calculation for very low-volume device-intensive APCs (80 FR 70389).

For CY 2017, we proposed and finalized a payment policy for low-volume device-intensive procedures that is similar to the policy applied to the procedure described by CPT code 0308T in CY 2016. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79660 through 79661), we established our current policy that the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC be

calculated using the median cost instead of the geometric mean cost, for the reasons described previously for the policy applied to the procedure described by CPT code 0308T in CY 2016. The CY 2018 final rule geometric mean cost for the procedure described by CPT code 0308T (based on 19 claims containing the device HCPCS C-code, in accordance with the device-intensive edit policy) was $21,302, and the median cost was $19,521. The final CY 2018 payment rate (calculated using the median cost) was $17,560.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58951), for CY 2019, we continued with our policy of establishing the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC based on calculations using the median cost instead of the geometric mean cost. For more information on the specific policy for assignment of low-volume device-intensive procedures for CY 2019, we refer readers to section III.D.13. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58917 through 58918).

For CY 2020, we finalized our policy to continue establishing the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC using the median cost instead of the geometric mean cost. In CY 2020, this policy applied to CPT code 0308T which we assigned to APC 5495 (Level 5 Intraocular Procedures) in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61301).

For CY 2021, we proposed to continue our current policy of establishing the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC using the median cost instead of the geometric mean cost. For CY 2021, this policy would not apply to any procedure. As discussed in section III.D.3. of the CY 2021 OPPS/ASC proposed rule, we received no claims data with CPT code 0308T, which we previously assigned as a low-volume device-intensive procedure for CY 2017 through CY 2020. As such, we proposed to assign 0308T a payment weight based on the most recently available data, from the CY 2020 OPPS final rule, and therefore proposed to assign CPT code 0308T to APC 5495 (Level 5 Intraocular Procedures). Additionally, in the absence of CY 2019 claims data for the CY 2021 OPPS/ASC proposed rule, we proposed to use the most recently available data, from the CY 2020 OPPS final rule, to establish the device offset percentage for 0308T. Therefore, the proposed CY 2021 device offset percentage for CPT code 0308T was based on the CY 2020 OPPS final rule device offset percentage of 82.21 percent for CPT code 0308T. For more discussion on the proposed APC assignment and proposed payment rate for CPT code 0308T, see CY 2021 OPPS/ASC proposed rule (85 FR 48840).

Comment: One commenter supported our proposed device offset percentage for CPT code 0308T.

Response: We thank the commenter for their support.

After consideration of the public comment we received, we are finalizing our proposal, without modification, to use the CY 2020 median cost in determining the OPPS and ASC relative payment weights for 0308T and to assign the CY 2020 OPPS final rule device offset percentage of 82.21 percent as the CY 2021 device offset for CPT code 0308T. For more discussion on the APC assignment and payment rate for CPT code 0308T, please see section III.D of this CY 2021 OPPS/ASC final rule with comment period.

V. OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

A. OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs and biologicals. Throughout this final rule with comment period, we use the term ''biological'' because this is the term that appears in section 1861(t) of the Act. A ''biological'' as used in this final rule with comment period includes (but is not necessarily limited to) a ''biological product'' or a ''biologic'' as defined under section 351 of the Public Health Service Act. As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), this pass-through payment provision requires the Secretary to make additional payments to hospitals for: Current orphan drugs for rare diseases and conditions, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. ''Current'' refers to those types of drugs or biologicals mentioned above that are hospital outpatient services under Medicare Part B for which transitional pass-through payment was made on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain ''new'' drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996 and whose cost is ''not insignificant'' in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as ''drugs.'' As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the product as a hospital outpatient service under Medicare Part B. Proposed CY 2021 pass-through drugs and biologicals and their designated APCs were assigned status indicator ''G'' in Addenda A and B to the proposed rule (which are available via the internet on the CMS website).

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. The methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64. These regulations specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the APC payment that CMS determines is associated with the drug or biological.

Section 1847A of the Act establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In the proposed rule, the term ''ASP methodology'' and ''ASP-based'' are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on our website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html*.

The pass-through application and review process for drugs and biologicals

is described on our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html*.

2. Transitional Pass-Through Payment Period for Pass-Through Drugs, Biologicals, and Radiopharmaceuticals and Quarterly Expiration of Pass-Through Status

As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the product as a hospital outpatient service under Medicare Part B. Our current policy is to accept pass-through applications on a quarterly basis and to begin pass-through payments for newly approved pass-through drugs and biologicals on a quarterly basis through the next available OPPS quarterly update after the approval of a product's pass-through status. However, prior to CY 2017, we expired pass-through status for drugs and biologicals on an annual basis through notice-and-comment rulemaking (74 FR 60480). In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79662), we finalized a policy change, beginning with pass-through drugs and biologicals newly approved in CY 2017 and subsequent calendar years, to allow for a quarterly expiration of pass-through payment status for drugs, biologicals, and radiopharmaceuticals to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through drugs, biologicals, and radiopharmaceuticals.

This change eliminated the variability of the pass-through payment eligibility period, which previously varied based on when a particular application was initially received. We adopted this change for pass-through approvals beginning on or after CY 2017, to allow, on a prospective basis, for the maximum pass-through payment period for each pass-through drug without exceeding the statutory limit of 3 years. Notice of drugs whose pass-through payment status is ending during the calendar year will continue to be included in the quarterly OPPS Change Request transmittals.

Comment: One commenter commended CMS for continuing the policy to provide for quarterly expiration of pass-through payment status, which allows a pass-through period that is as close to a full three years as possible.

Response: We thank the commenter for their input and support of this policy change, which was adopted in the CY 2017 OPPS/ASC final rule (81 FR 79654 through 79655).

3. Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2020

There are 29 drugs and biologicals whose pass-through payment status will expire during CY 2020 as listed in Table 36. Most of these drugs and biologicals will have received OPPS pass-through payment for 3 years during the period of April 1, 2017 through December 31, 2020. However, there are two groups of drugs and biologicals included in Table 36 whose total period of OPPS pass-through payment is greater than 3 years. The first group are five drugs and biologicals that have already had 3 years of pass-through payment status but for which pass-through payment status was extended for an additional 2 years from October 1, 2018 until September 30, 2020 under section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018 (Pub. L. 115–141). The drugs covered by this provision include: HCPCS code A9586 (Florbetapir f18, diagnostic, per study dose, up to 10 millicuries); HCPCS code J1097 (Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml); HCPCS code Q4195 (Puraply, per square centimeter); HCPCS code Q4196 (Puraply am, per square centimeter); and HCPCS code Q9950 (Injection, sulfur hexafluoride lipid microspheres, per ml). The second group are two diagnostic radiopharmaceuticals: HCPCS code Q9982 (Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries) and HCPCS code Q9983 (Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries) whose pass-through payment status was extended for an additional 9 months from January 1, 2020 to September 30, 2020 under Division N, Title I, Subtitle A, Section 107(a) of the Further Consolidated Appropriations Act of 2020, which amended section 1833(t)(6) of the Social Security Act and added a new section 1833(t)(6)(J) to the Act.

In accordance with the policy finalized in CY 2017 and described earlier, pass-through payment status for drugs and biologicals newly approved in CY 2017 and subsequent years will expire on a quarterly basis, with a pass-through payment period as close to 3 years as possible. With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through payment status (specifically, anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including diagnostic radiopharmaceuticals, contrast agents, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), our standard methodology for providing payment for drugs and biologicals with expiring pass-through payment status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year (which was proposed to be $130 for CY 2021), as discussed further in section V.B.2. of the CY 2021 OPPS/ASC proposed rule. We proposed that if the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we proposed to provide separate payment at the applicable relative ASP-based payment amount (which was proposed at ASP+6 percent for non-340B drugs for CY 2021, as discussed further in section V.B.3. of the CY 2021 OPPS/ASC proposed rule).

We did not receive any public comments regarding our proposals. Therefore, we are adopting these proposals as final for CY 2021 without modification. The packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B of the CY 2021 OPPS/ASC final rule (which is available via the internet on the CMS website).

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TABLE 36.--DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS WILL EXPIRE BETWEEN MARCH 31, 2020 AND DECEMBER 31, 2020

CY 2020 HCPCS Code	Long Descriptor	CY 2020 Status Indicator	CY 2020 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9488	Injection, conivaptan hydrochloride, 1 mg	G	9488	04/01/2017	03/31/2020
J1428	Injection, eteplirsen, 10 mg	G	9484	04/01/2017	03/31/2020
J1627	Injection, granisetron extended release, 0.1 mg	G	9486	04/01/2017	03/31/2020
J3358	Ustekinumab, for intravenous injection, 1 mg	G	9487	04/01/2017	03/31/2020
J7328	Hyaluronan or derivative, gelsyn-3, for intra-articular injection, 0.1 mg	G	1862	04/01/2017	03/31/2020
J9285	Injection, olaratumab, 10 mg	G	9485	04/01/2017	03/31/2020
Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg	G	1847	04/01/2018	03/31/2020
J0565	Injection, bezlotoxumab, 10 mg	G	9490	07/01/2017	06/30/2020
J2326	Injection, nusinersen, 0.1 mg	G	9489	07/01/2017	06/30/2020
A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	9084	10/01/2018	09/30/2020
J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	G	9324	10/01/2018	09/30/2020
J1301	Injection, edaravone, 1 mg	G	9493	10/01/2017	09/30/2020

CY 2020 HCPCS Code	Long Descriptor	CY 2020 Status Indicator	CY 2020 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J2350	Injection, ocrelizumab, 1 mg	G	9494	10/01/2017	09/30/2020
J2797	Injection, rolapitant, 0.5 mg	E1	9464	04/01/2018	09/30/2020
J9023	Injection, avelumab, 10 mg	G	9491	10/01/2017	09/30/2020
J9173	Injection, durvalumab, 10 mg	G	9492	10/01/2017	09/30/2020
Q4195	Puraply, per square centimeter	G	9175	01/01/2019	09/30/2020
Q4196	Puraply am, per square centimeter	G	9176	01/01/2019	09/30/2020
Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9085	10/01/2018	09/30/2020
Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	G	9459	01/01/2020	09/30/2020
Q9983	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries	G	9458	01/01/2020	09/30/2020
J0567	Injection, cerliponase alfa, 1 mg	G	9014	01/01/2018	12/31/2020
J0599	Injection, c-1 esterase inhibitor (human), (haegarda), 10 units	G	9015	01/01/2018	12/31/2020
J1628	Injection, guselkumab, 1 mg	G	9029	01/01/2018	12/31/2020
J3316	Injection, triptorelin, extended-release, 3.75 mg	G	9016	01/01/2018	12/31/2020
J7345	Aminolevulinic acid hcl for topical administration, 10% gel, 10 mg	G	9301	01/01/2018	12/31/2020
J9153	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine	G	9302	01/01/2018	12/31/2020
J9203	Injection, gemtuzumab ozogamicin, 0.1 mg	G	9495	01/01/2018	12/31/2020
J9229	Injection, inotuzumab ozogamicin, 0.1 mg	G	9028	01/01/2018	12/31/2020

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4. Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Expiring in CY 2021

We proposed to end pass-through payment status in CY 2021 for 25 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status between April 1, 2018 and January 1, 2019, are listed in Table 37. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will end by December 31, 2021, are assigned status indicator ''G'' in Addenda A and B to the CY 2021 OPPS/ASC proposed rule (which are available via the internet on the CMS website).

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For CY 2021, we

proposed to continue to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2021. We proposed that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2021 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which was proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which was proposed at ASP+6 percent, is $0.

In the case of policy-packaged drugs (which include the following: Anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), we proposed that their pass-through payment amount would be equal to ASP+6 percent for CY 2021 minus a payment offset for the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological as described in section V.A.6. of the CY 2021 OPPS/ASC proposed rule. We proposed this policy because, if not for the pass-through payment status of these policy-packaged products, payment for these products would be packaged into the associated procedure.

We proposed to continue to update pass-through payment rates on a quarterly basis on the CMS website during CY 2021 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2021, consistent with our CY 2020 policy for diagnostic and therapeutic radiopharmaceuticals, we proposed to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2021, we proposed to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which was proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we proposed to provide pass-through payment at WAC+3 percent (consistent with our proposed policy in section V.B.2.b. of the proposed rule), the equivalent payment provided to pass-through payment drugs and biologicals without ASP information. Additional detail on the WAC+3 percent payment policy can be found in section V.B.2.b. of the proposed rule. If WAC information also is not available, we proposed to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

We did not receive any public comments regarding our proposals. Therefore, we are adopting these proposals as final for CY 2021 without modification. The drugs and biologicals for which pass-through payment status will expire between March 31, 2021 and December 31, 2021 are shown in Table 37.

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TABLE 37: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING DURING CY 2021

CY 2020 HCPCS Code	CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9462	C9462	Injection, delafloxacin, 1 mg	G	9462	04/01/2018	03/31/2021
J0185	J0185	Injection, aprepitant, 1 mg	G	9463	04/01/2018	03/31/2021
J0517	J0517	Injection, benralizumab, 1 mg	G	9466	04/01/2018	03/31/2021
J3304	J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	G	9469	04/01/2018	03/31/2021
J7203	J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu	G	9468	04/01/2018	03/31/2021
J7318	J7318	Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg	G	9174	04/01/2018	03/31/2021
J9311	J9311	lnjection, rituximab 10 mg and hyaluronidase	G	9467	04/01/2018	03/31/2021
Q2041	Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9035	04/01/2018	03/31/2021
Q2042	Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9194	04/01/2018	03/31/2021
Q5104	Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg	G	9036	04/01/2018	03/31/2021

CY 2020 HCPCS Code	CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
A9513	A9513	Lutetium lu 177, dotatate, therapeutic, 1 millicurie	G	9067	07/01/2018	06/30/2021
J3398	J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes	G	9070	07/01/2018	06/30/2021
J7170	J7170	Injection, emicizumab-kxwh, 0.5 mg	G	9257	07/01/2018	06/30/2021
J9057	J9057	Injection, copanlisib, 1 mg	G	9030	07/01/2018	06/30/2021
Q9991	Q9991	Injection, buprenorphine extended-release (sublocade), less than or equal to 100 mg	G	9073	07/01/2018	06/30/2021
Q9992	Q9992	Injection, buprenorphine extended-release (sublocade), greater than 100 mg	G	9239	07/01/2018	06/30/2021
J1454	J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	G	9099	10/01/2018	09/30/2021
Q5105	Q5105	Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for esrd on dialysis), 100 units	G	9096	10/01/2018	09/30/2021
Q5106	Q5106	Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for non-esrd use), 1000 units	G	9097	10/01/2018	09/30/2021
A9590	A9590	Iodine i-131 iobenguane, therapeutic, 1 millicurie	G	9339	01/01/2019	12/31/2021
J0222	J0222	Injection, Patisiran, 0.1 mg	G	9180	01/01/2019	12/31/2021
J0291	J0291	Injection, plazomicin, 5 mg	G	9183	01/01/2019	12/31/2021
J1943	J1943	Injection, aripiprazole lauroxil, (aristada initio), 1 mg	G	9179	01/01/2019	12/31/2021
J2798	J2798	Injection, risperidone, (perseris), 0.5 mg	G	9181	01/01/2019	12/31/2021
J9204	J9204	Injection, mogamulizumab-kpkc, 1 mg	G	9182	01/01/2019	12/31/2021

5. Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Continuing in CY 2021

We proposed to continue pass-through payment status in CY 2021 for 46 drugs and note that 22 additional drugs were granted pass-through status since publication of the proposed rule. Thus, for CY 2021, there are 68 drugs and biologicals with pass-through status. These drugs and biologicals, which were approved for pass-through payment status with effective dates beginning between April 1, 2019 and January 1, 2021, are listed in Table 38. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will continue after December 31, 2021, were assigned status indicator ''G'' in Addenda A and B to the CY 2021 OPPS/ASC proposed rule (which are available via the internet on the CMS website).

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For CY 2021, we proposed to continue to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2021. We proposed that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2021 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which was proposed at ASP+6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which was proposed at ASP+6 percent, is $0.

In the case of policy-packaged drugs (which include the following: Anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), we proposed that their pass-through payment amount would be equal to ASP+6 percent for CY 2021 minus a payment offset for any predecessor drug products contributing to the pass-through payment as described in section V.A.6. of the CY 2021 OPPS/ASC proposed rule. We proposed this policy because, if not for the pass-through payment status of these policy-packaged products, payment for these products would be packaged into the associated procedure.

We proposed to continue to update pass-through payment rates on a quarterly basis on our website during CY 2021 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2021, consistent with our CY 2020 policy for diagnostic and therapeutic radiopharmaceuticals, we proposed to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2021, we proposed to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which was proposed at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, we proposed to provide pass-through payment at WAC+3 percent (consistent with our proposed policy in section V.B.2.b. of the proposed rule), the equivalent payment provided to pass-through payment drugs and biologicals without ASP information. Additional detail on the WAC+3 percent payment policy can be found in section V.B.2.b. of the proposed rule. If WAC information also is not available, we proposed to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

We did not receive any public comments regarding our proposals. Therefore, we are adopting these proposals for CY 2021 without modification. The drugs and biologicals that have pass-through payment status expire after December 31, 2021 are shown in Table 38.

TABLE 38: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS CONTINUING THROUGH CY 2021

CY 2020 HCPCS Code	CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J7169	J7169	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	G	9198	04/01/2019	03/31/2022
C9046	C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	G	9307	04/01/2019	03/31/2022
J0642	J0642	Injection, levoleucovorin 0(khapzory), 0.5 mg	G	9334	01/01/2020	03/31/2022
J1095	J1095	Injection, dexamethasone 9 percent, intraocular, 1 microgram	G	9172	04/01/2019	03/31/2022
J3031	J3031	Injection, fremanezumab-vfrm, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)	G	9197	04/01/2019	03/31/2022
J3245	J3245	Injection, tildrakizumab, 1 mg	G	9306	04/01/2019	03/31/2022
J7208	J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi) 1 i.u.	G	9299	04/01/2019	03/31/2022
J9119	J9119	Injection, cemiplimab-rwlc, 1 mg	G	9304	04/01/2019	03/31/2022
J9313	J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	G	9305	04/01/2019	03/31/2022
Q5108	Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg	G	9173	04/01/2019	03/31/2022
Q5110	Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram	G	9193	04/01/2019	03/31/2022
Q5111	Q5111	Injection, Pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg	G	9195	04/01/2019	03/31/2022
C9047	C9047	Injection, caplacizumab-yhdp, 1 mg	G	9199	07/01/2019	06/30/2022
J0121	J0121	Injection, omadacycline, 1 mg	G	9311	07/01/2019	06/30/2022
J1096	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	G	9308	07/01/2019	06/30/2022
J1303	J1303	Injection, ravulizumab-cwvz, 10 mg	G	9312	07/01/2019	06/30/2022

CY 2020 HCPCS Code	CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J9036	J9036	Injection, bendamustine hydrochloride (belrapzo/bendamustine), 1 mg	G	9313	07/01/2019	06/30/2022
J9210	J9210	Injection, emapalumab-lzsg, 1 mg	G	9310	07/01/2019	06/30/2022
J9269	J9269	Injection, tagraxofusp-erzs, 10 micrograms	G	9309	07/01/2019	06/30/2022
J3111	J3111	Injection, romosozumab-aqqg, 1 mg	G	9327	10/01/2019	09/30/2022
J9356	J9356	Injection, trastuzumab, 10 mg and hyaluronidase-oysk	G	9314	10/01/2019	09/30/2022
C9054	J0691	Injection, lefamulin (xenleta), 1 mg	G	9332	01/01/2020	12/31/2022
C9055	J1632	Injection, brexanolone, 1mg	G	9333	01/01/2020	12/31/2022
J9309	J9309	Injection, polatuzumab vedotin-piiq, 1 mg	G	9331	01/01/2020	12/31/2022
Q5107	Q5107	Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg	G	9329	01/01/2020	12/31/2022
Q5117	Q5117	Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg	G	9330	01/01/2020	12/31/2022
J0179	J0179	Injection, brolucizumab-dbll, 1 mg	G	9340	04/01/2020	03/31/2023
C9056	J0223	Injection, givosiran, 0.5 mg	G	9343	04/01/2020	03/31/2023
C9053	J0791	Injection, crizanlizumab-tmca, 1 mg	G	9342	04/01/2020	03/31/2023
C9057	J1201	Injection, cetirizine hydrochloride, 1 mg	G	9344	04/01/2020	03/31/2023
J7331	J7331	Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg	G	9337	04/01/2020	03/31/2023
Q5114	Q5114	Injection, Trastuzumab-dkst, biosimilar, (ogivri), 10 mg	G	9341	04/01/2020	03/31/2023
Q5115	Q5115	Injection, rituximab-abbs, biosimilar (truxima), 10 mg	G	9336	04/01/2020	03/31/2023
C9058	Q5120	Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo) 0.5 mg	G	9345	04/01/2020	03/31/2023
C9059	C9059	Injection, meloxicam, 1 mg	G	9371	07/01/2020	06/30/2023
C9061	C9061	Injection, teprotumumab-trbw, 10 mg	G	9355	07/01/2020	06/30/2023
C9063	C9063	Injection, eptinezumab-jjmr, 1 mg	G	9357	07/01/2020	06/30/2023

CY 2020 HCPCS Code	CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9122	C9122	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	G	9346	07/01/2020	06/30/2023
J0742	J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	G	9362	07/01/2020	06/30/2023
J0896	J0896	Injection, luspatercept-aamt, 0.25 mg	G	9347	07/01/2020	06/30/2023
J1429	J1429	Injection, golodirsen, 10 mg	G	9356	07/01/2020	06/30/2023
J7204	J7204	Injection, factor VIII, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per iu	G	9354	07/01/2020	06/30/2023
J9177	J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	G	9364	07/01/2020	06/30/2023
J9358	J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	G	9353	07/01/2020	06/30/2023
Q5116	Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg	G	9350	07/01/2020	06/30/2023
Q5119	Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	G	9367	07/01/2020	06/30/2023
C9060	A9591	Fluoroestradiol F 18, diagnostic, 1 millicurie	G	9370	10/01/2020	09/30/2023
C9062	J9144	Injection, daratumumab, 10 mg and hyaluronidase-fihj	G	9378	10/01/2020	09/30/2023
C9064	J9281	Mitomycin pyelocalyceal instillation, 1 mg	G	9374	10/01/2020	09/30/2023
C9065	C9065	Injection, romidepsin, non-lyophilized (e.g. liquid), 1mg	G	9379	10/01/2020	09/30/2023
C9066	J9317	Injection, sacituzumab govitecan-hziy, 2.5 mg	G	9376	10/01/2020	09/30/2023
C9067	C9067	Gallium ga-68, dotatoc, diagnostic, 0.01 mCi	G	9323	10/01/2020	09/30/2023
J7351	J7351	Injection, bimatoprost, intracameral implant, 1 microgram	G	9351	10/01/2020	09/30/2023
J9227	J9227	Injection, isatuximab-irfc, 10 mg	G	9377	10/01/2020	09/30/2023
Q5112	Q5112	Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg	G	9382	10/01/2020	09/30/2023
Q5113	Q5113	Injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg	G	9349	10/01/2020	09/30/2023

CY 2020 HCPCS Code	CY 2021 HCPCS Code	Long Descriptor	CY 2021 Status Indicator	CY 2021 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
Q5121	Q5121	Injection, infliximab-axxq, biosimilar, (AVSOLA), 10 mg	G	9381	10/01/2020	09/30/2023
J1437	J1437	Injection, ferric derisomaltose, 10 mg	G	9388	01/01/2021	12/31/2023
J9198	J9198	Gemcitabine hydrochloride, (Infugem), 100 mg	G	9387	01/01/2021	12/31/2023
N/A	C9068	Copper Cu-64, dotatate, diagnostic, 1 millicurie	G	9383	01/01/2021	12/31/2023
N/A	C9069	Injection, belantamab mafodontin-blmf, 0.5 mg	G	9384	01/01/2021	12/31/2023
N/A	C9070	Injection, tafasitamab-cxix, 2 mg	G	9385	01/01/2021	12/31/2023
N/A	C9071	Injection, viltolarsen, 10 mg	G	9386	01/01/2021	12/31/2023
N/A	C9072	Injection, immune globulin (Asceniv), 500 mg	G	9392	01/01/2021	12/31/2023
N/A	C9073	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9391	01/01/2021	12/31/2023
N/A	J0693	Injection, cefiderocol, 5 mg	G	9380	01/01/2021	12/31/2023
N/A	J9316	Injection, pertuzumab, trastuzumab, and hyaluronidase-zzxf, per 10 mg	G	9390	01/01/2021	12/31/2023
N/A	J9223	Injection, lurbinectedin, 0.1 mg	G	9389	01/01/2021	12/31/2023

6. Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals To Offset Costs Packaged into APC Groups

Under the regulations at 42 CFR 419.2(b), nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure are packaged in the OPPS. This category includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and other diagnostic drugs. Also under 42 CFR 419.2(b), nonpass-through drugs and biologicals that function as supplies in a surgical procedure are packaged in the OPPS. This category includes skin substitutes and other surgical-supply drugs and biologicals. As described earlier, section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we deduct from the pass-through payment for policy-packaged drugs, biologicals, and radiopharmaceuticals an amount reflecting the portion of the APC payment associated with predecessor products in order to ensure no duplicate payment is made. This amount reflecting the portion of the APC payment associated with predecessor products is called the payment offset.

The payment offset policy applies to all policy packaged drugs, biologicals, and radiopharmaceuticals. For a full description of the payment offset policy as applied to diagnostic radiopharmaceuticals, contrast agents, stress agents, and skin substitutes, we

refer readers to the discussion in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70430 through 70432). For CY 2021, as we did in CY 2020, we proposed to continue to apply the same policy packaged offset policy to payment for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes. The proposed APCs to which a payment offset may be applicable for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes are identified in Table 39.

TABLE 39: APCS TO WHICH A POLICY-PACKAGED DRUG OR RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2021

CY 2021 APC	CY 2021 APC Title
Diagnostic Radiopharmaceutical	
5591	Level 1 Nuclear Medicine and Related Services
5592	Level 2 Nuclear Medicine and Related Services
5593	Level 3 Nuclear Medicine and Related Services
5594	Level 4 Nuclear Medicine and Related Services
Contrast Agent	
5571	Level 1 Imaging with Contrast
5572	Level 2 Imaging with Contrast
5573	Level 3 Imaging with Contrast
Stress Agent	
5722	Level 2 Diagnostic Tests and Related Services
5593	Level 3 Nuclear Medicine and Related Services
Skin Substitute	
5054	Level 4 Skin Procedures
5055	Level 5 Skin Procedures

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We proposed to continue to post annually on our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files.html* a file that contains the APC offset amounts that will be used for that year for purposes of both evaluating cost significance for candidate pass-through payment device categories and drugs and biologicals and establishing any appropriate APC offset amounts. Specifically, the file will continue to provide the amounts and percentages of APC payment associated with packaged implantable devices, policy-packaged drugs, and threshold packaged drugs and biologicals for every OPPS clinical APC.

Comment: One commenter requested that CMS release a copy of the APC offset file with future OPPS/ASC proposed rules to enable the public to

calculate the percentage of APC payment associated with packaged drug costs using APC offset data for the upcoming calendar year.

Response: We thank the commenter for their suggestion, and we will consider addressing this request in future rulemaking.

B. OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

1. Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Packaging Threshold

In accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to $50 per administration during CYs 2005 and 2006. In CY 2007, we used the four quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108–173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest $5 increment in order to determine the CY 2007 threshold amount of $55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at $130 for CY 2020 (84 FR 61312 through 61313).

Following the CY 2007 methodology, for this CY 2021 OPPS/ASC proposed rule, we used the most recently available four quarter moving average PPI levels to trend the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2021 and rounded the resulting dollar amount ($130.95) to the nearest $5 increment, which yielded a figure of $130. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from CMS' Office of the Actuary. For this CY 2021 OPPS/ASC proposed rule, based on these calculations using the CY 2007 OPPS methodology, we proposed a packaging threshold for CY 2021 of $130.

Comment: One commenter expressed their support for maintaining the drug packaging threshold for CY 2021 at $130. The commenter believes, however, that the drug packaging threshold has been increasing faster than payment increases under the OPPS. The commenter would like us to research if the drug packaging threshold should be lowered in future years.

Response: We appreciate the commenter's support of the drug packaging threshold level of $130. We also thank the commenter for their suggestion to consider reducing the drug packaging threshold in future years and will consider it for future rulemaking.

After consideration of the public comment, we are implementing our proposal without modification to have a drug packaging threshold for CY 2021 of $130.

b. Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Therapeutic Radiopharmaceuticals Under the Cost Threshold (''Threshold-Packaged Drugs'')

To determine the proposed CY 2021 packaging status for all nonpass-through drugs and biologicals that are not policy packaged, we calculated, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals (collectively called ''threshold-packaged'' drugs) that had a HCPCS code in CY 2019 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2019 claims processed before January 1, 2020 for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages, as described in section V.B.1.d. of the proposed rule, or for the following policy-packaged items that we proposed to continue to package in CY 2021: Anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure.

In order to calculate the per day costs for drugs, biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2021, we use the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638). For each drug and biological HCPCS code, we used an estimated payment rate of ASP+6 percent (which is the payment rate we proposed for separately payable drugs and biologicals (other than 340B drugs) for CY 2021, as discussed in more detail in section V.B.2.b. of the proposed rule) to calculate the CY 2021 proposed rule per day costs. We used the manufacturer-submitted ASP data from the fourth quarter of CY 2019 (data that were used for payment purposes in the physician's office setting, effective April 1, 2020) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2021, we proposed to use payment rates based on the ASP data from the fourth quarter of CY 2019 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to the proposed rule (which are available via the internet on the CMS website) because these were the most recent data available for use at the time of development of the proposed rule. These data also were the basis for drug payments in the physician's office setting, effective April 1, 2020. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, we used their mean unit cost derived from the CY 2019 hospital claims data to determine their per day cost.

We proposed to package items with a per day cost less than or equal to $130, and identify items with a per day cost greater than $130 as separately payable unless they are policy-packaged. Consistent with our past practice, we cross-walked historical OPPS claims data from the CY 2019 HCPCS codes that were reported to the CY 2020 HCPCS codes that we display in Addendum B to the CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website) for proposed payment in CY 2021.

Our policy during previous cycles of the OPPS has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period. We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year. Only HCPCS codes that are identified as separately payable in the final rule with comment period are subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs and biologicals in this CY 2021 OPPS/ASC proposed rule, we proposed to use ASP data from the fourth quarter of CY 2019, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective April 1, 2020, along with updated hospital claims data from CY 2019. We note that we also

proposed to use these data for budget neutrality estimates and impact analyses for this CY 2021 OPPS/ASC proposed rule.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B for this final rule with comment period will be based on ASP data from the third quarter of CY 2020. These data will be the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2020. These payment rates would then be updated in the January 2021 OPPS update, based on the most recent ASP data to be used for physicians' office and OPPS payment as of January 1, 2021. For items that do not currently have an ASP-based payment rate, we proposed to recalculate their mean unit cost from all of the CY 2019 claims data and updated cost report information available for the CY 2021 final rule with comment period to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in the proposed rule may be different from the same drugs' HCPCS codes' packaging status determined based on the data used for the final rule with comment period. Under such circumstances, we proposed to continue to follow the established policies initially adopted for the CY 2005 OPPS (69 FR 65780) in order to more equitably pay for those drugs whose costs fluctuate relative to the proposed CY 2021 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2020. These established policies have not changed for many years and are the same as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434). Specifically, for CY 2021, consistent with our historical practice, we proposed to apply the following policies to these HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals whose relationship to the drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs and biologicals that were paid separately in CY 2020 and that are proposed for separate payment in CY 2021, and that then have per day costs equal to or less than the CY 2021 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2021 final rule, would continue to receive separate payment in CY 2021.
- HCPCS codes for drugs and biologicals that were packaged in CY 2020 and that are proposed for separate payment in CY 2021, and that then have per day costs equal to or less than the CY 2021 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2021 final rule, would remain packaged in CY 2021.
- HCPCS codes for drugs and biologicals for which we proposed packaged payment in CY 2021 but that then have per-day costs greater than the CY 2021 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2021 final rule, would receive separate payment in CY 2021.

We did not receive any public comments on our proposal to recalculate the mean unit cost for items that do not currently have an ASP-based payment rate from all of the CY 2019 claims data and updated cost report information available for this CY 2021 final rule with comment period to determine their final per day cost. We also did not receive any public comments on our proposal to continue to follow the established policies, initially adopted for the CY 2005 OPPS (69 FR 65780), when the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in the proposed rule may be different from the same drug HCPCS code's packaging status determined based on the data used for the final rule with comment period. Therefore, for CY 2021, we are finalizing these two proposals without modification.

c. Policy Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned earlier in this section, under the OPPS, we package several categories of nonpass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Because the products are packaged according to the policies in 42 CFR 419.2(b), we refer to these packaged drugs, biologicals, and radiopharmaceuticals as ''policy-packaged'' drugs, biologicals, and radiopharmaceuticals. These policies are either longstanding or based on longstanding principles and inherent to the OPPS and are as follows:

- Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations (§ 419.2(b)(4));
- Intraoperative items and services (§ 419.2(b)(14));
- Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including, but not limited to, diagnostic radiopharmaceuticals, contrast agents, and pharmacologic stress agents) (§ 419.2(b)(15)); and
- Drugs and biologicals that function as supplies when used in a surgical procedure (including, but not limited to, skin substitutes and similar products that aid wound healing and implantable biologicals) (§ 419.2(b)(16)).

The policy at § 419.2(b)(16) is broader than that at § 419.2(b)(14). As we stated in the CY 2015 OPPS/ASC final rule with comment period: ''We consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy'' (79 FR 66875). The category described by § 419.2(b)(15) is large and includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and some other products. The category described by § 419.2(b)(16) includes skin substitutes and some other products. We believe it is important to reiterate that cost consideration is not a factor when determining whether an item is a surgical supply (79 FR 66875).

Comment: One commenter requested that we develop a policy to provide separate payment for drugs that are administered at the time of ophthalmic surgery and have an FDA-approved indication to treat or prevent post-operative issues.

Response: A surgical procedure episode consists of both pre-operative and post-operative care in addition to the surgical procedure itself. If a drug used to address a post-operative concern, such as pain management, is billed together with a surgical procedure, we assume that the pain management drug was given as a part of the overall surgical procedure, and based on our policy, it is required to be packaged.

Comment: One commenter recommended that CMS continue to apply radiolabeled product edits to the nuclear medicine procedures to ensure that all packaged costs are included on nuclear medicine claims in order to establish appropriate payment rates in the future. The commenter was concerned that many providers performing nuclear medicine procedures are not including the cost of diagnostic radiopharmaceuticals used

for the procedures in their claims submissions. The commenter believes this lack of drug cost reporting could be causing the cost of nuclear medicine procedures to be underreported and therefore request that the radiolabeled product edits be reinstated.

Response: We appreciated the commenter's feedback; however, we do not plan to reinstate the radiolabeled product edits to nuclear medicine procedures, which required a diagnostic radiopharmaceutical to be present on the same claim as a nuclear medicine procedure for payment to be made under the OPPS. As previously discussed in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61314), the edits were in place between CY 2008 and CY 2014 (78 FR 75033). We believe the period of time in which the edits were in place was sufficient for hospitals to gain experience reporting procedures involving radiolabeled products and to become accustomed to ensuring that they code and report charges so that their claims fully and appropriately reflect the costs of those radiolabeled products. As with all other items and services recognized under the OPPS, we expect hospitals to code and report their costs appropriately, regardless of whether there are claims processing edits in place.

Comment: The HOP Panel and several commenters requested that diagnostic radiopharmaceuticals be paid separately in all cases, not just when the drugs have pass-through payment status. One commenter suggested payment based upon ASP, WAC, AWP, or mean unit cost data derived from hospital claims. Some commenters mentioned that pass-through payment status helps the diffusion of new diagnostic radiopharmaceuticals into the market, but is not enough to make up for what the commenters believe is inadequate payment after pass-through status expires. Commenters opposed incorporating the cost of the drug into the associated APC, and provided evidence showing procedures in which diagnostic radiopharmaceuticals are considered to be a surgical supply, which the commenter believed are often paid at a lower rate than the payment rate for the diagnostic radiopharmaceutical itself when the drug had pass-through payment status. Additionally, commenters proposed alternative payment methodologies such as subjecting diagnostic radiopharmaceuticals to the drug packaging threshold, creating separate APC payments for diagnostic radiopharmaceuticals that cost more than $500, or using ASP, WAC, or AWP to account for packaged radiopharmaceutical costs.

Response: We thank commenters for their suggestions. Commenters made many of these suggestions and we addressed them in previous rules, including the CY 2019 OPPS/ASC final rule (83 FR 58955 through 58966) and the CY 2020 OPPS/ASC final rule (84 FR 61314 through 61315). We continue to believe that diagnostic radiopharmaceuticals are an integral component of many nuclear medicine and imaging procedures and charges associated with them should be reported on hospital claims to the extent they are used. Therefore, the payment for the radiopharmaceuticals is reflected within the payment for the primary procedure. In response to the comment regarding the proposed cost of the packaged procedure in CY 2021 being substantially lower than the payment rate of the radiopharmaceutical when it was on pass-through payment status plus the payment rate of the procedure associated with the radiopharmaceutical, we note that rates are established in a manner that uses the geometric mean of reported costs to furnish the procedure based on data submitted to CMS from all hospitals paid under the OPPS to set the payment rate for the service. Accordingly, the costs that are calculated by Medicare reflect the average costs of items and services that are packaged into a primary procedure and will not necessarily equal the sum of the cost of the primary procedure and the average sales price of the specific items and services used in the procedure in each case. Furthermore, the costs will be based on the reported costs submitted to Medicare by the hospitals and not the list price established by the manufacturer. Claims data that include the radiopharmaceutical packaged with the associated procedure reflect the combined cost of the procedure and the radiopharmaceutical used in the procedure. Additionally, we do not believe it is appropriate to create a new packaging threshold specifically for diagnostic radiopharmaceuticals as such a threshold would not align with our overall packaging policy and commenters have submitted only limited data to support a specific threshold. With respect to the request that we create a new APC for each radiopharmaceutical product, we do not believe it is appropriate to create unique APCs for diagnostic radiopharmaceuticals. Diagnostic radiopharmaceuticals function as supplies during a diagnostic test or procedure and following our longstanding packaging policy, these items are packaged under the OPPS. Packaging supports our goal of making OPPS payments consistent with those of a prospective payment system, which packages costs into a single aggregate payment for a service, encounter, or episode of care. Furthermore, diagnostic radiopharmaceuticals function as supplies that enable the provision of an independent service, and are not themselves the primary therapeutic modality, and therefore, we do not believe they warrant separate payment through creation of a unique APC at this time. We welcome ongoing dialogue with stakeholders regarding suggestions for payment changes for consideration for future rulemaking.

After consideration of the public comments we received, we are finalizing our proposals without modification regarding products that are packaged consistent with the policies in 42 CFR 419.2(b).

d. Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological but Different Dosages

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages because we believe that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others. We continue to believe that making packaging determinations on a drug-specific basis eliminates payment incentives for hospitals to report certain HCPCS codes for drugs and allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, we proposed to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2021.

For CY 2021, in order to propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same drug or biological, we aggregated both our CY 2019 claims data and our pricing information at ASP+6 percent across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS

code with the lowest dosage descriptor. The following drugs did not have pricing information available for the ASP methodology for this CY 2021 OPPS/ASC proposed rule, and as is our current policy for determining the packaging status of other drugs, we used the mean unit cost available from the CY 2019 claims data to make the proposed packaging determinations for these drugs: HCPCS code C9257 (Injection, bevacizumab, 0.25 mg); HCPCS code J1840 (Injection, kanamycin sulfate, up to 500 mg); HCPCS code J1850 (Injection, kanamycin sulfate, up to 75 mg); HCPCS code J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units); HCPCS code J7100 (Infusion, dextran 40, 500 ml); and HCPCS code J7110 (Infusion, dextran 75, 500 ml).

For all other drugs and biologicals that have HCPCS codes describing different doses, we then multiplied the proposed weighted average ASP+6 percent per unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological from our claims data to determine the estimated per day cost of each drug or biological at less than or equal to the proposed CY 2021 drug packaging threshold of $130 (so that all HCPCS codes for the same drug or biological would be packaged) or greater than the proposed CY 2021 drug packaging threshold of $130 (so that all HCPCS codes for the same drug or biological would be separately payable). The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply in CY 2018 was displayed in Table 25 of the CY 2021 OPPS/ASC proposed rule (82 FR 48879).

We did not receive any public comments on this proposal. Therefore, for CY 2021, we are finalizing our proposal, without modification, to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages. The packaging status of each drug and biological HCPCS code to which this methodology applies in CY 2021 is displayed in Table 40.

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TABLE 40: HCPCS CODES TO WHICH THE CY 2021 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2021 HCPCS Code	CY 2021 Long Descriptor	CY 2021 Status Indicator (SI)
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	N
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	N
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N

CY 2021 HCPCS Code	CY 2021 Long Descriptor	CY 2021 Status Indicator (SI)
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7030	Infusion, normal saline solution, 1000 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7050	Infusion, normal saline solution, 250 cc	N
J7100	Infusion, dextran 40, 500 ml	N
J7110	Infusion, dextran 75, 500 ml	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
J8520	Capecitabine, oral, 150 mg	N
J8521	Capecitabine, oral, 500 mg	N
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N

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2. Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a ''specified covered outpatient drug'' (known as a SCOD) is defined as a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or is a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of SCODs. These exceptions are—

- A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.
- A drug or biological for which a temporary HCPCS code has not been assigned.
- During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY 2006 and subsequent years be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the Government Accountability Office (GAO) in CYs 2004 and 2005, and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary for purposes of paragraph (14). We refer to this alternative methodology as the ''statutory default.'' Most physician Part B drugs are paid at ASP+6 percent in accordance with section 1842(o) and section 1847A of the Act.

Section 1833(t)(14)(E)(ii) of the Act provides for an adjustment in OPPS payment rates for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act

required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section 1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to take into account the findings of the MedPAC study.[69]

It has been our policy since CY 2006 to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. In the CY 2021 OPPS/ASC proposed rule, we proposed to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs, but we also are applying this provision to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

For a detailed discussion of our OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68383 through 68385). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386 through 68389), we first adopted the statutory default policy to pay for separately payable drugs and biologicals at ASP+6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act. We have continued this policy of paying for separately payable drugs and biologicals at the statutory default for CYs 2014 through 2020.

b. Proposed CY 2021 Payment Policy

For CY 2021, we proposed to continue our payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals, with the exception of 340B-acquired drugs, at ASP+6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). We proposed to pay for separately payable nonpass-through drugs acquired with a 340B discount at a net rate of ASP minus 28.7 percent (as described in section V.B.6). We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59371), the CY 2019 OPPS/ASC final rule with comment period (83 FR 58979 through 58981), and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61321 through 61327) for more information about our current payment policy for drugs and biologicals acquired with a 340B discount.

In the case of a drug or biological during an initial sales period in which data on the prices for sales of the drug or biological are not sufficiently available from the manufacturer, section 1847A(c)(4) of the Act permits the Secretary to make payments that are based on WAC. Under section 1833(t)(14)(A)(iii)(II) of the Act, the amount of payment for a separately payable drug equals the average price for the drug for the year established under, among other authorities, section 1847A of the Act. As explained in greater detail in the CY 2019 PFS final rule, under section 1847A(c)(4) of the Act, although payments may be based on WAC, unlike section 1847A(b) of the Act (which specifies that payments using ASP or WAC must be made with a 6 percent add-on), section 1847A(c)(4) of the Act does not require that a particular add-on amount be applied to WAC-based pricing for this initial period when ASP data is not available. Consistent with section 1847A(c)(4) of the Act, in the CY 2019 PFS final rule (83 FR 59661 to 59666), we finalized a policy that, effective January 1, 2019, WAC-based payments for Part B drugs made under section 1847A(c)(4) of the Act will utilize a 3-percent add-on in place of the 6-percent add-on that was being used according to our policy in effect as of CY 2018. For the CY 2019 OPPS, we followed the same policy finalized in the CY 2019 PFS final rule (83 FR 59661 to 59666). In the CY 2020 OPPS/ASC final rule with comment period, we adopted a policy to utilize a 3-percent add-on instead of a 6-percent add-on for drugs that are paid based on WAC under section 1847A(c)(4) of the Act pursuant to our authority under section 1833(t)(14)(A)(iii)(II) (84 FR 61318). For CY 2021, we proposed to continue to utilize a 3-percent add-on instead of a 6-percent add-on for WAC-based drugs pursuant to our authority under section 1833(t)(14)(A)(iii)(II) of the Act, which provides, in part, that the amount of payment for a SCOD is the average price of the drug in the year established under section 1847A of the Act. We also proposed to apply this provision to non-SCOD separately payable drugs. Because we proposed to establish the average price for a WAC-based drug under section 1847A of the Act as WAC+3 percent instead of WAC+6 percent, we believe it is appropriate to price separately payable WAC-based drugs at the same amount under the OPPS. We proposed that, if finalized, our proposal to pay for drugs or biologicals at WAC+3 percent, rather than WAC+6 percent, would apply whenever WAC-based pricing is used for a drug or biological under 1847A(c)(4). For drugs and biologicals that would otherwise be subject to a payment reduction because they were acquired under the 340B Program, the payment amount for these drugs (proposed as a net rate of WAC minus 28.7 percent) would continue to apply. We refer readers to the CY 2019 PFS final rule (83 FR 59661 to 59666) for additional background on this policy.

We proposed that payments for separately payable drugs and biologicals would be included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act. We also propose that the budget neutral weight scalar would not be applied in determining payments for these separately payable drugs and biologicals.

We note that separately payable drug and biological payment rates listed in Addenda A and B to the CY 2021 OPPS/ASC proposed rule (available via the internet on the CMS website), which illustrate the proposed CY 2021 payment of ASP+6 percent for separately payable nonpass-through drugs and biologicals and ASP+6 percent for pass-through drugs and biologicals, reflect either ASP information that is the basis for calculating payment rates for drugs and biologicals in the physician's office setting effective April 1, 2020, or WAC, AWP, or mean unit cost from CY 2019 claims data and updated cost report information available for the proposed rule. In general, these published payment rates are not the same as the actual January 2021 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2021 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2020 (July 1, 2020 through September 30, 2020) will be used to set the payment rates that are released for

[69] Medicare Payment Advisory Committee. June 2005 Report to the Congress. Chapter 6: Payment for pharmacy handling costs in hospital outpatient departments. Available at: *http://www.medpac.gov/docs/default-source/reports/June05_ch6.pdf?sfvrsn=0.*

the quarter beginning in January 2021 near the end of December 2020. In addition, payment rates for drugs and biologicals in Addenda A and B to the proposed rule for which there was no ASP information available for April 2020 are based on mean unit cost in the available CY 2019 claims data. If ASP information becomes available for payment for the quarter beginning in January 2021, we will price payment for these drugs and biologicals based on their newly available ASP information. Finally, there may be drugs and biologicals that have ASP information available for the proposed rule (reflecting April 2020 ASP data) that do not have ASP information available for the quarter beginning in January 2021. These drugs and biologicals would then be paid based on mean unit cost data derived from CY 2019 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to the proposed rule were not for January 2021 payment purposes and are only illustrative of the CY 2021 OPPS payment methodology using the most recently available information at the time of issuance of the proposed rule.

Comment: Multiple commenters expressed their support for paying for separately payable drugs and biologicals at ASP plus 6 percent. The commenters believe this policy is consistent with statute and Congressional intent, and generates more predictable payment for providers than previous payment methodologies for drugs and biologicals. The commenters believe the ASP plus 6 percent payment policy ensures equivalent payment for drugs and biologicals between the outpatient hospital setting and the physician office, which encourages Medicare beneficiaries to receive care in the most clinically appropriate setting.

Response: We appreciate the commenters' support for our policy.

Comment: One commenter requested that an add-on percentage of greater than 6 percent of ASP be paid for separately payable radiopharmaceuticals to reflect higher overhead and handling costs for these products.

Response: The add-on percentage of 6 percent is generally viewed as reflecting the overhead and handling cost of most drugs, radiopharmaceuticals, and biologicals that are separately payable in the OPPS even though the overhead and handling costs for individual products may be higher or lower than 6 percent of the ASP. It is not practical to calculate the overhead and handling costs for each drug and radiopharmaceutical. We believe that the add-on percentage of 6 percent is appropriate for separately payable radiopharmaceuticals.

After considering the public comments we received, we are finalizing our proposals related to payment for specified covered outpatient drugs (SCODs) and other separately payable drugs and biologicals without modification.

c. Biosimilar Biological Products

For CY 2016 and CY 2017, we finalized a policy to pay for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act and to subject nonpass-through biosimilar biological products to our annual threshold-packaged policy (for CY 2016, 80 FR 70445 through 70446; and for CY 2017, 81 FR 79674). In the CY 2018 OPPS/ASC proposed rule (82 FR 33630), for CY 2018, we proposed to continue this same payment policy for biosimilar biological products.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59351), we noted that, with respect to comments we received regarding OPPS payment for biosimilar biological products, in the CY 2018 PFS final rule, CMS finalized a policy to implement separate HCPCS codes for biosimilar biological products. Therefore, consistent with our established OPPS drug, biological, and radiopharmaceutical payment policy, HCPCS coding for biosimilar biological products is based on the policy established under the CY 2018 PFS final rule.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59351), after consideration of the public comments we received, we finalized our proposed payment policy for biosimilar biological products, with the following technical correction: all biosimilar biological products are eligible for pass-through payment and not just the first biosimilar biological product for a reference product. In the CY 2019 OPPS/ASC proposed rule (83 FR 37123), for CY 2019, we proposed to continue the policy in place from CY 2018 to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product.

In addition, in CY 2018, we adopted a policy that biosimilars without pass-through payment status that were acquired under the 340B Program would be paid the ASP of the biosimilar minus 22.5 percent of the reference product's ASP (82 FR 59367). We adopted this policy in the CY 2018 OPPS/ASC final rule with comment period because we believe that biosimilars without pass-through payment status acquired under the 340B Program should be treated in the same manner as other drugs and biologicals acquired through the 340B Program. As noted earlier, biosimilars with pass-through payment status are paid their own ASP+6 percent of the reference product's ASP. Separately payable biosimilars that do not have pass-through payment status and are not acquired under the 340B Program are also paid their own ASP plus 6 percent of the reference product's ASP. If a biosimilar does not have ASP pricing, but instead has WAC pricing, the WAC pricing add-on of either 3 percent or 6 percent is calculated from the biosimilar's WAC and is not calculated from the WAC price of the reference product.

As noted in the CY 2019 OPPS/ASC proposed rule (83 FR 37123), several stakeholders raised concerns to us that the payment policy for biosimilars acquired under the 340B Program could unfairly lower the OPPS payment for biosimilars not on pass-through payment status because the payment reduction would be based on the reference product's ASP, which would generally be expected to be priced higher than the biosimilar, thus resulting in a more significant reduction in payment than if the 22.5 percent was calculated based on the biosimilar's ASP. We agreed with stakeholders that the current payment policy could unfairly lower the price of biosimilars without pass-through payment status that are acquired under the 340B Program. In addition, we noted that we believed that these changes would better reflect the resources and production costs that biosimilar manufacturers incur. We also stated that we believe this approach is more consistent with the payment methodology for 340B-acquired drugs and biologicals, for which the 22.5 percent reduction is calculated based on the drug or biological's ASP, rather than the ASP of another product. In addition, we explained that we believed that paying for biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP, rather than 22.5 percent of the reference product's ASP, will more closely approximate hospitals' acquisition costs for these products.

Accordingly, in the CY 2019 OPPS/ASC proposed rule (83 FR 37123), we proposed changes to our Medicare Part B drug payment methodology for biosimilars acquired under the 340B Program. Specifically, for CY 2019 and subsequent years, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act, we proposed to pay nonpass-through biosimilars acquired under the 340B

Program at ASP minus 22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 22.5 percent of the reference product's ASP. This proposal was finalized without modification in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58977).

For CY 2021, we proposed to continue our policy to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. We also proposed to continue our current policy for paying for nonpass-through biosimilars acquired under the 340B program, except that we proposed to pay for these biosimilars at the biosimilar's ASP minus 28.7 percent of the biosimilar's ASP instead of the biosimilar's ASP minus 28.7 percent of the reference product's ASP, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act. ASP minus 28.7 percent reflects the proposed net payment rate. However, in this final rule, as discussed in section V.B.6, we are not adopting our proposal to pay for drugs acquired under the 340B program at ASP minus 28.7 percent but instead are continuing to pay for 340B drugs under the OPPS at ASP minus 22.5 percent in the OPPS. Accordingly, we are also continuing our policy to pay for biosimilars acquired through the 340B program at the biosimilar's ASP minus 22.5 percent of the biosimilar's ASP.

Comment: Multiple commenters supported our proposal to continue our policy from CY 2018 to make biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product.

Response: We appreciate the commenters' support of this established policy.

Comment: Multiple commenters supported our proposal to pay nonpass-through biosimilars acquired under the 340B Program at ASP minus 28.7 percent of the biosimilar's ASP in accordance with section 1833(t)(14)(A)(iii)(II) of the Act.

Response: We appreciate the commenters' support. Please see section V.B.6 of this final rule with comment period for a discussion of payment for biosimilars acquired under the 340B program. As noted above, we are not finalizing our proposal to pay for 340B drugs or biologicals at a net rate of ASP minus 28.7 percent.

Comment: One commenter did not support our proposal to continue our CY 2018 policy to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. The commenter believes biosimilars are not new or innovative drugs or biologicals because they believe the reference product is the only new and innovative product. Therefore, the commenter stated that biosimilars should not be considered for pass-through payment status at all. Additionally, the commenter stated that there should be a ''level playing field'' between biosimilars and their reference products in order to increase competition and reduce costs for beneficiaries. The commenter does not believe it is fair for biosimilars of a reference product to be receiving pass-through payment of ASP+6 percent of the reference product's ASP. The commenter pointed out that when the reference product is no longer eligible for pass-through payment, if it is acquired under the 340B program, hospitals would be paid for the product at ASP minus 22.5 percent. The commenter believes that this difference in the payment rates for biosimilars and their reference products could potentially lead to increased Medicare spending on biosimilars as providers utilize biosimilars instead of the biosimilars' reference products because of the higher payment rates for biosimilars in these circumstances.

Response: As discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58977), we continue to believe that eligibility for pass-through payment status reflects the unique, complex nature of biosimilars and is important as biosimilars become established in the market, just as it is for all other new drugs and biologicals. In terms of the potential increased payment for biosimilars under our policy to allow biosimilars to be eligible for pass-through status, overall increased competition due to the presence of more biosimilars on the market as a result of this policy is expected to drive payments down for both Medicare and for beneficiaries over time, even if there may be increased spending on biosimilars in the short term.

Comment: Several commenters recommended that CMS provide additional support for biosimilars in the form of beneficial payment policies. Some of these recommendations included a delayed effective date for the 340B payment reduction; a smaller reduction in payment for biosimilars acquired under the 340B program; an add-on based on the reference product's ASP when the biosimilar is subject to the 340B payment reduction; increased payment for biosimilars in general; and biosimilar value-based models.

Response: We thank the commenters for their feedback. However, we maintain that our proposed payment policy for biosimilars adequately supports these products by permitting both reference products and their associated biosimilars to receive the same percentage add-on amount, which is calculated based on the ASP of the reference product, regardless of the biosimilar's ASP. Similarly, for products acquired under the 340B program, we note that CMS pays for nonpass-through biosimilars acquired under the 340B Program at ASP minus 22.5 percent of the biosimilar's ASP rather than ASP minus 22.5 percent of the reference product's ASP. If the payment reduction were based on the reference product's ASP, which would generally be expected to be priced higher than the biosimilar, it would result in a more significant payment decrease than if the 22.5 percent were calculated based on the biosimilar's ASP. Please see section V.B.6 for a discussion of payment for biosimilars acquired under 340B. Biosimilars will be treated the same as other separately payable drugs and cannot be excluded from the 340B discount once their pass-through period has ended. We do not believe that additional add-on payments for biosimilars obtained under the 340B program are necessary to encourage their utilization. We note value-based models are outside of the scope of this rule.

For CY 2021, after consideration of the public comments we received, we are finalizing our proposed payment policy for biosimilar products, without modification, to continue the policy established in CY 2018 to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product. We are also finalizing our alternative proposal to pay nonpass-through biosimilars acquired under the 340B Program at the biosimilar's ASP minus 22.5 percent of the biosimilar's ASP, in accordance with section 1833(t)(14)(A)(iii)(II) of the Act. Our final policy regarding the payment rate for drugs and biologicals that are acquired under the 340B program is described in section V.B.6 of this final rule with comment period.

3. Payment Policy for Therapeutic Radiopharmaceuticals

For CY 2021, we proposed to continue the payment policy for therapeutic radiopharmaceuticals that began in CY 2010. We pay for separately payable therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and

biologicals. If ASP information is unavailable for a therapeutic radiopharmaceutical, we base therapeutic radiopharmaceutical payment on mean unit cost data derived from hospital claims. We believe that the rationale outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) for applying the principles of separately payable drug pricing to therapeutic radiopharmaceuticals continues to be appropriate for nonpass-through, separately payable therapeutic radiopharmaceuticals in CY 2021. Therefore, we proposed for CY 2021 to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent, based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521). We also proposed to rely on CY 2019 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable and to update the payment rates for separately payable therapeutic radiopharmaceuticals according to our usual process for updating the payment rates for separately payable drugs and biologicals on a quarterly basis if updated ASP information is unavailable. For a complete history of the OPPS payment policy for therapeutic radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524). The proposed CY 2021 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals were included in Addenda A and B to the CY 2021 OPPS/ASC proposed rule (which are available via the internet on the CMS website).

Comment: One commenter supported the continuation of this policy to provide a predicable payment methodology and avoid the payment swings that occurred prior to adoption of the statutory default rate.

Response: We thank the commenter for their support.

We did not receive any additional public comments on this proposal. Therefore, we are finalizing our proposal, without modification, to continue to pay all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP+6 percent. We are also finalizing our proposal to continue to rely on CY 2019 mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP data are unavailable. The CY 2021 final payment rates for nonpass-through separately payable therapeutic radiopharmaceuticals are included in Addenda A and B to this final rule with comment period (which are available via the internet on the CMS website).

4. Payment for Blood Clotting Factors

For CY 2020, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee (83 FR 58979). That is, for CY 2020, we provided payment for blood clotting factors under the OPPS at ASP+6 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2020 updated furnishing fee was $0.226 per unit.

For CY 2021, we proposed to pay for blood clotting factors at ASP+6 percent, consistent with our proposed payment policy for other nonpass-through, separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Our policy to pay for a furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician's office and in the inpatient hospital setting. These methodologies were first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update is based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the PFS and OPPS/ASC proposed rules are published, we are not able to include the actual updated furnishing fee in the proposed rules. Therefore, in accordance with our policy, as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we proposed to announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on our website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html*.

We proposed to provide payment for blood clotting factors under the same methodology as other separately payable drugs and biologicals under the OPPS and to continue payment of an updated furnishing fee. We will announce the actual figure of the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions and posting on the CMS website.

We did not receive any public comments on our proposal. Therefore, we are finalizing our proposal, without modification, to provide payment for blood clotting factors under the same methodology as other separately payable drugs and biologicals under the OPPS and to continue payment of an updated furnishing fee. We will announce the actual figure of the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions and posting on the CMS website.

5. Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes But Without OPPS Hospital Claims Data

For CY 2021, we proposed to continue to use the same payment policy as in CY 2020 for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data, which describes how we determine the payment rate for drugs, biologicals, or radiopharmaceuticals without an ASP. For a detailed discussion of the payment policy and methodology, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70442 through 70443). The proposed CY 2021 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data is listed in Addendum B to the CY 2021 OPPS/ASC proposed rule, which is available via the internet on the CMS website.

We did not receive any comments on our proposal. Therefore, we are finalizing our CY 2021 proposal without modification, including our proposal to assign drug or biological products status indicator ''K'' and pay for them separately for the remainder of CY 2021 if pricing information becomes available. The CY 2021 payment status of each of the nonpass-through drugs, biologicals, and radiopharmaceuticals

with HCPCS codes but without OPPS hospital claims data is listed in Addendum B to this final rule with comment period, which is available via the internet on the CMS website.

6. CY 2021 OPPS Payment Methodology for 340B Purchased Drugs

a. Overview and Background

Section Overview

Under the OPPS, payment rates for drugs are typically based on their average acquisition cost. This payment is governed by section 1847A of the Act, which generally sets a default rate of average sales price (ASP) plus 6 percent for certain drugs; however, the Secretary has statutory authority to adjust that rate under the OPPS. As described below, beginning in CY 2018, the Secretary adjusted the 340B drug payment rate to ASP minus 22.5 percent to approximate a minimum average discount for 340B drugs, which was based on findings of the GAO and MedPAC that hospitals were acquiring drugs at a significant discount under HRSA's 340B Drug Pricing Program. As described in the following sections, in December 2018, the United States District Court for the District of Columbia (the district court) concluded that the Secretary lacked the authority to bring the default rate in line with average acquisition cost unless the Secretary obtained survey data from hospitals on their acquisition costs. HHS disagreed with that ruling and appealed the decision. HHS meanwhile gathered the relevant survey data from 340B hospitals. As described in detail below, those survey data confirmed that the ASP minus 22.5 percent rate does not underpay 340B hospitals, and the survey data could support an even lower payment rate. The following sections expand upon the points discussed in this overview.

Background

In the CY 2018 OPPS/ASC proposed rule (82 FR 33558 through 33724), we proposed changes to the OPPS payment methodology for drugs and biologicals (hereinafter referred to collectively as ''drugs'') acquired under the 340B Program. We proposed these changes to better, and more accurately, reflect the resources and acquisition costs that these hospitals incur. We stated our belief that such changes would allow Medicare beneficiaries (and the Medicare program) to pay a more appropriate amount when hospitals participating in the 340B Program furnish drugs to Medicare beneficiaries that are purchased under the 340B Program. Subsequently, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), we finalized our proposal and adjusted the payment rate for separately payable drugs and biologicals (other than drugs with pass-through payment status and vaccines) acquired under the 340B Program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. We stated that our goal was to make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs, while recognizing the intent of the 340B Program to allow covered entities, including eligible hospitals, to stretch scarce resources in ways that enable hospitals to continue providing access to care for Medicare beneficiaries and other patients. Critical access hospitals are not paid under the OPPS, and therefore are not subject to the OPPS payment policy for 340B-acquired drugs. We also excepted rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals from the 340B payment adjustment in CY 2018. In addition, as stated in the CY 2018 OPPS/ASC final rule with comment period, this policy change does not apply to drugs with pass-through payment status, which are required to be paid based on the ASP methodology, or vaccines, which are excluded from the 340B Program.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79706), we implemented section 603 of the Bipartisan Budget Act of 2015. As a general matter, applicable items and services furnished in certain off-campus outpatient departments of a provider on or after January 1, 2017 are not considered covered outpatient services for purposes of payment under the OPPS and are paid ''under the applicable payment system,'' which is generally the Physician Fee Schedule (PFS). However, consistent with our policy to pay separately payable, covered outpatient drugs and biologicals acquired under the 340B Program at ASP minus 22.5 percent, rather than ASP+6 percent, when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59015 through 59022), we finalized a policy to pay ASP minus 22.5 percent for 340B-acquired drugs and biologicals furnished in non-excepted off-campus PBDs paid under the PFS. We adopted this payment policy effective for CY 2019 and subsequent years.

We clarified in the CY 2019 OPPS/ASC proposed rule (83 FR 37125) that the 340B payment adjustment applies to drugs that are priced using either WAC or AWP, and that it has been our policy to subject 340B-acquired drugs that use these pricing methodologies to the 340B payment adjustment since the policy was first adopted. The 340B payment adjustment for WAC-priced drugs is WAC minus 22.5 percent. 340B-acquired drugs that are priced using AWP are paid an adjusted amount of 69.46 percent of AWP. The 69.46 percent of AWP is calculated by first reducing the original 95 percent of AWP price by 6 percent to generate a value that is similar to ASP or WAC with no percentage markup. Then we apply the 22.5 percent reduction to ASP/WAC-similar AWP value to obtain the 69.46 percent of AWP, which is similar to either ASP minus 22.5 percent or WAC minus 22.5 percent.

As discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), to effectuate the payment adjustment for 340B-acquired drugs, we implemented modifier ''JG'', effective January 1, 2018. Hospitals paid under the OPPS, other than a type of hospital excluded from the OPPS (such as critical access hospitals), or excepted from the 340B drug payment policy for CY 2018, were required to report modifier ''JG'' on the same claim line as the drug HCPCS code to identify a 340B-acquired drug. For CY 2018, rural sole community hospitals, children's hospitals and PPS-exempt cancer hospitals were excepted from the 340B payment adjustment. These hospitals were required to report informational modifier ''TB'' for 340B-acquired drugs, and continue to be paid ASP+6 percent. We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59370) for a full discussion and rationale for the CY 2018 policies and use of modifiers ''JG'' and ''TB''.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58981), we continued the Medicare 340B payment policies that were implemented in CY 2018 and adopted a policy to pay for nonpass-through 340B-acquired biosimilars at ASP minus 22.5 percent of the biosimilar's ASP, rather than of the reference product's ASP. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61321) we continued the 340B policies that were implemented in CY 2018 and CY 2019.

Our CY 2018 and 2019 OPPS payment policies for 340B-acquired drugs have been the subject of ongoing litigation. On December 27, 2018, in the case of *American Hospital Association, et al.* v. *Azar, et al.,* the district court concluded in the context of reimbursement requests for CY 2018 that the Secretary exceeded his statutory authority by adjusting the Medicare payment rates

for drugs acquired under the 340B Program to ASP minus 22.5 percent for that year.[70] In that same decision, the district court recognized the '''havoc that piecemeal review of OPPS payment could bring about' in light of the budget neutrality requirement,'' and ordered supplemental briefing on the appropriate remedy.[71] On May 6, 2019, after briefing on remedy, the district court issued an opinion that reiterated that the 2018 rate reduction exceeded the Secretary's authority, and declared that the rate reduction for 2019 (which had been finalized since the Court's initial order was entered) also exceeded his authority.[72] Rather than ordering HHS to pay plaintiffs their alleged underpayments, however, the district court recognized that crafting a remedy is ''no easy task, given Medicare's complexity,'' [73] and initially remanded the issue to HHS to devise an appropriate remedy while also retaining jurisdiction. The district court acknowledged that ''if the Secretary were to retroactively raise the 2018 and 2019 340B rates, budget neutrality would require him to retroactively lower the 2018 and 2019 rates for other Medicare Part B products and services.'' [74] *Id.* at 19. ''And because HHS has already processed claims under the previous rates, the Secretary would potentially be required to recoup certain payments made to providers; an expensive and time-consuming prospect.'' [75]

We respectfully disagreed with the district court's understanding of the scope of the Secretary's adjustment authority. On July 10, 2019, the district court entered final judgment. The agency appealed to the United States Court of Appeals for the District of Columbia Circuit, (hereinafter referred to as ''the D.C. Circuit''), and on July 31, 2020 the court entered an opinion reversing the district court's judgement in this matter. Nonetheless, before the D.C. Circuit upheld our authority to pay ASP minus 22.5 percent, we stated in the CY 2020 OPPS/ASC final rule with comment period that we were taking the steps necessary to craft an appropriate remedy in the event of an unfavorable decision on appeal. Notably, after the CY 2020 OPPS/ASC proposed rule was issued, we announced in the **Federal Register** (84 FR 51590) our intent to conduct a 340B hospital survey to collect drug acquisition cost data for certain quarters in CY 2018 and 2019. We stated that such survey data may be used in setting the Medicare payment amount for drugs acquired by 340B hospitals for cost years going forward, and also may be used to devise a remedy for prior years if the district court's ruling is upheld on appeal. The district court itself acknowledged that CMS may base the Medicare payment amount on average acquisition cost when survey data are available.[76] No 340B hospital disputed in the rulemakings for CY 2018 and 2019 that the ASP minus 22.5 percent formula was a conservative adjustment that represented the minimum discount that hospitals receive for drugs acquired through the 340B program, which is significant because 340B hospitals have internal data regarding their own drug acquisition costs. We stated in the CY 2020 OPPS/ASC final rule with comment period that we thus anticipated that survey data collected for CY 2018 and 2019 would confirm that the ASP minus 22.5 percent rate is a conservative amount that overcompensates covered entity hospitals for drugs acquired under the 340B program. We also explained that a remedy that relies on such survey data could avoid the complexities referenced in the district court's opinion.

We noted that under current law, any changes to the OPPS must be budget neutral, and reversal of the payment adjustment for 340B drugs, which raised rates for non-drug items and services by an estimated $1.6 billion for 2018 alone, could have a significant economic impact on the approximately 3,900 facilities that are paid for outpatient items and services covered under the OPPS. In addition, we stated that any remedy that increases payments to 340B hospitals could significantly affect beneficiary cost-sharing. The items and services that could be affected by the remedy were provided to millions of Medicare beneficiaries, who, by law, are required to pay cost-sharing for most items and services, which is usually 20 percent of the total Medicare payment rate. Accordingly, we solicited comments on how to formulate an appropriate remedy in the event of an unfavorable decision on appeal. Those comments are summarized in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61323 through 61327).

b. Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Outpatient Drugs (SCODs)

As discussed in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61326), we announced in the **Federal Register** (84 FR 51590) our intent to conduct a 340B hospital survey to collect drug acquisition cost data for the fourth quarter of CY 2018 and the first quarter of CY 2019. We noted that the survey data may be used in setting the Medicare payment amount for drugs acquired by 340B hospitals for cost years going forward, and also may be used to devise a remedy for prior years in the event of an adverse decision on appeal in the pending litigation. We stated that we believed it was prudent to use the Secretary's existing authority to collect survey data to set OPPS payment rates for drugs acquired under the 340B Program at rates based on hospitals' costs to acquire such drugs. We also stated that we believe it is appropriate for the Medicare program to pay for SCODs purchased under the 340B program at a rate that approximates what hospitals actually pay to acquire the drugs, and we believe it is inappropriate for Medicare to subsidize other programs through Medicare payments for separately payable drugs. We stated that this approach would ensure that the Medicare program uses Medicare trust fund dollars prudently, while maintaining beneficiary access to these drugs and allowing beneficiary cost-sharing to be based on the amounts hospitals actually pay to acquire the drugs.

Section 1833(t)(14)(D)(i)(I) of the Act required the Comptroller General of the United States to conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each SCOD and, not later than April 1, 2005, to furnish data from such surveys to the Secretary for purposes of setting payment rates under the OPPS for SCODs for 2006. The Comptroller General was then required to make recommendations to the Secretary under section 1833(t)(14)(D)(i)(II) of the Act regarding the frequency and methodology of subsequent surveys to be conducted by the Secretary under clause (ii). Clause (ii) of section 1833(t)(14)(D) of the Act provides that the Secretary, taking into account such recommendations, shall conduct periodic subsequent surveys to determine the hospital acquisition cost for SCODs for use in setting payment rates under subparagraph (A) of section 1833(t)(14).

[70] *American Hosp. Ass'n, et al.* v. *Azar, et al.,* No. 1:18-cv-2084 (D.D.C. Dec. 27, 2018).

[71] *Id.* at 35 (quoting *Amgen, Inc.* v. *Smith,* 357 F.3d 103, 112 (D.C. Cir. 2004) (citations omitted)).

[72] *See* May 6, 2019 Memorandum Opinion, Granting in Part Plaintiffs' Motion for a Permanent Injunction; Remanding the 2018 and 2019 OPPS Rules to HHS at 10–12.

[73] *Id.* at 13.

[74] *Id.* at 19.

[75] *Id.* (citing Declaration of Elizabeth Richter).

[76] *See American Hosp. Assoc.* v. *Azar,* 348 F. Supp. 3d 62, 82 (D.D.C. 2018).

In response to the requirements at section 1833(t)(14)(D)(i)(I) and (II) of the Act, the Government Accountability Office (GAO) surveyed hospitals and prepared a report that included its recommendations for the Secretary regarding the frequency and methodology for subsequent surveys.[77] While GAO recognized that collecting accurate and current drug price data was important to ensure the agency does not pay too much or too little for drugs, GAO's 2006 report recommended that CMS conduct a streamlined hospital survey once or twice per decade because of the significant operational difficulties and burden that such a survey would place on hospitals and CMS.[78] In response to questions about whether the data undercounted rebates, GAO acknowledged that their data did not include drug rebates or 340B rebates as part of its calculation.[79] In the CY 2006 OPPS final rule, we explained that the data collected by the GAO was ultimately not used to set payment rates, in part because the data did not fully account for rebates from manufacturers or other price concessions or payments from group purchasing organizations made to hospitals (70 FR 68640). Instead, we adopted a policy to pay hospitals at ASP+6 percent because we believed ASP+6 percent was a reasonable level of payment for both the hospital acquisition and pharmacy overhead cost of drugs and biologicals (70 FR 68642).

Between 2006 and 2017, we have generally paid for separately payable drugs for which ASP data is available at ASP plus 6 percent. Beginning in 2018, we adopted the current policy to pay for 340B-acquired drugs at ASP minus 22.5 percent to better align Medicare payment with acquisition costs for 340B-acquired drugs. The Medicare Payment Advisory Commission (MedPAC) has consistently stated that Medicare should institute policies that improve the program's value to beneficiaries and taxpayers. For example, in its March 2019 Report to the Congress, MedPAC noted that outpatient payments increased in part due to rapid growth in Part B drug spending. MedPAC stated this rapid growth in OPPS specifically, was ''largely driven by the substantial margins for drugs obtained through the 340B Drug Pricing Program.'' [80] While we continue to believe that ASP plus 6 percent represents a reasonable proxy for Part B drug acquisition costs for most hospitals, we do not believe the same is true for hospitals that acquire Part B drugs under the 340B program since such hospitals are able to purchase drugs at deeply discounted 340B ceiling prices, or at even lower ''sub-ceiling'' prices. For this reason, we concluded that it was appropriate to survey 340B hospitals to gather drug acquisition cost data for drugs acquired under the 340B program to allow us to pay hospitals for these drugs at amounts that approximate the hospitals' acquisition costs.

Population of Surveyed Hospitals

Because of our longstanding belief that ASP plus 6 percent is a reasonable proxy for hospital acquisition costs and overhead for separately payable drugs, we did not believe it was necessary or appropriate to burden hospitals that are not eligible to acquire drugs under the 340B program with a drug acquisition cost survey where we have a proxy for hospital acquisition costs for those drugs. ASP data does not, however, include 340B drug prices. (CY 2011 OPPS/ASC final rule with comment period (75 FR 71800, 71960)). When GAO surveyed hospitals in 2005, it found that the survey ''created a considerable burden for hospitals as the data suppliers and considerable costs for GAO as the data collector,'' and recommended that CMS survey hospitals only once or twice per decade to ''occasionally validat[e] CMS's proxy for SCODs' average acquisition costs—the [ASP] data that manufacturers report.'' GAO Report to Congress: *Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS,* 4 (April 2006). Section 1833(t)(14)(D)(ii) requires the Secretary, in conducting periodic subsequent surveys, to take into account GAO's recommendations on the frequency and methodology of subsequent surveys. We considered GAO's conclusion that the 2005 survey created ''considerable burden'' for hospitals and, thus, only surveyed 340B hospitals given our belief that the current payment rate for non-340B hospitals continues to be an appropriate rate. For the same reason, we also limited the data we requested from 340B hospitals to acquisition costs for 340B-acquired drugs, rather than for drugs purchased outside the 340B program for 340B participating hospitals. We note that section 1833(t)(14)(D)(ii) refers to use of surveys conducted by the Secretary to determine the hospital acquisition costs for SCODs in setting payment rates under subparagraph (A). Therefore, we stated that we believed it is appropriate to read the two provisions together to permit the Secretary to survey 340B hospitals only, and formulate a 340B payment policy for this hospital group that is distinct from the payment policy for non-340B hospitals.

Survey Methodology

Under the authority at section 1833(t)(14)(D)(ii) to conduct periodic subsequent surveys to determine hospital acquisition costs, we administered the survey to 1,422 340B covered entity hospitals between April 24 and May 15, 2020. We requested that all hospitals that participated in the 340B program, including rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals (which are currently exempt from the Medicare 340B payment rate adjustment), supply their average acquisition cost for each SCOD purchased under the 340B program during the last quarter of CY 2018 (October 1, 2018 through December 31, 2018) and/or the first quarter of 2019 (January 1, 2019 through March 31, 2019), which could be the 340B ceiling price, a 340B sub-ceiling price, or another amount, depending on the discounts the hospital received when it acquired a particular drug. The ceiling price is the maximum amount covered entities may permissibly be required to pay for a drug under section 340B(a)(1) of the Public Health Service Act, so we would not expect any 340B hospital to have acquisition costs for any 340B-acquired drug that are greater than the ceiling price. For this reason, where the acquisition price for a particular drug was not available or not submitted in response to the survey, we stated that we would use the 340B ceiling price for that drug as a proxy for the hospitals' acquisition cost in order to produce the most conservative drug discount when data was missing or not submitted.

We incorporated valuable input from stakeholders on the development and construction of the 340B acquisition cost survey. We collected the stakeholders' input in two rounds of public comment through the survey Paperwork Reduction Act (PRA) submission process. We published the initial 340B drug hospital acquisition cost survey proposal in the **Federal Register** (84 FR 51590) for a 60-day public comment period that began September 30, 2019 and ended November 29, 2019. After incorporating comments from the 60-day public comment period, we released a revised 340B acquisition cost survey proposal in the **Federal Register** (85 FR 7306) for a

[77] *https://www.gao.gov/new.items/d06372.pdf.*

[78] *Id.* at 18.

[79] *https://www.gao.gov/new.items/d06372.pdf* (Appendix I: Purchase Price for Drug SCODs).

[80] *http://www.medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec.pdf?sfvrsn=0.*

30-day public comment period from February 7, 2020 to March 9, 2020.

After incorporating the stakeholders' comments and suggestions from the second public comment period, OMB approved CMS' survey design (OMB control number 0938–1374, expires 10/31/2021), and CMS released the 340B acquisition cost survey to the relevant 340B hospitals under the OPPS. As mentioned earlier in this section, the survey was open from April 24, 2020, to May 15, 2020. The survey sample was 100 percent of the potential respondent universe, or all hospitals that acquired drugs under the 340B Program and were paid under OPPS in the fourth quarter of 2018 and/or the first quarter of 2019. We provided respondents with two options to complete the survey: The Detailed Survey and the Quick Survey.

Respondents that selected the Detailed Survey provided acquisition costs for each individual SCOD. We requested that these respondents report the net acquisition cost for each SCOD that they acquired under the 340B program (that is, the sub-ceiling price after all applicable discounts). We stated that if the acquisition cost for the SCOD was unknown, the respondent may leave the field blank and we would use the 340B ceiling price as a proxy for the acquisition cost for that drug. In the survey instructions, we stated that acquisition cost for purposes of the survey meant the price that the hospitals paid upon receiving the product, including, but not limited to, prices paid for 340B drugs purchased via a replenishment model under the 340B program, or under penny pricing. We explained that applicable discounts are any discounts below the discounted ceiling price. We also made clear that for purposes of the survey the 340B drug acquisition cost should be reported regardless of whether the drug was dispensed at all, or whether the drug was dispensed in multiple settings. We only requested the acquisition cost of the drugs acquired under the 340B program during the specified timeframes: The fourth quarter of 2018 and/or the first quarter of 2019. We also stated that acquisition costs for drugs acquired by 340B hospitals outside of the 340B program should not be submitted in response to the survey.

The Quick Survey option allowed the hospital to indicate that it preferred that CMS utilize the 340B ceiling prices obtained from (HRSA) as reflective of their hospital acquisition costs. Additionally, we stated that in instances where the acquisition price for a particular drug is not available or submitted in response to the survey, we would use the 340B ceiling price for that drug as a proxy for the hospitals' acquisition cost because the price for a drug acquired under the 340B program cannot be higher than the 340B ceiling price by statute. Finally, we noted that where a hospital did not affirmatively respond to the Detailed or Quick Survey within the open period of response, we would use the 340B ceiling prices in lieu of their responses because the ceiling price represents the highest possible price that a 340B hospital could permissibly be required to pay for a 340B-acquired drug.

c. Analysis of Hospital Acquisition Cost Survey Data for 340B Drugs

The results of the survey, which closed on May 15, 2020 were as follows: Seven percent (n=100) of surveyed hospitals affirmatively responded via the Detailed Survey option; 55 percent (n=780) of surveyed hospitals affirmatively responded via the Quick Survey option; and the remaining 38 percent (n=542) of surveyed hospitals did not respond affirmatively to either survey option. As previously noted, we applied 340B ceiling prices for hospitals that did not affirmatively respond to the survey; such action may skew the survey results towards the *minimum* average discount (that is, the ceiling price) that a 340B hospital would receive on a drug.

We also examined the hospital characteristics of those hospitals that submitted either a Detailed or Quick Survey to the general 340B survey population. The characteristics we analyzed included hospital bed count, teaching hospital status, hospital type, and geographic classification as a rural or urban hospital. Our findings showed that the hospital survey respondents, including respondents to both the Quick and Detailed surveys, were generally similar to the hospital characteristics of the aggregate 340B survey population.

d. Proposed Payment Policy for Drugs Acquired Under the 340B Program for CY 2021

(1) Grouping Hospitals by 340B Covered Entity Status

Section 1833(t)(14)(A)(iii)(I) authorizes the Secretary to set the amount of payment for SCODs at an amount equal to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D). In the CY 2021 OPPS/ASC proposed rule, we stated that we were exercising the authority to vary the amount of payment for the group of hospitals that is enrolled in the 340B program because their drug acquisition costs vary significantly from those not enrolled in that program. Section 1833(t)(14)(A)(iii) of the Act allows the Secretary to exercise discretion to vary payment by hospital group, ''as defined by the Secretary based on the volume of covered OPD services or other relevant characteristics.'' We stated that we believe that it is within the Secretary's authority to distinguish between hospital groups based on whether or not they are covered entities under section 340B(a)(4) of the PHSA that are eligible to receive drugs and biologicals at discounted rates under the 340B program. We also stated that we believe that the significant drug acquisition cost discounts that 340B covered entity hospitals receive enable these hospitals to acquire drugs at much lower costs than non-340B hospitals incur for the same drugs. Accordingly, we explained that we believe it is appropriate to use 340B covered entity status as a relevant characteristic to group hospitals for purposes of payment based on average acquisition cost under section 1833(t)(14)(A)(iii)(I).

(2) Applying a Single Reduction Amount to ASP for 340B-Acquired Drugs

Section 1833(t)(14)(A)(iii)(I) provides that the payment amount for a SCOD for a year is equal to the average acquisition cost for the drug ''as determined by the Secretary taking into account'' the survey data collected under subparagraph (D). As we explained in the CY 2021 OPPS/ASC proposed rule (85 FR 48886), we interpret the reference to acquisition costs being ''determined'' by the Secretary, ''taking into account'' survey data, to give us discretion to determine the appropriate payment rate based on data collected from the hospital acquisition cost survey for 340B drugs. We proposed to apply a single discount factor to ASP for drugs acquired by 340B hospitals in lieu of calculating individual acquisition cost amounts for 340B-acquired drugs. We note that 340B ceiling prices are protected from disclosure both because the prices themselves are sensitive, and because they could potentially be used to reverse-engineer average manufacturer prices, which are protected under section 1927(b)(3)(D) of the Act. We also pledged confidentiality of individual responses regarding acquisition prices for each SCOD to the extent required by law. Given that the survey data is heavily weighted towards

340B ceiling prices (because 340B ceiling prices were used for any SCODs within the Detailed Survey for which a hospital did not provide responses, for hospitals that selected the Quick Survey option, and for hospitals that did not affirmatively respond), and since ceiling prices are protected by law from public disclosure, we instead proposed to establish one aggregate discount amount relative to ASP for SCODs acquired under the 340B program rather than proposing drug-specific prices, which could reveal sensitive or protected pricing information.

(3) Methodology To Calculate ASP Reduction Amount Based on Survey Data

As we explained in the CY 2021 OPPS/ASC proposed rule and as described in detail in the following sections, we analyzed the survey results and applied various statistical methodologies to determine an appropriate average or typical amount by which to reduce ASP that would approximate hospital acquisition costs for 340B drugs and biologicals. In fairness to hospitals, we generally chose methodologies that yield the most conservative reduction to ASP when establishing the payment rate, and thus would be most generous to hospitals. This includes the use of 340B ceiling prices, which must be kept confidential, where applicable in the survey results. Based on our analysis of the available information, we estimated that the typical acquisition cost for 340B drugs for hospitals paid under the OPPS is ASP minus 34.7 percent.

We explained in the proposed rule that we determined the average discount of 34.7 percent by assessing a number of factors including: Multiple measures of central tendencies (arithmetic mean, median, geometric mean); the effect of including penny priced drugs; mapping of multi-source NDCs to a single HCPCS code; weighting values by volume/utilization; and applying trimming methodologies to remove anomalous or outlier data. The analysis of each of these variables is discussed in the next section.

(a) Selecting an Averaging Methodology

When determining the appropriate average reduction amount relative to ASP for 340B drugs, we assessed multiple measures of central tendencies, including the arithmetic mean, median, and geometric mean, on the typical 340B discount based on drug acquisition cost survey data. Based upon the cumulative data from the Detailed Survey option, the Quick Survey option, and imputed responses for hospitals that did not affirmatively respond, we analyzed the effects of each averaging method, combining the data from all three sources in both survey quarters (fourth quarter 2018 and first quarter 2019). Using the raw data without accounting for outliers, we explained in the proposed rule that we determined that the arithmetic mean would result in an average discount from ASP of approximately 66.3 percent; the median would result in an average discount from ASP of approximately 70.4 percent, and the geometric mean would result in an average discount from ASP of approximately 58.3 percent.

Under the OPPS, we generally calculate resource costs for a given service using the geometric mean. The geometric mean minimizes the effects of the outliers without ignoring them. Minimizing outliers is consistent with our methodology to estimate an average or typical 340B discount that is representative across all 340B SCODs. Therefore, we proposed to utilize the geometric mean discount to ASP from both survey quarters—2018 Q4 and 2019 Q1—as a component of our overall analysis of the survey data. Without any further adjustments, we explained that applying the geometric mean to the survey results would result in an average drug acquisition cost estimate of ASP minus 58.3 percent for 340B-acquired drugs.

(b) Volume Weighting Survey Data

While we realize the geometric mean minimizes the effects of some outliers, it does not take into consideration several other important factors. Notably, we explained in the proposed rule that we believe that in calculating the average discount that 340B drugs receive relative to ASP, we should take into account how often those drugs were billed by all hospitals under the OPPS for 2018 and 2019, to give a better reflection of each drug's overall utilization under the OPPS. Therefore, we volume-weighted the drug discounts determined from the survey to mirror the drug utilization in the OPPS. That is, drugs that were commonly used were assigned a higher weight while those less commonly used were assigned a lower weight. We explained that we incorporated volume weighting into our analysis by assessing the utilization rate of each individual drug (using its HCPCS code) under the OPPS for CY 2018 and CY 2019. Specifically, we calculated the average discount by taking the utilization of each drug under the OPPS into account to arrive at a case-weighted average for each HCPCS code. For example, a highly utilized HCPCS code for an oncology drug would be weighted higher than a drug for snake anti-venom that has relatively low utilization in the OPPS. In the proposed rule, we stated that the data for CY 2018 Q4 was volume weighted based upon OPPS utilization during CY 2018 as determined using OPPS claims data. The data for CY 2019 Q1 was volume weighted based upon OPPS utilization during CY 2019 as determined using OPPS claims data. As we explained in the proposed rule, this resulted in a change in the geometric mean to an average discount of 58.0 percent from 58.3 percent non-weighted.

(c) Addressing HCPCS Codes With Multiple NDCs

In addition, we stated in the proposed rule that a small portion of the SCODs that were subject to the 340B drug acquisition cost survey contain multiple NDCs that map to a single HCPCS code. This is because these drugs are multiple source drugs, meaning that they were manufactured by different entities and have varying package sizes or strengths, and thus, multiple different NDCs for the same drug. For payment purposes under the OPPS, we pay for drug products based on the drug's HCPCS code, regardless of which NDC is used. Hospitals that completed the Detailed Survey option were instructed to report their average acquisition costs for each drug during the surveyed quarters per HCPCS code. However, for those hospitals that opted for the Quick Survey option or that did not affirmatively respond, we were unable to determine which combination of NDCs mapped to the HCPCS codes these entities would have used during the given quarters. Therefore, we analyzed the effects of averaging all of the NDCs' acquisition costs for a given HCPCS code when determining the average discount, as well as selecting the NDC with the highest acquisition cost for a given HCPCS code and using that NDC's acquisition cost amount to determine the average discount. When we calculated the average discount using an average of the acquisition costs for all of the NDCs assigned to the HCPCS code, the average volume weighted geometric mean discount off of ASP is 58.0 percent. The 58.0 percent was calculated by taking all of the various NDCs (across various manufacturers, package sizes, and strengths) for the same drug and averaging the unit costs together in order to arrive at a single amount for each HCPCS code for a drug. When we calculated the average discount using the highest acquisition cost NDC for each HCPCS code for a

drug, the average volume weighted geometric mean discount from ASP is 47.0 percent. This was achieved by analyzing all of the various NDCs (across various manufacturers, package sizes, and strengths) assigned to the HCPCS code for the same drug and selecting the NDC that has the highest unit cost in order to arrive at a single cost for each HCPCS code. Consistent with the general principle of choosing the methodological approach that is most generous to hospitals, we proposed to use the highest acquisition cost NDC for each HCPCS code for a drug to determine the average 340B discount.

(d) Addressing Penny Pricing in the Survey Data

As part of our analysis of the survey data, we examined the effect of including ''penny priced'' drugs on the average discount off of ASP. The 340B ceiling price is statutorily defined as the Average Manufacturer Price (AMP) reduced by the rebate percentage, which is commonly referred to as the Unit Rebate Amount (URA).[81] The calculation of the 340B ceiling price is defined in section 340B(a)(1) of the PHSA. Penny pricing occurs when, under section 1927(c)(2)(A) of the Social Security Act, the AMP increases at a rate faster than inflation, in which case the manufacturer is required to pay an additional rebate amount, which is reflected in an increased URA and could result in a 340B ceiling price of zero. However, as HRSA noted in the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation Final Rule (82 FR 1210), although infrequent, there are instances when the 340B ceiling price is zero. HRSA did not believe that it is consistent with the statutory scheme to set the price at zero. In this circumstance, HRSA required that manufacturers charge $0.01 for the drug, which they believed best effectuates the statutory scheme by requiring a payment.[82] We proposed to exclude penny priced drugs to remove outliers that may distort the average discount in order to provide the most conservative estimate of the average 340B discount from ASP.

In the proposed rule, we acknowledged that penny pricing of drugs is not intended to be permanent and, by its very nature, is dynamic, meaning the select group of drugs to which penny pricing applies could vary from quarter to quarter. We analyzed the inclusion and exclusion of penny pricing on the overall average discount of 340B drugs compared to ASP. As expected, we found that excluding penny pricing provides a much more conservative estimate of the average 340B discount from ASP relative to including penny pricing. When we excluded penny pricing, the geometric mean volume weighted average discount, using the highest NDC for a drug's HCPCS code, decreased to 40.9 percent from 47.0 percent. We observed penny pricing in less than 10 percent of the drugs surveyed. Because penny pricing is dynamic and the drugs to which it applies may vary from quarter to quarter, we believe it is appropriate to exclude penny pricing from our survey analysis, although we acknowledge that penny pricing, when it does apply, represents the acquisition cost for the drug to which it applies.

We stated in the proposed rule that we were concerned that including a discount of a penny priced drug from the two quarters surveyed may inappropriately increase the average discount, where the drug may not have been priced based on penny pricing in following or preceding quarters. However, it also is the case that a drug could have penny pricing for any given quarter and it could be appropriate to include penny priced drugs in the calculation of the average acquisition cost because in such cases, penny prices do represent the maximum (ceiling) price the 340B hospital would pay for that drug. Nonetheless, in order to provide for a more conservative discount estimate, we proposed to exclude penny priced drugs from our analysis, but solicited public comment on whether such a policy accurately represents 340B drug acquisition costs.

(e) Addressing Outliers

In response to the Detailed Survey, hospitals provided some drug acquisition cost data that exceeded 340B ceiling prices, and in some cases even exceeded the ASP or ASP+6 percent payment rate for certain drugs. As previously noted, covered entities cannot be required to pay more than the ceiling price to acquire a drug under the 340B program. Therefore, we attributed any Detailed Survey acquisition cost data greater than the ceiling price to potential data entry error; for instance, miscalculation or incorrect decimal point placement. However, because hospitals may have been overcharged for their drug acquisition costs and could have accurately reported acquisition costs greater than the HRSA ceiling price, we did not eliminate these data from our calculations. Instead, consistent with our standard methodology for processing extreme outliers under the OPPS, we excluded responses for any SCODs that were three standard deviations from the geometric mean. We believe applying a three standard deviation limit to the reported acquisition data is appropriate because it removes outliers from both the high and low reported values. In addition, applying a three standard deviations limit may be more representative of the respondents' acquisition cost, even though it may not eliminate some data values that are above the ceiling price. While this approach means that some values above the ceiling price will be included in our data analysis, we did not propose to trim them because we proposed to apply a standard trimming methodology. The cumulative application of this trimming methodology, along with other methodologies applied to the survey data described above, results in an average acquisition cost for drugs that hospitals acquire under the 340B program of ASP minus 34.7 percent. For the reasons previously discussed, we proposed to exclude survey data from the Detailed Survey that is more than three standard deviations from the mean. We note that we also explored capping any survey submissions received at the 340B ceiling price, as no covered entity can be required to pay more than the ceiling price. This approach, holding all other methodological approaches constant, would have resulted in an average acquisition cost of ASP minus 41.5 percent for drugs acquired under the 340B program.

Table 41, *Aggregate 340B Drug Program Cost Savings Percentage Relative to ASP,* shows the aggregate 340B drug program discount percentage relative to ASP using several different statistical measures. In this table, we outlined some additional figures following a similar path as described above. For example, we arrived at the 33.8 percent figure in Table 41 under median, and penny pricing excluded, by initially choosing the median as the averaging methodology, and then performing trimming methodologies as described above, which include volume weighting by HCPCS code, using the highest NDC per HCPCS code, and using only data within three standard deviations of the median. This would have resulted in a final proposed discount of 33.8 percent. While this final discount appears more generous to hospitals than our proposal, we do not believe it would be appropriate. Specifically, we believe using the

[81] *https://www.hrsa.gov/opa/updates/2015/may.html.*

[82] *https://www.govinfo.gov/content/pkg/FR-2017-01-05/pdf/2016-31935.pdf.*

geometric mean as outlined in the methodology above is the most generous methodology for establishing a final discount amount that also maintains accuracy and consistency with past OPPS practices. As described previously, under the OPPS, we generally calculate resource costs for a given service using the geometric mean. The geometric mean minimizes the effects of the outliers without ignoring them. As an additional example, under the arithmetic mean methodology with penny pricing included in Table 41, the final discount was determined to be 23.1 percent. We arrived at this figure of 23.1 percent by initially choosing the arithmetic mean as the averaging methodology, and then performing trimming methodologies as described above, with the exception of including penny prices in this figure. Similar to the discussion above regarding the use of the median, we do not think utilizing the arithmetic mean would be appropriate or consistent with the averaging methodologies historically used under the OPPS. The arithmetic mean could easily skew towards outlier data and anomalous data not captured by previously described trimming methodologies. Additionally, with this 23.1 percent figure, while penny pricing is a valid maximum (that is, ceiling) price for drugs to which it applies, as noted above we believed it was appropriate to exclude penny priced drugs for purposes of our proposal.

We explained in the CY 2021 OPPS/ASC proposed rule that we believe the manner in which we arrived at the proposed payment amount of ASP minus 34.7 percent for 340B-acquired drugs is an appropriate and accurate method of determining the average discount or typical discount. We also noted that we believe it is reflective of stakeholder's actual acquisition costs, and is as generous as possible without compromising accuracy. We explained that we believe the geometric mean is the most appropriate averaging methodology as it mitigates the effects of outliers relative to the arithmetic mean and median and is consistent with OPPS payment methodologies. Although ceiling prices are protected by statute and the respondents to the survey were given a pledge of confidentiality, we also emphasized that we were exploring and previously sought comment on the possibility of providing microdata to qualified researchers through their restricted access infrastructure, in accordance with best practices for transparency.

Table 41: AGGREGATE 340B DRUG PROGRAM COST SAVINGS PERCENTAGE RELATIVE TO ASP*

	Weighted by HCPCS Volume, Highest NDC per HCPCS used, and only Data with 3 Standard Deviations of the Mean					
	With Penny Pricing Included			With Penny Pricing Excluded		
	Arithmetic Mean	Median	Geometric Mean	Arithmetic Mean	Median	Geometric Mean
Average 2018Q4-2019Q1	23.1%	39.6%	39.4%	20.3%	33.8%	34.7%

* Based on Combined Survey Data.

(4) Determining an Add-on Payment for 340B Drugs

Under the OPPS, Medicare pays for separately payable drugs at rates that approximate their acquisition costs, such as at ASP or WAC. These drugs typically also receive an add-on payment. Under the OPPS, section 1833(t)(14)(E) authorizes, but does not require, the Secretary to make an adjustment to payment rates for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs.

In the MedPAC report from 2005,[83] MedPAC recommended that the Secretary:

- Establish separate, budget neutral payments to cover the costs that hospitals incur for handling separately paid drugs, biologicals, and radiopharmaceuticals;
- define a set of handling fee APCs that group drugs, biologicals, and radiopharmaceuticals based on attributes of the products that affect handling costs;
- instruct hospitals to submit charges for those APCs; and
- base payment rates for the handling fee APCs on submitted charges, reduced to costs.

Because we took a conservative approach in estimating the average acquisition costs for 340B-acquired drugs, we stated in the proposed rule that we did not believe that it was imperative to establish an add-on for overhead and handling as we believe that such a conservative estimate may already account for the costs of overhead and handling. In addition, our current 340B drug payment policy under the OPPS pays separately payable drugs at ASP minus 22.5 percent with no add-on payment because this payment rate represents the minimum average discount that a 340B entity would receive on a drug. We emphasized that we believe hospitals receive a significant margin on 340B drugs under our current policy, so an additional add-on payment is not necessary. Nonetheless, under the methodology in section 1847A, we explained that the Part B payments for separately payable drugs and biologicals furnished by practitioners and certain suppliers generally include an add-on set at 6 percent of the ASP for the specific drug. As discussed in the CY 2019 Physician Fee Schedule final rule with comment period (83 FR 59661–59662), the 6 percent add-on is widely believed to include services associated with drug acquisition that are not separately paid for, such as handling, storage, and other overhead. We noted

[83] *http://medpac.gov/docs/default-source/reports/June05_ch6.pdf?sfvrsn=0.*

that we realize that the acquisition costs for drugs acquired under the 340B program are significantly lower than for those drugs purchased outside of the 340B program, so we did not find it appropriate to base the add-on for 340B drugs on the 340B acquisition cost as previously discussed. However, we explained that we believe that it is reasonable to assume that a given drug will have similar overhead and other administrative costs regardless of whether the drug was purchased under the 340B Program or a by non-340B entity. Additionally, we stated that utilizing a drug add-on will ensure a level of payment parity with the add-on that applies to Part B drugs outside of the 340B program.

Therefore, for CY 2021 and subsequent years, we proposed to pay for drugs acquired under the 340B program at ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP, for a net payment rate of ASP minus 28.7 percent. Under this payment methodology, we explained that each drug would receive the same add-on payment regardless of whether it is paid at the 340B rate or at the traditional ASP rate for drugs not purchased under the 340B program. We noted that this add-on percentage would be more generous to hospitals than adding 6 percent of the reduced 340B rate. As an example, assuming a non-340B drug is paid its ASP of $1,000 and $60 for the 6 percent add-on, the 340B rate would be $653 ($1,000—$347) plus $60 or $713 total, instead of $653 plus $39.18 (6 percent of the reduced rate of $653) which would equal $39.18 or $692.18 total. We proposed that this payment methodology would be our Medicare payment policy for 340B-acquired drugs going forward for CY 2021 and subsequent years.

(5) 340B Payment Policy for Drugs for Which ASP Is Unavailable

As we clarified in the CY 2019 OPPS/ASC proposed rule, the 340B payment adjustment applies to drugs that are priced using either WAC or AWP, and it has been our policy to subject 340B-acquired drugs that use these pricing methodologies to the 340B payment adjustment since the policy was first adopted. We proposed the 340B payment adjustment for WAC-priced drugs would mirror that of ASP payment with payment being WAC minus 34.7 percent plus 6 percent of the drug's WAC, except for when WAC plus 3 percent policy applies under 1847A(c)(4) and as discussed in V.B.2.b., for which we would propose a payment rate of WAC minus 34.7 percent plus 3 percent of the drug's WAC. Previously, AWP-priced drugs have had a payment rate of 69.46 percent of AWP when the 340B payment adjustment is applied. The 69.46 percent of AWP was calculated by first reducing the original 95 percent of AWP price by 6 percent to generate a value that is similar to ASP or WAC with no percentage markup. Then we applied the 22.5 percent reduction to ASP/WAC-similar AWP value to obtain the 69.46 percent of AWP, which is similar to either ASP minus 22.5 percent or WAC minus 22.5 percent. Similarly, for CY 2021, we proposed to pay for drugs paid at AWP under the 340B program at 95 percent AWP first reduced by 6 percent to generate a value that is similar to ASP or WAC with no percentage mark up. Then we proposed to apply the net 28.7 percent reduction resulting in a payment rate of 63.90 percent of AWP.

(6) 340B Payment Policy Exemptions

In the CY 2018 OPPS/ASC proposed rule, we sought public comment on whether, due to access to care issues, certain groups of hospitals, such as those with special adjustments under the OPPS (for example, children's hospitals or PPS-exempt cancer hospitals) should be excepted from a policy to adjust OPPS payments for drugs acquired under the 340B program. Specifically, in accordance with section 1833(t)(7)(D)(ii) of the Act, we make transitional outpatient payments (TOPs) to both children's and PPS-exempt cancer hospitals. This means that these hospitals are permanently held harmless to their ''pre-BBA amount,'' and they receive hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS. Accordingly, if we were to reduce drug payments to these hospitals on a per claim basis, it is very likely that the reduction in payment would be paid back to these hospitals at cost report settlement, given the TOPs structure. We believed further study on the effect of the 340B drug payment policy was warranted for classes of hospitals that receive statutory payment adjustments under the OPPS. Accordingly, we stated that we continued to believe it is appropriate to exempt children's and PPS-exempt cancer hospitals from the alternative 340B drug payment methodology.

In addition to the children's and PPS-exempt cancer hospitals, Medicare has long recognized the particularly unique needs of rural communities and the financial challenges rural hospital providers face. Across the various Medicare payment systems, CMS has established a number of special payment provisions for rural providers to maintain access to care and to deliver high quality care to beneficiaries in rural areas. With respect to the OPPS, section 1833(t)(13) of the Act gave the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act. We have continued this 7.1 percent payment adjustment since 2006.

For CY 2021 and subsequent years, similar to previous years, we proposed that rural sole community hospitals (as described under the regulations at 42 CFR 412.92 and designated as rural for Medicare purposes), children's hospitals, and PPS-exempt cancer hospitals would be excepted from the 340B payment adjustment and that these hospitals continue to report informational modifier ''TB'' for 340B-acquired drugs, and continue to be paid ASP+6 percent. We may revisit our policy to exempt rural SCHs, as well as other the hospital types that are exempt from the 340B drug payment reduction, in future rulemaking.

As discussed in section V.B.2.c. of the CY 2019 OPPS/ASC proposed rule, we proposed to pay nonpass-through biosimilars acquired under the 340B Program at the biosimilar's ASP minus 22.5 percent of the biosimilar's ASP. Similarly, for CY 2021, we proposed to pay nonpass-through biosimilars acquired under the 340B Program at the biosimlar's ASP minus the net payment discount reduction, 34.7 percent plus an add-on of 6 percent, of the biosimilar's ASP, for a net payment rate of the biosimilar's ASP minus 28.7 percent of the biosimilar's ASP.

Summary of Proposed Policy

In summary, we proposed for CY 2021 and subsequent years to pay for drugs acquired under the 340B program at ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP, for a net payment rate of ASP minus 28.7 percent using the authority under section 1833(t)(14)(A)(iii)(I) of the Act.

This proposal included our previously discussed methodology used to arrive at the 34.7 percent average discount that we proposed to apply to all drugs acquired under the 340B program. This methodology included using the geometric mean of the survey data, volume weighting the average based upon utilization of the drug in the OPPS, using the highest priced NDC when multiple NDCs are available for a single HCPCS code, eliminating penny pricing from the average, and eliminating any data outside of 3 standard deviations from the mean when calculating the average discount of 34.7 percent. We explained in the proposed rule that our intent was that, if finalized, this payment methodology would apply beginning on January 1, 2021 and any changes to this permanent payment policy would be required to be adopted through notice and comment rulemaking. We also proposed that Rural SCHs, PPS-exempt cancer hospitals and children's hospitals would be exempted from the 340B payment policy for CY 2021 and subsequent years. Finally, we proposed in the alternative to continue our current policy of paying ASP minus 22.5 percent for 340B-acquired drugs as we prevailed on appeal to the D.C. Circuit in the litigation.

For the reasons discussed below, we are finalizing our alternative proposal to continue our current policy of paying ASP minus 22.5 percent for 340B-acquired drugs. However, we also summarize and respond below to the comments we received on our proposal to pay for 340B-acquired drugs at a net rate of ASP minus 28.7 percent based on survey data.

Comments Regarding 340B Survey Methodology and Implementation

Comment: Several commenters contended that CMS' plan to collect acquisition cost data from 340B hospitals only, and not from other providers that are paid under the OPPS, but that do not participate in the 340B program, violates section 1833(t)(14)(D)(iii) of the Act. Specifically, they stated that although the Medicare statute allows for a survey of hospitals based on drug acquisition costs, the statute does not allow the Secretary to use subclause (I) of section 1833(t)(14)(A)(iii) to target a subset of hospitals for the survey and subclause (II) of section 1833(t)(14)(A)(iii) for other non-340B hospitals. While commenters agreed that the Secretary has authority under section 1833(t)(14)(A)(iii)(I) to set payment rates that vary by hospital group based on relevant hospital characteristics such as volume of outpatient services, they maintained that the Secretary is not permitted to survey only one group of hospitals for acquisition costs for purposes of setting the payment rates under the OPPS. Furthermore, commenters stated that section 1833(t)(14)(D)(iii) requires that surveys conducted by the Secretary ''shall have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug (SCODs).'' Commenters continued to state that because the survey had what they contended was a low response rate, they believed CMS was unable to gain enough data to yield a statistically significant estimate of average hospital acquisition cost for each specified covered outpatient drug. Additionally, some of these commenters contended that the acquisition data collected in response to the survey only included data from the fourth quarter of 2018 and the first quarter of 2019, and that this was an inadequate sample due to yearly fluctuations in drug pricing.

Response: We disagree with the commenters' assertion that the manner in which we collected drug and biological acquisition cost data from 340B hospitals is inconsistent with the statute, as well as the commenters' interpretation of section 1833(t)(14)(D)(iii) that the survey of hospital acquisition costs for SCODs must be administered to all hospitals or all hospital types. Section 1833(t)(14)(D)(iii) does not require the Secretary to survey all hospitals, it requires Medicare to have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each SCOD. The statute does not prescribe how we develop the sampling methodology. Surveying 340B hospitals, for which average sales price (ASP) data does not serve as a reliable proxy for their acquisition costs, is necessary to accurately determine payment amounts for drugs acquired under the 340B program. However, we do not believe it is necessary to survey non-340B hospitals because our ASP data includes drug acquisition costs from these hospitals, which are an adequate proxy of the average drug acquisition costs of such providers. Surveying non-340B hospitals would unnecessarily burden such hospitals, for which we already have an adequate proxy for drug acquisition costs.

Unlike the reasonable proxy that exists for average acquisition drug costs for non-340B enrolled hospitals (that is, ASP data), the significant drug acquisition cost discounts that 340B participating hospitals receive are much greater than those received by hospitals not participating in the 340B program; accordingly, 340B enrollment status is a relevant characteristic for drug acquisition costs. The statutory provision at issue—section 1833(t)(14)(A)(iii)(I)—explicitly states that the average acquisition cost for a drug for a year ''at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics).'' We believe it is within the Secretary's discretion under section 1833(t)(14)(A)(iii)(I) to choose to distinguish between hospital groups based on whether or not they are covered entities eligible to receive drugs and biologicals at discounted rates under the 340B program. We also note that section 1833(t)(14)(D)(ii) refers to use of the hospital acquisition costs for SCODs in setting payment rates under subparagraph (A) of section 1833(t)(14), and therefore, we believe it is appropriate to read the two provisions together to permit the Secretary to survey 340B hospitals only. Conversely, no provision compels the Secretary to impose an unnecessary survey burden on non-340B hospitals, for which we have an adequate proxy for average acquisition drug costs. As previously stated, we believe the sampling timeframe is appropriate due to the numerous factors taken into consideration to provide a conservative estimate as well as the proposed application of the ASP reduction, which was proposed as a single reduction amount applied to each drug's ASP.

Comment: Some commenters had concerns with the survey response rate. Commenters stated that only providing approximately 3 weeks to complete the survey during the initial stages of the PHE was concerning. Commenters believed this was why CMS received what they contended was a low response rate of 62 percent (7 percent Detailed Surveys and 55 percent Quick Surveys). Several commenters who completed the Quick Survey noted in their comments that they chose this method due to it being the least burdensome option, and that ceiling prices were not necessarily reflective of their acquisition costs. For these reasons, commenters felt it would be inappropriate for CMS to base OPPS payment for 340B drugs on these survey results.

Response: We thank commenters for their feedback. We respectfully disagree with commenters' assertion that CMS received an inadequate response rate on

which to base OPPS payment for 340B-acquired drugs. As commenters noted, a combined 62 percent of the 340B participating providers responded to the survey through a Detailed or Quick Survey submission. For the remaining 38 percent of non-affirmative responders, we noted in the survey instructions that we would utilize 340B ceiling prices as proxies for the hospitals' highest possible acquisition costs. We believe the 340B ceiling price is a fair proxy for the hospitals' acquisition costs because hospitals cannot be required to pay more than the 340B ceiling price (and, in fact, often pay much less) for a 340B drug. Therefore, we explained in the proposed rule that we believed using the 340B ceiling price was the most conservative, and yet appropriate, way to calculate the discount for the 38 percent of non-affirmative responders.

Comment: Commenters were generally supportive of CMS' application of a 6 percent add-on based upon the product's ASP as part of our proposal to pay for 340B-acquired drugs under the OPPS based on survey data. Commenters did not find it appropriate to base payment on ASP minus 34.7 percent, which would not include a 6 percent add-on, and instead supported a payment amount of ASP minus 28.7 percent, which includes the 6 percent add-on. Commenters believed this add-on was necessary, and they felt it would be appropriate for the same drug to receive the same add-on payment regardless of whether it was purchased through the 340B program or at the current policy of ASP minus 22.5 percent.

Response: We thank the commenters for their support on this proposal. We still do not believe that it is imperative to establish an add-on for overhead and handling, as we believe that our conservative estimate of average acquisition costs may already account for the costs of overhead and handling. However, as explained further below, we are not finalizing our proposal to pay for 340B-acquired drugs based on hospital survey data at ASP minus 28.7 percent, which we proposed would include a 6 percent add-on. Nonetheless, we will consider this information for potential future rulemaking.

Comment: Commenters generally did not agree that our proposed methodology, including our use of 340B ceiling prices for Quick Survey respondents and as a proxy for non-affirmative responses, together with a 6 percent add-on, as well as the manner in which we calculated the proposed discount, yielded a conservative estimate of hospitals' costs to acquire 340B drugs. Commenters often stated that CMS should also take into consideration the costs that 340B entities incur to maintain their status and comply with 340B program requirements. Commenters contended that 340B program compliance costs are quite considerable and that CMS should consider these administrative costs in determining an OPPS payment rate for 340B-acquired drugs.

Response: As outlined in the section above, *Methodology to Calculate ASP Reduction Amount Based on Survey Data,* CMS considered numerous factors in order to calculate what we believe was a conservative discount amount. Section 1833(t)(14)(A)(iii)(I) authorizes the Secretary to set the amount of payment for SCODs at an amount equal to the average acquisition cost for the drug for that year, but the statute does not mention covering 340B program compliance cost. Accordingly, we do not believe it is necessary to provide additional payment for costs that commenters state they must pay in order to remain compliant with the 340B program. We reiterate that we do not believe CMS payment is required for these costs as Medicare payments for drugs are not intended to cross-subsidize other programs. Nonetheless, we believe that such a conservative estimate and the add-on of 6 percent of the product's ASP would already allow for a significant margin to offset these costs.

Comment: Commenters stated that not every entity is able to purchase all drugs at the 340B ceiling price and that some drugs must be purchased under WAC-based pricing. Furthermore, stakeholders contended that their systems are limited in determining which drugs were purchased at the 340B price and thus were limited in their ability to assign the ''JG'' modifier. Therefore, commenters stated they applied the ''JG'' modifier to all of their purchased drugs, even if the drug was purchased under WAC-based pricing. Commenters stated that WAC-based pricing is significantly higher than 340B pricing; 30 to 90 percent greater according to one stakeholder. Additionally, commenters believed using ceiling prices as proxies was a flawed methodology as these data do not come directly from those being surveyed, even if they are the highest prices hospitals can pay to acquire these drugs.

Response: The ceiling price is the maximum amount covered entities may permissibly be required to pay for a drug under section 340B(a)(1) of the Public Health Service Act, so we would not expect a 340B hospital to have acquisition costs for any drug that is acquired through the 340B program that are greater than the ceiling price. For this reason, where the acquisition price for a particular drug was not available or submitted in response to the survey, we stated that we would use the 340B ceiling price for that drug as a proxy for the hospital's acquisition cost in order to produce a conservative drug discount estimate when data was missing or not submitted. We believed using ceiling prices as proxies was the most appropriate option when drug acquisition cost information was not available, because this price represents the most conservative discount that a 340B entity could have received. In addition, while some commenters expressed generalized disagreement with our proposed approach, we did not receive any comments demonstrating that 340B hospitals pay more than the ceiling price for a particular drug, or that 340B hospitals pay more than ASP minus 28.7 for a particular drug when acquired under the 340B program at their negotiated 340B price. Thus, similar to our policy of paying ASP minus 22.5 percent, this proposed approach of paying ASP minus 28.7 percent appears to be in line with hospital acquisition costs for such drugs, which is reinforced by the fact that we did not receive public comments demonstrating that 340B hospitals pay more for particular drugs acquired under the 340B program. However, because we are not finalizing our proposal to pay for 340B drugs based on hospital survey data for CY 2021, we will take these comments into account for potential future rulemaking.

Additionally, the payment rate of ASP minus 22.5 percent only applies to drugs acquired under the 340B program and therefore, the ''JG'' modifier should only be appended to claim lines for these drugs. Hospitals should not append the ''JG'' modifier for drugs for which the hospital paid an amount based on WAC where the drug was not acquired under the 340B program.

Comment: Commenters generally did not make specific recommendations about CMS' methodology for calculating the reduction that would be applied to ASP for 340B-acquired drugs. Rather, most commenters expressed opposition to the policy in general. However, several commenters expressed support for CMS' exclusion of penny pricing in our calculation of the proposed payment rate. Additionally, several commenters encouraged CMS to eliminate any drugs with inflationary penalties, as the commenters believed these penalties are unevenly distributed among drugs and

among hospitals and may skew our data if included. Additionally, some commenters were not supportive of CMS' volume weighting methodology. Commenters stated that taking into account how often those drugs were billed by all hospitals under the OPPS for 2018 and 2019 was inappropriate as 340B utilization may differ from all OPPS hospital utilization.

Response: We thank commenters for their input on our proposal. We believe the methodology for developing the proposed payment adjustment appropriately provided for a conservative estimate for the ASP reduction. At this time, we do not believe it would be appropriate to eliminate all drugs with inflationary penalties; however, we will take this point into consideration for future potential rulemaking. Additionally, as outlined in our summary above, our volume weighting methodology took into account how often drugs were billed by all hospitals under the OPPS for 2018 and 2019, to better reflect each drug's overall utilization under the OPPS. We calculated the average discount by taking the utilization of each drug under the OPPS into account to arrive at a case-weighted average for each HCPCS code. Therefore, we volume-weighted the drug discounts determined from the survey to mirror the drug utilization in the OPPS. We note that the 340B hospitals drug utilization pattern did not vary significantly from the overall OPPS utilization. Therefore, drugs that were commonly used were assigned a higher weight while those less commonly used were assigned a lower weight. For example, a highly utilized HCPCS code for an oncology drug would be weighted higher than that of a drug for snake anti-venom that has a relative low utilization in the OPPS. We incorporated volume weighting into our analysis by assessing the utilization rate of each individual drug (using its HCPCS code) under the OPPS for CY 2018 and CY 2019. For the purposes of creating an average discount, we believe this is the most appropriate methodology. Nonetheless, we will consider these comments for potential future rulemaking.

Comment: Several commenters asked for the release of data that CMS used in order to calculate the 340B payment reduction. Commenters expressed a desire to replicate CMS' calculations based on the data submitted in response to the 340B Drug Acquisition Cost Survey.

Response: We do not intend to release an individual hospitals' SCOD acquisition cost data to the public. During the Paperwork Reduction Act process for the 340B survey, we pledged to maintain the confidentiality of individual responses that include acquisition prices for each SCOD to the extent required by law. However, we stated we would make average acquisition prices reported for SCODs across all hospitals surveyed public. We believe the confidentiality of drug prices applies to individual drugs purchased by individual hospitals, which we have no intent to make public. Additionally, this confidentiality extends to the ceiling prices used in the survey. Therefore, we are unable to publicly disclose the ceiling prices for the same reason. As we stated in the proposed rule, we are exploring the possibility of providing microdata to qualified researchers through their restricted access infrastructure, in accordance with best practices for transparency. We will continue to explore if there is an appropriate method in which to release microdata to qualified researchers.

e. Alternative Proposal To Continue Policy To Pay ASP Minus 22.5 Percent

Previously, we adopted the OPPS 340B payment policy based on the average minimum discount for 340B-acquired drugs being approximately ASP minus 22.5 percent. The estimated discount was based on a MedPAC analysis identifying 22.5 percent as a conservative minimum discount that 340B entities receive when they purchase drugs under the 340B program, which we discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52496). We continue to believe that ASP minus 22.5 percent is an appropriate payment rate for 340B-acquired drugs under the authority of 1833(t)(14)(A)(iii)(II) for the reasons we stated when we adopted this policy in CY 2018 (82 FR 59216). On July 31, 2020, the D.C. Circuit reversed the decision of the district court, holding that this interpretation of the statute was reasonable. Therefore, we also proposed in the alternative that the agency could continue the current Medicare payment policy for CY 2021. If adopted, we stated that this proposed policy would continue the current Medicare payment policy for CY 2021.

Based on feedback from stakeholders, we believe maintaining the current payment policy of paying ASP minus 22.5 percent for 340B drugs is appropriate in order to maintain consistent and reliable payment for these drugs both for the remainder of the PHE and after its conclusion to give hospitals some certainty as to payments for these drugs. Continuing our current policy also gives us more time to conduct further analysis of hospital survey data for potential future use for 340B drug payment. We note that any changes to the current 340B payment policy would be adopted through public notice and comment rulemaking.

While we believe our methods to conduct the 340B Drug Acquisition Cost Survey, as well as the methodology we used to calculate the proposed average or typical discount received by 340B entities on 340B drugs, are valid, we nonetheless recognize stakeholders' concerns. As described above, the utilization of the survey data is complex, and we wish to continue to evaluate how to balance and weigh the use of the survey data, the necessary adjustments to the data, and the weighting and incorporation of ceiling prices—all to determine how best to take the relevant factors into account for potentially using the survey to set Medicare OPPS drug payment policy. We appreciate the feedback from commenters and will continue to assess it as we explore whether survey data should be considered hospital acquisition cost data for purposes of paying for drugs acquired under section 1833(t)(14)(A)(iii)(I) in future years.

Comments on Maintaining Current 340B Payment Reduction of ASP Minus 22.5 Percent

Comment: A few commenters voiced their support for the current OPPS payment policy for 340B-acquired drugs. These commenters generally believed that approximating payment based on acquisition costs is appropriate; however, they also recommended reform to the 340B program itself.

Response: We thank the commenters for their support of our 340B payment policies. We note that comments related to reform of the 340B program are out of scope for purposes of this final rule, and we also note that the 340B program is administered by the Health Resources and Services Administration, not CMS; however, we thank commenters for their input.

Comment: Many commenters did not support CMS finalizing the proposal to pay a net payment rate of ASP minus 28.7 percent for 340B-acquired drugs. These commenters stated that they opposed any reduction in payment for 340B drugs in general, but preferred the proposal to maintain ASP minus 22.5 percent if CMS continued to adjust payment for 340B drugs. Commenters stated that the profits derived from participation in the 340B program allowed them to deliver charity or uncompensated care to their patients. Commenters detailed a wide variety of programs that they fund with profits

from the 340B program, and stated they may not be able to continue these programs without profits from Medicare payments for 340B-acquired drugs. Many commenters stated that the current 340B payment rate has hurt hospitals financially and undermined hospitals' ability to provide safety-net care to their low-income patients, thereby threatening the patients' access to care. They stated that any policy proposal to reduce payment for 340B-acquired drugs was contrary to the congressional intent for the 340B program. Commenters asserted that CMS should pay hospitals participating in the 340B program the statutory default payment amount of ASP plus 6 percent.

Response: We note that we have not seen evidence that the current OPPS 340B drug payment policy has limited patient access to 340B drugs. Further, Medicare payments for drugs are not intended to cross-subsidize other programs. As noted in the CY 2018 OPPS/ASC final rule with comment period, we continue to believe that ASP minus 22.5 percent for drugs acquired through the 340B Program represents the average minimum discount that 340B enrolled hospitals receive. Additionally, as discussed throughout this section, the proposed payment reduction based on the survey data was calculated in a conservative manner. We disagree with commenters that the OPPS 340B payment policy has had a negative impact on Medicare patients and are not aware of any access issues related to the implementation of this policy. Further, we note that under the current policy, Medicare patients who receive 340B drugs for which the Medicare program paid ASP minus 22.5 percent have much lower cost sharing than if these beneficiaries received 340B drugs for which the Medicare program paid ASP+6 percent. As a result, we continue to believe that ASP minus 22.5 percent is a reasonable payment rate for these drugs. We note that the 340B drug payment policy is consistent with our authority under the statute, as confirmed by the D.C. Circuit's decision. As explained further below, we are finalizing our proposal to continue our current policy of generally paying under the OPPS for 340B-acquired drugs at ASP minus 22.5 percent.

Comment: We received several comments regarding OPPS payment for biosimilars acquired under the 340B program. Commenters suggested a variety of modified payment methodologies for biosimilars. Some commenters believed biosimilars should be excluded from the adjustment for 340B-acquired drugs altogether, and some commenters stated if CMS moves forward with the net reduction of ASP minus 28.7 percent, the agency should maintain the reduction for biosimilars at ASP minus 22.5 percent. Additionally, several commenters suggested the add-on payment of 6 percent should be based on the reference product's ASP when calculating the net payment rate for biosimilars under the survey methodology. Finally, some commenters had concerns that new biosimilars on pass-through status would have a competitive advantage over its reference product.

Response: We are finalizing our alternate proposal to continue paying for 340B-acquired drugs under the OPPS at a rate of ASP − 22.5 percent, and thus we do not believe any changes to our biosimilar policy are necessary for CY 2021. We believe the continuation of our current biosimilar policy will allow for appropriate payment and access to these important treatments. Regarding comments related to biosimilars and the perceived competitive advantage, we do not believe that the temporary payments provided by pass-through status will create the substantial competitive advantage that commenters described. We also note we are continuing the policy from previous years regarding biosimilars and 340B payment, under which we will pay ASP minus 22.5 percent of the biosimilar's ASP. We thank the commenters for the comments regarding biosimilar add-on payment under the survey methodology (ASP minus a net 28.7 percent), and we will take these comments into consideration for potential future rulemaking. Please see section V.B.2.C. for additional discussion regarding biosimilars and section V.A.1. for additional discussion on drug pass-through payments.

Comment: Many commenters opposed both the CY 2021 proposal to pay for drugs acquired under the 340B program at the net payment rate of ASP minus 28.7 percent, as well as the alternative proposal of continuing the current 340B program payment reduction of ASP minus 22.5 percent. These commenters urged CMS to withdraw its proposed policy and contended that the policy was an unlawful application of the CMS' authority.

Commenters also stated that reducing payment for drugs acquired through the 340B Program does not help reduce high drug costs. Many commenters opposed the current 340B policy and argued that it takes away resources designated for safety net hospitals to subsidize non-340B hospitals because the payment reduction is budget neutral. The commenters requested that CMS end its policy of paying for drugs obtained through the 340B program at ASP minus 22.5 percent and restore the statutory default payment rate of ASP plus 6 percent.

Response: We respectfully disagree with the commenters' assertions that our 340B drug payment policy is illegal or an unlawful application of the law. It is also beyond the scope of the CY 2021 rulemaking, nor is it the intent of the 340B payment policy to address all aspects of a larger drug pricing issue. We disagree with commenters that the OPPS 340B payment policy has taken away resources designated for safety net hospitals, and we are not aware of any access to care issues related to the implementation of this policy. As discussed in this section of the CY 2021 final rule with comment period, the D.C. Circuit has confirmed that our 340B drug payment policy is within our authority in section 1833(t)(14) of the Act. Thus, we are finalizing our alternate proposal, without modification, to continue to pay ASP minus 22.5 percent for 340B-acquired drugs, including when furnished in nonexcepted off-campus PBDs paid under the PFS. Our final policy continues the 340B Program policies that were implemented in CY 2018 with the exception of the way we are calculating payment for 340B-acquired biosimilars, which is discussed in section V.B.2.c. of the CY 2019 OPPS/ASC final rule with comment period, and continues the policy we finalized in CY 2019 to pay ASP minus 22.5 percent for 340B-acquired drugs and biologicals furnished in nonexcepted off-campus PBDs paid under the PFS.

Furthermore, although we are finalizing our alternate proposal, without modification, to pay ASP minus 22.5 percent for 340B-acquired drugs, we believe our proposal to pay for 340B-acquired drugs at ASP minus 34.7 percent based on hospital survey data, plus an add-on of 6 percent of the product's ASP, for a net payment rate of ASP minus 28.7 percent could be within the Secretary's authority under section 1833(t)(14). The 340B payment rate proposal of ASP minus 28.7 percent was based on drug acquisition cost data derived from the CMS 2020 Hospital Acquisition Cost Survey for 340B-Acquired SCODs, authorized under subclause 1833(t)(14)(D). Specifically, we applied the statutory authority under section 1833(t)(14)(A)(iii)(I) to collect 340B drug acquisition cost data and limited our survey to the 340B hospital groups. A more detailed discussion of the CMS 2020 Hospital Acquisition Cost Survey methodology is included earlier in this section. Although we are continuing the current 340B payment

policy, we will continue to consider the 340B drug payment rate of under the ASP minus 34.7 percent, plus an add-on of 6 percent of the product's ASP, for a net payment rate of ASP minus 28.7 percent in potential future rulemaking.

Comment: Several commenters stated that CMS has not provided sufficient analysis for the continuation of the 340B payment policy, believing that CMS has not considered changes in utilization and volume for hospitals that are actively participating in the 340B program since the policy was initially proposed in 2017. They further noted that CMS has not analyzed the impact of the prior year reimbursement changes for drugs acquired under the 340B program for the affected hospitals. They also contended that CMS has not provided evidence that the payment policy remains budget neutral by recalculating the policy's impact to make sure the conversion factor is properly adjusted.

Response: In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), we implemented the 340B drug payment policy and adjusted the payment rate for separately payable drugs and biologicals (other than drugs with pass-through payment status and vaccines) acquired under the 340B Program. This adjustment changed the payment rate from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent for drugs subject to this policy. In that rule, we stated that our goal was to make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs. We believe the current 340B drug payment policy reflects the average minimum discount that 340B participating hospitals receive for drugs acquired under the 340B Program and we believe it is inappropriate for Medicare to subsidize other programs through Medicare payments for separately payable drugs. While commenters remarked on the continuation of this policy since CY 2018, the commenters did not provide us with any evidence that ASP minus 22.5 percent is no longer a conservative estimate of their drug acquisition costs. Moreover, we note that the data collected in our 2020 Hospital Acquisition Cost Survey for 340B-acquired SCODs found the average 340B program drug discount to be 34.7 percent. Additionally, in the CY 2021 OPPS/ASC proposed rule (85 FR 48890), we proposed that we could continue the current Medicare 340B payment policy of ASP minus 22.5 percent as an alternative, as the D.C. Circuit concluded that this policy was a reasonable application of the Secretary's statutory authority under 1833(t)(14)(A)(iii)(II) of the Act.

With respect to OPPS budget neutrality and the conversion factor, OPPS budget neutrality is generally developed on a prospective basis by isolating the effect of any changes in payment policy or data under the prospective OPPS with all other factors held constant. We note that since the CY 2018 implementation of the 340B drug payment policy in which we developed a budget neutrality adjustment for the policy, the adjusted percentage payment has remained at ASP minus 22.5 percent. As a result, while some of the claims may change based on drug payment and billing, as indicated by the ''JG'' modifier, these drugs, including their utilization and expected payments, would be included as part of the broader budget neutrality adjustments, but collectively they would not have a separate budget neutrality adjustment specifically for the 340B drug payment policy. We note that in rulemaking where we proposed to establish or modify the adjustment, we have included in the impact analysis the estimated effects on different categories of providers based on the policy. Finally, we note that we monitor the payment and utilization patterns associated with this adjustment and for drug spending more broadly, and will continue to do so.

Comment: Several commenters expressed confusion as to whether our proposed policy would affect drugs purchased at their retail pharmacies or whether this payment reduction applied to Federally Qualified Health Centers (FQHCs).

Response: The 340B payment policy originally adopted in the CY 2018 OPPS/ASC final rule with comment period and continued in subsequent years applies to certain hospitals paid under the OPPS. 340B payment policy exceptions under the OPPS include rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals. FQHCs and retail pharmacies are not paid under the OPPS, and therefore are not affected by this policy.

Comment: As previously discussed, several commenters recommended CMS avoid any further action on a 340B payment reduction until the issue is settled in the courts. Commenters noted that although CMS prevailed in the D.C. Circuit, a petition for a rehearing was filed on September 14, 2020. Commenters believed CMS should wait until this decision has been finalized by the courts before moving forward with a continuation of the 340B payment reduction.

Response: On October 16, 2020, the D.C. Circuit denied the appellees' petition for rehearing en banc. We believe our 340B drug payment policy is within the Secretary's statutory authority at 1833(t)(14)(A)(iii)(II) of the Act, which was confirmed by the D.C. Circuit. Thus, we are finalizing our alternate proposal, without modification, to continue our current policy of paying ASP minus 22.5 percent for 340B-acquired drugs.

Comment: Several commenters requested that we make our 340B policy exemptions permanent. Additionally, commenters asked CMS to extend the exemption to urban SCHs, Medicare Dependent Hospitals, and Rural Referral Centers.

Response: We thank commenters for their recommendations. At this time, we do not believe it is appropriate to revise our policy on 340B policy exemptions and we believe we should maintain our current policy. Nonetheless, we will take these comments into consideration for future rulemaking.

Summary of Finalized Policy

We are finalizing our alternate proposal, without modification, to continue our current policy of paying ASP minus 22.5 percent for 340B-acquired drugs and biologicals, including when furnished in nonexcepted off-campus PBDs paid under the PFS. Our finalized policy continues the 340B Program policies that were implemented in CY 2018 with the exception of the way we are calculating payment for 340B-acquired biosimilars, which is discussed in section V.B.2.c. of the CY 2019 OPPS/ASC final rule with comment period, and would continue the policy we finalized in CY 2019 to pay ASP minus 22.5 percent for 340B-acquired drugs and biologicals furnished in nonexcepted off-campus PBDs paid under the PFS. We are also continuing the 340B payment adjustment for WAC-priced drugs, which is WAC minus 22.5 percent. 340B-acquired drugs that are priced using AWP will continue to be paid an adjusted amount of 69.46 percent of AWP.

Additionally, we are finalizing our proposal to continue to exempt rural sole community hospitals (as described under the regulations at 42 CFR 412.92 and designated as rural for Medicare purposes), children's hospitals, and PPS-exempt cancer hospitals from the 340B payment adjustment. These hospitals must continue to report informational modifier ''TB'' for 340B-acquired drugs, and will continue to be paid ASP plus 6 percent. We may revisit our policy to exempt rural SCHs, as well

as other hospital types, from the 340B drug payment reduction in future rulemaking. Finally, we are continuing to require hospitals to use of modifiers to identify 340B-acquired drugs. We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59370) for a full discussion and rationale for the CY 2018 policies and the requirements for use of modifiers ''JG'' and ''TB''. We note that any future changes to our policy regarding payment for 340B drugs will be adopted through notice and comment rulemaking.

7. High Cost/Low Cost Threshold for Packaged Skin Substitutes

a. Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74938), we unconditionally packaged skin substitute products into their associated surgical procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure. As part of the policy to package skin substitutes, we also finalized a methodology that divides the skin substitutes into a high cost group and a low cost group, in order to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures (78 FR 74933).

Skin substitutes assigned to the high cost group are described by HCPCS codes 15271 through 15278. Skin substitutes assigned to the low cost group are described by HCPCS codes C5271 through C5278. Geometric mean costs for the various procedures are calculated using only claims for the skin substitutes that are assigned to each group. Specifically, claims billed with HCPCS code 15271, 15273, 15275, or 15277 are used to calculate the geometric mean costs for procedures assigned to the high cost group, and claims billed with HCPCS code C5271, C5273, C5275, or C5277 are used to calculate the geometric mean costs for procedures assigned to the low cost group (78 FR 74935).

Each of the HCPCS codes described earlier are assigned to one of the following three skin procedure APCs according to the geometric mean cost for the code: APC 5053 (Level 3 Skin Procedures): HCPCS codes C5271, C5275, and C5277); APC 5054 (Level 4 Skin Procedures): HCPCS codes C5273, 15271, 15275, and 15277); or APC 5055 (Level 5 Skin Procedures): HCPCS code 15273). In CY 2020, the payment rate for APC 5053 (Level 3 Skin Procedures) was $497.02, the payment rate for APC 5054 (Level 4 Skin Procedures) was $1,622.74, and the payment rate for APC 5055 (Level 5 Skin Procedures) was $2,766.13. This information also is available in Addenda A and B of the CY 2020 OPPS/ASC final rule with comment period, correction notice (which is available via the internet on the CMS website).

We have continued the high cost/low cost categories policy since CY 2014, and we proposed to continue it for CY 2021. Under this current policy, skin substitutes in the high cost category are reported with the skin substitute application CPT codes, and skin substitutes in the low cost category are reported with the analogous skin substitute HCPCS C-codes. For a discussion of the CY 2014 and CY 2015 methodologies for assigning skin substitutes to either the high cost group or the low cost group, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 74932 through 74935) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66882 through 66885).

For a discussion of the high cost/low cost methodology that was adopted in CY 2016 and has been in effect since then, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434 through 70435). Beginning in CY 2016 and in subsequent years, we adopted a policy where we determined the high cost/low cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. We assigned each skin substitute that exceeded either the MUC threshold or the PDC threshold to the high cost group. In addition, we assigned any skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group (84 FR 61327 through 61328).

However, some skin substitute manufacturers have raised concerns about significant fluctuation in both the MUC threshold and the PDC threshold from year to year using the methodology developed in CY 2016. The fluctuation in the thresholds may result in the reassignment of several skin substitutes from the high cost group to the low cost group which, under current payment rates, can be a difference of approximately $1,000 in the payment amount for the same procedure. In addition, these stakeholders were concerned that the inclusion of cost data from skin substitutes with pass-through payment status in the MUC and PDC calculations would artificially inflate the thresholds. Skin substitute stakeholders requested that CMS consider alternatives to the current methodology used to calculate the MUC and PDC thresholds and also requested that CMS consider whether it might be appropriate to establish a new cost group in between the low cost group and the high cost group to allow for assignment of moderately priced skin substitutes to a newly created middle group.

We share the goal of promoting payment stability for skin substitute products and their related procedures as price stability allows hospitals using such products to more easily anticipate future payments associated with these products. We have attempted to limit year-to-year shifts for skin substitute products between the high cost and low cost groups through multiple initiatives implemented since CY 2014, including: Establishing separate skin substitute application procedure codes for low-cost skin substitutes (78 FR 74935); using a skin substitute's MUC calculated from outpatient hospital claims data instead of an average of ASP+6 percent as the primary methodology to assign products to the high cost or low cost group (79 FR 66883); and establishing the PDC threshold as an alternate methodology to assign a skin substitute to the high cost group (80 FR 70434 through 70435).

To allow additional time to evaluate concerns and suggestions from stakeholders about the volatility of the MUC and PDC thresholds, in the CY 2018 OPPS/ASC proposed rule (82 FR 33627), we proposed that a skin substitute that was assigned to the high cost group for CY 2017 would be assigned to the high cost group for CY 2018, even if it does not exceed the CY 2018 MUC or PDC thresholds. We finalized this policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59347). We stated in the CY 2018 OPPS/ASC proposed rule that the goal of our proposal to retain the same skin substitute cost group assignments in CY 2018 as in CY 2017 was to maintain similar levels of payment for skin substitute products for CY 2018 while we study our skin substitute payment methodology to determine whether refinements to the existing policies are consistent with our policy goal of providing payment stability for skin substitutes.

We stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59347) that we would continue to study issues related to the payment of skin

substitutes and take these comments into consideration for future rulemaking. We received many responses to our request for comments in the CY 2018 OPPS/ASC proposed rule about possible refinements to the existing payment methodology for skin substitutes that would be consistent with our policy goal of providing payment stability for these products. In addition, several stakeholders have made us aware of additional concerns and recommendations since the release of the CY 2018 OPPS/ASC final rule with comment period. As discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58967 through 58968), we identified four potential methodologies that have been raised to us that we encouraged the public to review and provide comments on. We stated in the CY 2019 OPPS/ASC final rule with comment period that we were especially interested in any specific feedback on policy concerns with any of the options presented as they relate to skin substitutes with differing per day or per episode costs and sizes and other factors that may differ among the dozens of skin substitutes currently on the market.

For CY 2020, we sought more extensive comments on the two policy ideas that generated the most comment from the CY 2019 comment solicitation. One of the ideas was to establish a payment episode between 4 to 12 weeks where a lump-sum payment would be made to cover all of the care services needed to treat the wound. There would be options for either a complexity adjustment or outlier payments for wounds that require a large amount of resources to treat. The other policy idea would be to eliminate the high cost and low cost categories for skin substitutes and have only one payment category and set of procedure codes for the application of all graft skin substitute products.

b. Discussion of CY 2019 and CY 2020 Comment Solicitations for Episode-Based Payment for Graft Skin Substitute Procedures

The methodology that commenters discussed most in response to our comment solicitation in CY 2019 and that stakeholders raised in subsequent meetings we have had with the wound care community has been a lump-sum ''episode-based'' payment for a wound care episode. Commenters that supported an episode-based payment believe that it would allow health care professionals to choose the best skin substitute to treat a patient's wound and would give providers flexibility with the treatments they administer. These commenters also believe an episode-based payment helps to reduce incentives for providers to use excessive applications of skin substitute products or use higher cost products to generate more payment for the services they furnish. In addition, they believe that episode-based payment could help with innovations with skin substitutes by encouraging the development of products that require fewer applications. These commenters noted that episode-based payment would make wound care payment more predictable for hospitals and provide incentives to manage the cost of care that they furnish. Finally, commenters that supported an episode-based payment believe that workable quality metrics can be developed to monitor the quality of care administered under the payment methodology and limit excessive applications of skin substitutes.

However, many commenters opposed establishing an episode-based payment. One of the main concerns of commenters who opposed episode-based payment was that wound care is too complex and variable to be covered through such a payment methodology. These commenters stated that every patient and every wound is different; therefore, it would be very challenging to establish a standard episode length for coverage. They noted that it would be too difficult to risk-stratify and specialty-adjust an episode-based payment, given the diversity of patients receiving wound care and their providers who administer treatment, as well as the variety of pathologies covered in treatment. Also, these commenters questioned how episodes would be defined for patients when they are having multiple wounds treated at one time or have another wound develop while the original wound was receiving treatment. These commenters expressed concerns that episode-based payment would be burdensome both operationally and administratively for providers. They believe that CMS will need to create a large number of new APCs and HCPCS codes to account for all of the patient situations that would be covered with an episode-based payment, which would increase provider burden. Finally, these commenters had concerns about the impact of episode-based payment on the usage of higher cost skin substitute products. They believe that a single payment could discourage the use of higher-cost products because of the large variability in the cost of skin substitute products, which could limit innovations for skin substitute products.

The wide array of views on episode-based payment for skin substitute products and the unforeseen issues that may arise from the implementation of such a policy encouraged us to continue to study the issues associated with episode-based payment. Therefore, we sought further comments from stakeholders and other interested parties regarding skin substitute payment policies that could be applied in future years to address concerns about excessive utilization and spending on skin substitute products, while avoiding administrative issues such as establishing additional HCPCS codes to describe different treatment situations.

One possible policy construct that we sought comments on was whether to establish a payment period for skin substitute application services (CPT codes 15271 through 15278 and HCPCS codes C5271 through C5278) between 4 weeks and 12 weeks. Under this option, we could also assign CPT codes 15271, 15273, 15275, and 15277, and HCPCS codes C5271, C5273, C5275, and C5277 to comprehensive APCs with the option for a complexity adjustment that would allow for an increase in the standard APC payment for more resource-intensive cases. Our research has found that most wound care episodes require one to three skin substitute applications. Those cases would likely receive the standard APC payment for the comprehensive procedure. Then the complexity adjustment could be applied for the relatively small number of cases that require more intensive treatments.

Several commenters were in favor of establishing a comprehensive APC with either an option for a complexity adjustment or outlier payments to pay for higher cost skin substitute application procedures. The commenters supported the idea of having a traditional comprehensive APC payment for standard wound care cases with a complexity adjustment or outlier payment to handle complicated or costly cases. However, they also expressed concerns about how many payment levels would be available in the skin substitute procedures APC group since a complexity adjustment can only be used if there is an existing higher-paying APC to which the service receiving the complexity adjustment may be assigned. A couple of commenters wanted more opportunities for services to receive a complexity adjustment through using clusters of procedure codes that reflect the full range of wound care services a beneficiary receives instead of using code pairs to determine if a complexity adjustment should apply. Other commenters suggested that episodic

payments be risk-adjusted to account for clinical conditions and co-morbidities of beneficiaries with outlier payments and that complexity adjustments be linked to beneficiaries with more comorbidities.

Some commenters opposed the idea of a complexity adjustment for skin substitute application procedures. The commenters stated there was not enough detail in the comment solicitation to understand how a complexity adjustment would work with an episodic payment arrangement. Commenters also expressed concerns that payment rates for comprehensive APCs may not be representative of the wound care services that would be paid within those APCs. One commenter stated that payment policy is not the right way to resolve issues with the over-utilization and inappropriate use of skin substitutes because they are concerned that major changes in payment methodology, such as episodic payment, could lead to serious issues with the care beneficiaries receive. In recent meetings, stakeholders have expressed concerns that establishing a comprehensive APC for graft skin substitute procedures could lead to other unrelated wound care services such as hyperbaric oxygen treatments being bundled into those procedures. Some stakeholders have provided suggestions to provide additional payment for the treatment of complicated wounds, similar to a complexity adjustment, without bundling unrelated wound care services.

The additional comments we received in CY 2020 related to including a complexity adjustment with an episode-based payment, along with the comments we received on episode-based payment in general from the CY 2019 comment solicitation, show that there are many issues that continue to require study for this payment methodology. In addition, we also need more time to assess the benefits and drawbacks of episode-based payment compared to other possible options to change the payment methodology for graft skin substitute procedures. Therefore, in the CY 2021 OPPS/ASC proposed rule, we stated that will continue our review of the feasibility of using episode-based payment for graft skin substitute procedures, and we did not propose any episode-based payment for these procedures.

Comment: Several commenters expressed either their support for or their concerns about establishing episode-based payment for graft skin substitute procedures. Commenters made many suggestions about how a payment episode should be constructed and which services should be included or excluded from a payment episode.

Response: We appreciate the feedback we received from the commenters. We will continue to study issues related to changing the methodology for paying for skin substitute products and procedures for possible future rulemaking.

c. Discussion of CY 2019 and CY 2020 Comment Solicitations To Have a Single Payment Category for Graft Skin Substitute Procedures

Another policy option on which we solicited comments in CY 2019 and CY 2020 was to eliminate the high cost and low cost categories for skin substitutes and have only one payment category and set of procedure codes for the application of all graft skin substitute products. Under this option, the only available procedure codes to bill for graft skin substitute procedures would be CPT codes 15271 through 15278. HCPCS codes C5271 through C5278 would be eliminated. Providers would bill CPT codes 15271 through 15278 without having to consider either the MUC or PDC of the graft skin substitute product used in the procedure. There would be only one APC for the graft skin substitute application procedures described by CPT codes 15271 (Skin sub graft trnk/arm/leg), 15273 (Skin sub grft t/arm/lg child), 15275 (Skin sub graft face/nk/hf/g), and 15277 (Skin sub grft f/n/hf/g child). The payment rate would be based on the geometric mean cost of all graft skin substitute procedures for a given CPT code that are paid through the OPPS. For example, under the current skin substitute payment policy, there are two procedure codes (CPT code 15271 and HCPCS code C5271) that are reported for the procedure described as ''*application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area*''.

Commenters who supported this option believed it would remove the incentives for manufacturers to develop and providers to use high cost skin substitute products and would lead to the use of lower cost, quality products. Commenters noted that lower Medicare payments for graft skin substitute procedures would lead to lower copayments for beneficiaries. In addition, commenters believe a single payment category would reduce incentives to apply skin substitute products in excessive amounts. Commenters and stakeholders also believe a single payment category is clinically justified because they stated that many studies have shown that no one skin substitute product is superior to another. Supporters of a single payment category believed it would simplify coding for providers and reduce administrative burden. Finally, some stakeholders believed that a single payment category policy could serve as a transitional payment policy for graft skin substitute products while we continue to study the feasibility of establishing an episode-based payment for skin substitutes.

Most commenters and stakeholders were opposed to a single payment category for skin substitute products. Commenters and stakeholders stated that the large difference in resource costs between higher cost and lower cost skin substitute products would provide an incentive for hospitals to use the most inexpensive products, which would hurt both product innovation and the quality of care beneficiaries receive. Commenters and stakeholders were concerned that a single payment category would encourage providers to choose financial benefit over clinical efficacy when determining which skin substitute products to use.

These commenters and stakeholders also stated that a single payment category would increase incentives for providers to use cheaper products that require more applications to generate more revenue and emphasize volume over value. A couple of commenters believed that overall Medicare spending on skin substitutes would be higher with a single payment category than under the current payment methodology, which has separate payment for higher cost and lower cost skin substitutes. The reason spending would increase according to the commenters is that overpayment for low cost skin substitutes by Medicare would exceed the savings Medicare would receive on reduced payments for higher cost skin substitutes.

Further, commenters and stakeholders stated that a single payment rate would lead to too much heterogeneity in the products receiving payment through the skin substitute application procedures. That is, the same payment rate would apply to skin substitute products whether they cost less than $10 per cm^2 or over $200 per cm^2 and regardless of the type of wound they treat. Commenters and stakeholders would prefer to have multiple payment categories where the payment rate is more reflective of the cost of the product. Commenters and stakeholders believe that a single payment category would discourage providers from treating more complicated wounds and wounds larger than 100 cm^2.

The responses to the comment solicitation indicated that a single payment category could potentially reduce the cost of wound care services for graft skin substitute procedures for both beneficiaries and Medicare. In addition, a single payment category may help reduce administrative burden for providers. Conversely, we are cognizant of other commenters' concerns that a single payment category may hinder innovation of new graft skin substitute products and cause some products that are currently well-utilized to leave the market. Nonetheless, we are persuaded that a single payment category could potentially provide a more equitable payment for many products used with graft skin substitute procedures, while recognizing that procedures performed with expensive skin substitute products would likely receive substantially lower payment.

We believe some of the concerns that commenters who oppose a single payment category for skin substitute products raised might be mitigated if stakeholders have a period of time to adjust to the changes inherent in establishing a single payment category. Accordingly in CY 2020, we solicited public comments that provide additional information about how commenters believe we should transition from the current low cost/high cost payment methodology to a single payment category.

Such suggestions to facilitate the payment transition from a low cost/high cost payment methodology to a single payment category methodology included—

- Delaying implementation of a single category payment for 1 or 2 years after the payment methodology is adopted; and
- Gradually lowering the MUC and PDC thresholds over 2 or more years to add more graft skin substitute procedures into the current high cost group until all graft skin substitute procedures are assigned to the high cost group and it becomes a single payment category.

Those commenters in favor of a single payment category did not see a need for a transition period or wanted only a one-year transition period. Conversely, those commenters opposed to a single payment category either mentioned the idea of a transition period or wanted it to last multiple years, with one commenter suggesting a transition period of four years. In the end, having a transition period before establishing a single payment category did not affect the views of commenters who were initially opposed to establishing a single payment category, as they continued to oppose this policy option.

Based on the comments received regarding establishing a single payment category for graft skin substitute procedures, we stated that we need more time to consider the trade-offs between the potential benefits of a single category against the potential substantial drawbacks. We also need to consider the merits of this policy option compared to episode-based payment for graft skin substitute procedures. Therefore, we did not propose a single payment category for graft skin substitute procedures for CY 2021 in the CY 2021 OPPS/ASC proposed rule.

Comment: Several commenters expressed either their support or their concerns about a single payment category for graft skin substitute procedures. Commenters provided their views on whether a single payment category encourages value and cost savings for graft skin substitute procedures, or if a single payment category would discourage providers from using higher-cost skin substitute products that may have better clinical results for patients.

Response: We appreciate the feedback we received from the commenters. We will continue to study issues related to changing the methodology for paying for skin substitute products.

d. Packaged Skin Substitutes for CY 2021

For CY 2021, consistent with our policy since CY 2016, we proposed to continue to determine the high cost/low cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. Consistent with the methodology as established in the CY 2014 through CY 2018 final rules with comment period, we analyzed CY 2019 claims data to calculate the MUC threshold (a weighted average of all skin substitutes' MUCs) and the PDC threshold (a weighted average of all skin substitutes' PDCs). The final CY 2021 MUC threshold is $48 per cm^2 (rounded to the nearest $1) (proposed at $47 per cm^2) and the final CY 2021 PDC threshold is $949 (rounded to the nearest $1) (proposed at $936). We also proposed to clarify that our definition of skin substitutes includes synthetic skin substitute products in addition to biological skin substitute products, as described in section V.B.7.d. of the CY 2021 OPPS/ASC proposed rule. We also want to clarify that the availability of a HCPCS code for a particular human cell, tissue, or cellular or tissue-based product (HCT/P) does not mean that that product is appropriately regulated solely under section 361 of the PHS Act and the FDA regulations in 21 CFR part 1271. Manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.

For CY 2021, as we did for CY 2020, we proposed to assign each skin substitute that exceeds either the MUC threshold or the PDC threshold to the high cost group. In addition, we proposed to assign any skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group. For CY 2021, we proposed that any skin substitute product that was assigned to the high cost group in CY 2020 would be assigned to the high cost group for CY 2021, regardless of whether it exceeds or falls below the CY 2021 MUC or PDC threshold. This policy was established in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59346 through 59348).

For CY 2021, we proposed to continue to assign skin substitutes with pass-through payment status to the high cost category. We proposed to assign skin substitutes with pricing information but without claims data to calculate a geometric MUC or PDC to either the high cost or low cost category based on the product's ASP+6 percent payment rate as compared to the MUC threshold. If ASP is not available, we proposed to use WAC+3 percent to assign a product to either the high cost or low cost category. Finally, if neither ASP nor WAC is available, we proposed to use 95 percent of AWP to assign a skin substitute to either the high cost or low cost category. We proposed to continue to use WAC+3 percent instead of WAC+6 percent to conform to our proposed policy described in section V.B.2.b. of the CY 2021 OPPS/ASC proposed rule to establish a payment rate of WAC+3 percent for separately payable drugs and biologicals that do not have ASP data available. New skin substitutes without pricing information would be assigned to the low cost category until pricing information is available to compare to the CY 2021 MUC and PDC thresholds. For a discussion of our existing policy under which we assign skin substitutes without pricing information to the low cost category until pricing information

is available, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70436). Table 42 displays the final CY 2021 cost category assignment for each skin substitute product.

Comment: One commenter did not support our proposal to assign graft skin substitute products to a high cost or a low cost group based on if the MUC or PDC of a product exceeds a weighted average of either the MUC or PDC of all graft skin substitute products. The commenter believes the current two-tier system provides incentives for providers to use higher-cost graft skin substitute products instead of lower-cost products that have similar efficacy to the higher-cost products.

Response: As we explained in the CY 2014 OPPS/ASC final rule (78 FR 74933), the graft skin substitute procedures described by CPT codes 15271 through 15278 are clinically homogeneous, but there is a large amount of resource heterogeneity between different skin substitute products with the cost per cm^2 ranging from under $10 per cm^2 to over $200 per cm^2. We believe establishing high cost and low cost groups for skin substitutes makes the payment for these products more homogeneous and reduces the risk of excessive overpayment or underpayment to a provider when a skin substitute product is used.

Comment: Multiple commenters supported our proposal to continue to assign skin substitutes to the low cost or high cost group. Commenters also supported our proposal that any skin substitute product that was assigned to the high cost group in CY 2020 would be assigned to the high cost group for CY 2021, regardless of whether it exceeds or falls below the CY 2021 MUC or PDC threshold.

Response: We appreciate the support of the commenters for our proposals.

Comment: One commenter requested that CMS be more transparent when presenting the data regarding whether individual graft skin substitute products are assigned to either the high cost or low cost group. The commenter requested that we share more of the process details for determining high cost and low cost assignments and provide the calculation processes and formulas used to make the determinations.

Response: We already provide the information that the commenter seeks. In the CY 2021 OPPS/ASC final rule (85 FR 48891) and in previous OPPS proposed and final rules, we discuss in detail how both the MUC and PDC thresholds are calculated and which pricing data are used to determine if a graft skin substitute product is assigned to the high cost or low cost group. We provide drug cost statistics data on our website, which include cost data for all the graft skin substitute products that are used to calculate the overall MUC and PDC cost group thresholds. Links to the drug cost statistics data may be found on the same web page that has links to the OPPS preamble, OPPS claims accounting narrative, OPPS addenda, and other data related to the OPPS/ASC final rule.

Comment: One commenter requested that HCPCS code Q4235 (Amniorepair or altiply, per square centimeter) be assigned to the high cost skin substitute group based on either WAC plus 3 percent or 95 percent of AWP pricing data, which the commenter believed would demonstrate that the cost of these products exceeds the MUC threshold.

Response: The commenter did not provide the required information to make a determination on assignment to the high cost skin substitute group in time. Therefore, HCPCS code Q4235 will continue to be assigned to the low cost skin substitute group in this final rule.

Comment: Individual commenters have requested that the HCPCS codes Q4205 (Membrane graft or membrane wrap, per square centimeter), Q4222 (Progenamatrix, per square centimeter), Q4226 (MyOwn skin, includes harvesting and preparation procedures, per square centimeter), Q4227 (Amniocore, per square centimeter), and Q4232 (Corplex, per square centimeter) be assigned to the high cost skin substitute group based on either WAC plus 3 percent or 95 percent of AWP pricing data, which the commenters believed would demonstrate that the cost of these products exceeds the MUC threshold.

Response: HCPCS codes Q4205 and Q4226 were assigned to the high cost group starting in October 2020. We also note that we are assigning HCPCS codes Q4222, Q4227, and Q4232 to the high cost group starting on January 1, 2021.

Comment: Individual commenters have requested that HCPCS codes Q4206 (Fluid flow or fluid gf, 1 cc) and Q4231 (Corplex p, per cc) be assigned to the high cost skin substitute group based on either WAC plus 3 percent or 95 percent of AWP pricing data, which the commenters believed would demonstrate that the cost of these products exceeds the MUC threshold.

Response: HCPCS codes Q4206 and Q4231 are not graft skin substitute products. Therefore, these products cannot be assigned to either the high cost or low cost skin substitute group.

Comment: One commenter, the manufacturer, has requested that HCPCS codes Q4122 (Dermacell, per square centimeter) and Q4150 (Allowrap ds or dry, per square centimeter) continue to be assigned to the high-cost skin substitute group.

Response: HCPCS codes Q4122 and Q4150 were both assigned to the high-cost group in CY 2020 and also were proposed to be assigned to the high-cost group for CY 2021. Per our proposal, a skin substitute that has been proposed in the high-cost group in a proposed rule will remain in the high-cost group in the final rule. Also, any skin substitute assigned to the high-cost group in CY 2020 will continue to be assigned to the high-cost group in CY 2021 even if the MUC and PDC for the skin substitute product is below the overall MUC and PDC thresholds for all skin substitute products. Accordingly, we are finalizing our proposal to assign HCPCS codes Q4122 and Q4150 to the high-cost group in CY 2021.

After consideration of the public comments we received, we are finalizing our proposal to assign a skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low cost group, unless the product was assigned to the high cost group in CY 2020, in which case we would assign the product to the high cost group for CY 2021, regardless of whether it exceeds the CY 2021 MUC or PDC threshold. We are also finalizing our proposal to assign to the high cost group any skin substitute product that exceeds the CY 2021 MUC or PDC thresholds and assign to the low cost group any skin substitute product that does not exceed the CY 2021 MUC or PDC thresholds and was not assigned to the high cost group in CY 2020. We are finalizing our proposal to continue to use payment methodologies, including ASP+6 percent and 95 percent of AWP, for skin substitute products that have pricing information but do not have claims data to determine if their costs exceed the CY 2021 MUC. In addition, we are finalizing our proposal to continue to use WAC+3 percent instead of WAC+6 percent for skin substitute products that do not have ASP pricing information or claims data to determine if those products' costs exceed the CY 2021 MUC. We also are finalizing our proposal to retain our established policy to assign new skin substitute products with pricing information to the low cost group. Table 42 below includes the final CY 2021 cost category assignment for each skin substitute product.

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TABLE 42: SKIN SUBSTITUTE ASSIGNMENTS TO HIGH COST AND LOW COST GROUPS FOR CY 2021

CY 2021 HCPCS Code	CY 2021 Short Descriptor	CY 2020 High/Low Cost Assignment	Final CY 2021 High/Low Cost Assignment
C1849	Skin substitute, synthetic	High	High
C9363	Integra meshed bil wound mat	High	High*
Q4100	Skin substitute, nos	Low	Low
Q4101	Apligraf	High	High
Q4102	Oasis wound matrix	Low	Low
Q4103	Oasis burn matrix	High	High*
Q4104	Integra bmwd	High	High
Q4105	Integra drt or omnigraft	High	High
Q4106	Dermagraft	High	High
Q4107	Graftjacket	High	High
Q4108	Integra matrix	High	High*
Q4110	Primatrix	High	High*
Q4111	Gammagraft	Low	Low
Q4115	Alloskin	Low	Low
Q4116	Alloderm	High	High
Q4117	Hyalomatrix	Low	Low
Q4121	Theraskin	High	High*
Q4122	Dermacell	High	High

CY 2021 HCPCS Code	CY 2021 Short Descriptor	CY 2020 High/Low Cost Assignment	Final CY 2021 High/Low Cost Assignment
Q4123	Alloskin	High	High
Q4124	Oasis tri-layer wound matrix	Low	Low
Q4126	Memoderm/derma/tranz/integup	High	High
Q4127	Talymed	High	High*
Q4128	Flexhd/allopatchhd/matrixhd	High	High
Q4132	Grafix core, grafixpl core	High	High
Q4133	Grafix stravix prime pl sqcm	High	High
Q4134	Hmatrix	Low	Low
Q4135	Mediskin	Low	Low
Q4136	Ezderm	Low	Low
Q4137	Amnioexcel biodexcel, 1 sq cm	High	High
Q4138	Biodfence dryflex, 1cm	High	High
Q4140	Biodfence 1cm	High	High
Q4141	Alloskin ac, 1cm	High	High*
Q4143	Repriza, 1cm	High	High
Q4146	Tensix, 1cm	High	High
Q4147	Architect ecm px fx 1 sq cm	High	High
Q4148	Neox rt or clarix cord	High	High
Q4150	Allowrap ds or dry 1 sq cm	High	High
Q4151	Amnioband, guardian 1 sq cm	High	High
Q4152	Dermapure 1 square cm	High	High
Q4153	Dermavest, plurivest sq cm	High	High
Q4154	Biovance 1 square cm	High	High
Q4156	Neox 100 or clarix 100	High	High
Q4157	Revitalon 1 square cm	High	High*

CY 2021 HCPCS Code	CY 2021 Short Descriptor	CY 2020 High/Low Cost Assignment	Final CY 2021 High/Low Cost Assignment
Q4158	Kerecis omega3, per sq cm	High	High*
Q4159	Affinity 1 square cm	High	High
Q4160	Nushield 1 square cm	High	High
Q4161	Bio-connekt per square cm	High	High
Q4163	Woundex, bioskin, per sq cm	High	High
Q4164	Helicoll, per square cm	High	High
Q4165	Keramatrix, per square cm	Low	Low
Q4166	Cytal, per square centimeter	Low	Low
Q4167	Truskin, per square centimeter	Low	High
Q4169	Artacent wound, per sq cm	High	High
Q4170	Cygnus, per sq cm	Low	Low
Q4173	Palingen or palingen xplus	High	High
Q4175	Miroderm, per square cm	High	High
Q4176	Neopatch, per sq centimeter	High	High
Q4178	Floweramniopatch, per sq cm	High	High
Q4179	Flowerderm, per sq cm	High	High
Q4180	Revita, per sq cm	High	High
Q4181	Amnio wound, per square cm	High	High
Q4182	Transcyte, per sq centimeter	Low	High
Q4183	Surgigraft, 1 sq cm	High	High
Q4184	Cellesta or duo per sq cm	High	High*
Q4186	Epifix 1 sq cm	High	High
Q4187	Epicord 1 sq cm	High	High
Q4188	Amnioarmor 1 sq cm	Low	High
Q4190	Artacent ac 1 sq cm	Low	High

CY 2021 HCPCS Code	CY 2021 Short Descriptor	CY 2020 High/Low Cost Assignment	Final CY 2021 High/Low Cost Assignment
Q4191	Restorigin 1 sq cm	Low	Low
Q4193	Coll-e-derm 1 sq cm	Low	High
Q4194	Novachor 1 sq cm	High	High*
Q4195	Puraply 1 sq cm	High	High
Q4196	Puraply am 1 sq cm	High	High
Q4197	Puraply xt 1 sq cm	High	High
Q4198	Genesis amnio membrane 1 sq cm	Low	High
Q4200	Skin te 1 sq cm	Low	High
Q4201	Matrion 1 sq cm	Low	Low
Q4203	Derma-gide, 1 sq cm	High	High*
Q4204	Xwrap 1 sq cm	Low	Low
Q4205	Membrane graft or wrap sq cm	High	High
Q4208	Novafix per sq cm	High	High
Q4209	Surgraft per sq cm	Low	High
Q4210	Axolotl graf dualgraf sq cm	Low	Low
Q4211	Amnion bio or axobio sq cm	Low	High
Q4214	Cellesta cord per sq cm	Low	Low
Q4216	Artacent cord per sq cm	Low	Low
Q4217	Woundfix biowound plus xplus	Low	Low
Q4218	Surgicord per sq cm	Low	Low
Q4219	Surgigraft dual per sq cm	Low	High
Q4220	Bellacell HD, Surederm sq cm	Low	Low
Q4221	Amniowrap2 per sq cm	Low	Low
Q4222	Progenamatrix, per sq cm	Low	Low
Q4226	Myown harv prep proc sq cm	High	High

CY 2021 HCPCS Code	CY 2021 Short Descriptor	CY 2020 High/Low Cost Assignment	Final CY 2021 High/Low Cost Assignment
Q4227	Amniocore per sq cm	Low	High
Q4228	Bionextpatch, per sq cm	Low	Low
Q4229	Cogenex amnio memb per sq cm	Low	Low
Q4232	Corplex, per sq cm	Low	High
Q4234	Xcellerate, per sq cm	High	High
Q4235	Amniorepair or altiply sq cm	Low	Low
Q4236	Carepatch per sq cm	Low	Low
Q4237	cryo-cord, per sq cm	Low	High
Q4238	Derm-maxx, per sq cm	Low	High
Q4239	Amnio-maxx or lite per sq cm	Low	High
Q4247	Amniotext patch, per sq cm	Low	Low
Q4248	Dermacyte Amn mem allo sq cm	Low	Low
Q4249	Amniply, per sq cm	Low	High
Q4250	AmnioAMP-MP per sq cm	Low	Low
Q4254	Novafix dl per sq cm	Low	Low
Q4255	Reguard, topical use per sq	Low	Low

* These products do not exceed either the proposed MUC or PDC threshold for CY 2021, but are assigned to the high cost group because they were assigned to the high cost group in CY 2020.

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e. Synthetic Skin Graft Sheet Products To Be Reported With Graft Skin Substitute Procedure Codes

The CY 2014 OPPS/ASC final rule with comment period describes skin substitute products as ''. . . a category of products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers . . . [T]hese products do not actually function like human skin that is grafted onto a wound; they are not a substitute for a skin graft. Instead, these products are applied to wounds to aid wound healing and through various mechanisms of action that stimulate the host to regenerate lost tissue.'' (78 FR 74930 through 74931) The CY 2014 final rule also described skin substitutes as ''. . . a class of products that we treat as biologicals . . .'' and mentioned that prior to CY 2014, skin substitutes were separately paid in the OPPS as if they were biologicals according to the ASP methodology (78 FR 74930 through 74931).

The 2014 rule did not specifically mention whether synthetic products could be considered to be skin substitute products in the same manner as biological products, because there were no synthetic products at that time that were identified as skin substitute products. Then in 2018, a manufacturer made a request that an entirely synthetic product that it claimed is used in the same manner as biological skin substitutes, receive a HCPCS code that would allow the product to be billed with graft skin substitute procedure codes, including CPT codes 15271 through 15278 and C5271 through C5278, starting in 2019. Initially, the

synthetic product was not described as a graft skin substitute product. However, we now believe that both biological and synthetic products could be considered to be skin substitutes for Medicare payment purposes.

This view is supported by a paper referenced in a report we cited in the CY 2014 OPPS/ASC final rule with comment period titled ''Skin Substitutes for Treating Chronic Wounds Technology Assessment Report at ES–2'', which is available on the AHRQ website at: *https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/ta/skinsubs/HCPR0610_skinsubst-final.pdf*. That paper, titled ''Regenerative medicine in dermatology: biomaterials, tissue engineering, stem cells, gene transfer and beyond'' by Dieckmann et al.,[84] states that skin substitutes should be divided into two broad categories: biomaterial and cellular. The paper explains that ''. . . biomaterial skin substitutes do not contain cells (acellular) and are derived from natural or synthetic sources . . .''[85] The paper continues by describing biomaterial skin substitutes further: ''Synthetic sources include various degradable polymers such as polylactide and polyglycolide. Whether natural or synthetic, the biomaterial provides an extracellular matrix that allows for infiltration of surrounding cells.''[86] The paper by Dieckmann et al. indicates that skin substitute products may be synthetic products as well as biological products.

Therefore, for CY 2021 we proposed to include synthetic products in addition to biological products in our description of skin substitutes. Our new description would define skin substitutes as a category of biological and synthetic products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers. We also proposed to retain the additional description of skin substitute products from the CY 2014 OPPS final rule which states ''. . . that skin substitute products do not actually function like human skin that is grafted onto a wound; they are not a substitute for a skin graft. Instead, these products are applied to wounds to aid wound healing and through various mechanisms of action they stimulate the host to regenerate lost tissue . . .'' (78 FR 74930 through 74931).

Comment: Two commenters requested that CMS no longer use the term ''skin substitutes'' to describe products that do not function like human skin that is grafted onto a wound and are not substitutes for skin grafts, but do aid in wound healing by stimulating the patient to regenerate lost tissue. Instead, the commenters request that we use the term ''cellular and/or tissue based products for skin wounds'' that is abbreviated ''CTPs''. The commenters believe the term ''skin substitute'' is a misleading and clinically incorrect term that does not accurately describe all of the products that are considered to be cellular and tissue based products to treat skin wounds. Also, one of the commenters notes that the FDA discourages the use of the term ''skin substitute'' and that an international standards organization, the American Society for Testing and Materials (ASTM), has adopted the ''CTPs'' terminology as well. Finally, the commenter claims the ''CTPs'' terminology is used by physicians and clinicians throughout the wound care community.

Response: We appreciate the suggestion by the commenters, but we do not believe it is appropriate at this time to end our use of the term ''skin substitute.'' Notably, the CPT and HCPCS codes used to report graft procedures using cellular and tissue based products to heal skin wounds, CPT codes 15271 through 15278 and HCPCS codes C5271 through C5278, use the term ''skin substitute'' in the descriptor. We feel that we should use terminology that reflects the service descriptors that are reported in the OPPS. Also, the term ''skin substitute'' is well-understood by providers and industry stakeholders, even if it is not the most precise terminology to describe cellular and tissue based products to heal skin wounds. Finally, we did not propose to change the terminology used to describe products that do not function like human skin that is grafted onto a wound and are not substitutes for skin grafts, but do aid in wound healing by stimulating the patient to regenerate lost tissue. While we are not changing the use of the term ''skin substitute'', we appreciate the information from commenters.

Comment: A commenter expressed concern about our proposed definition of synthetic skin substitutes. The commenter believes it is possible under our proposal that bandages and standard dressings could be defined as skin substitutes. The commenter does support Medicare coverage of synthetic skin substitutes, but would like us to modify our proposal to prevent products that would normally be described as medical supplies to be defined as skin substitutes.

Response: The descriptor for HCPCS code C1849 (Skin substitute, synthetic, resorbable, per square centimeter) includes the term ''resorbable'', which means the graft skin substitute product must be able to be absorbed by the body. Bandages and standard dressings are not resorbable products and are removed and replaced on a regular basis while treating a wound. We find it highly unlikely that a bandage or standard dressing would be used for a graft skin substitute procedure. However to make it clear, we will modify our definition of a synthetic graft skin substitute product to exclude bandages and standard dressings.

Comment: Multiple commenters agreed with CMS that synthetic graft skin substitute products should receive payment under the OPPS, even if the commenters did not support our methodology for the payment of graft skin substitute products.

Response: We appreciate commenters' support for our proposal to pay for synthetic graft skin substitute products under the OPPS.

Comment: Several commenters requested that we establish product-specific HCPCS codes for synthetic graft skin substitute products. Most of the same commenters also requested that we delete HCPCS code C1849, but there was one commenter who supported both product-specific HCPCS codes and continuing to have HCPCS code C1849 be packaged in the OPPS. The primary reason commenters want product-specific codes for synthetic graft skin substitute is they feel that synthetic products should be assigned to either the high cost or low cost skin substitute group based on the cost of each individual product in a similar manner to biological skin substitute products. Commenters feel that because multiple synthetic graft skin substitute products can be assigned to HCPCS code C1849, there may be some synthetic products that should be in the low cost skin substitute group that will receive payment in the high cost skin substitute group if HCPCS code C1849 is assigned to the high cost group. Commenters also are concerned about the opposite situation, in which high cost synthetic products would potentially be underpaid if HCPCS code C1849 is assigned to the low cost skin substitute group. Commenters believed the only resolution to these issues with HCPCS code C1849 is to delete the code so there are not cases of synthetic products being either overpaid or underpaid.

[84] Dieckmann C, Renner R, Milkova L, et al. Regenerative medicine in dermatology: Biomaterials, tissue engineering, stem cells, gene transfer and beyond. Exp Dermatol 2010 Aug;19(8):697–706.

[85] Ibid, Dieckmann C, Renner R, Milkova L, et al.

[86] Ibid, Dieckmann C, Renner R, Milkova L, et al.

Commenters also expressed concerns about using a C-code to report synthetic graft skin substitute codes in Medicare. One commenter noted that the use of a C-code meant that synthetic graft skin substitute products would only be in a payable status under the OPPS, and cannot be reported for graft skin substitute application services provided in the physician office setting. Two commenters thought that a C-code might confuse providers by unintentionally implying that HCPCS code C1849 has pass-through status under the OPPS, even though HCPCS code C1849 does not have pass-through status. Another commenter had concerns that there would be a less rigorous process to determine that a graft skin substitute product can be reported with HCPCS code C1849 than the process CMS uses to assign biological skin substitute products to product-specific HCPCS codes. Finally, two commenters asked for more transparency from CMS regarding the reasons for the creation of HCPCS code C1849.

Response: HCPCS code C1849 was established in response to the need to pay for graft skin substitute application services performed with synthetic graft skin substitute products in the OPPS in a manner comparable to how we pay for graft skin substitute application services performed with biological graft skin substitute products. As mentioned earlier in this section, when we established our policy in the CY 2014 OPPS final rule to package graft skin substitute products into their associated application procedures (78 FR 74930 through 74931), we did not specifically mention whether synthetic products could be considered skin substitute products in the same manner as biological products. The reason for this was that there were no synthetic products at that time that were identified as skin substitute products.

We note that unless a graft skin substitute product has pass-through status, graft skin substitute products are not paid separately under unique HCPCS or CPT codes in OPPS. However, in CY 2018, a manufacturer requested that CMS develop methodologies to allow synthetic graft skin substitute products to receive payment in the outpatient hospital setting and in the physician office setting. After extensive review, we decided against establishing a product-specific HCPCS code for the synthetic graft skin substitute product. Instead, CMS decided to assign the synthetic product in CY 2019 to HCPCS codes A6460 and A6461, which were newly created HCPCS codes to report synthetic, resorbable wound dressings. HCPCS codes A6460 and A6461 are packaged under the OPPS and cannot be assigned to either the high cost or low cost skin substitute group. This meant that graft skin substitute products could not be billed with CPT codes 15271 through 15278 or HCPCS codes C5271 through C5278, even though synthetic graft skin substitute products and biological graft skin substitute products perform the same function and have similar efficacy.

Because all skin substitutes, except those with pass-through status, are packaged under the OPPS, we explored solutions that would permit synthetic skin substitute products to be billed with either CPT codes 15271 through 15278 or HCPCS codes C5271 though C5278. We decided to create HCPCS code C1849 to describe any synthetic graft skin substitute product, and we revised the payment logic for the graft skin substitute application procedure codes to allow HCPCS code C1849 to be billed with those procedures. So far, we have identified one synthetic graft skin substitute product that is described by HCPCS code C1849. Even though there are no OPPS claims data for the synthetic product, the manufacturer of the product was able to produce pricing data for the product. Using our alternative methodology to assign products to the high cost skin substitute group through WAC or AWP pricing that exceeds the MUC threshold, the data showed that the synthetic product would be assigned to the high cost group. As more synthetic graft skin substitute products are identified as being described by HCPCS code C1849, we will average the pricing data from the various products to determine an amount for the products described by HCPCS code C1849 to compare against the MUC threshold. This comparison will determine if HCPCS code C1849 should be assigned to the high cost or low cost skin substitute category.

Regarding other comments about HCPCS code C1849, it is correct that HCPCS C-codes are only payable under the OPPS and not under the PFS. We also note that while the process may be different to receive payment for synthetic graft skin substitute products reporting HCPCS code C1849 than for a new product-specific HCPCS code for a biological skin substitute product, synthetic graft skin substitute products must be described by C1849 to be eligible for payment in the OPPS. Like any other claim paid in the OPPS, claims reporting C1849 also are subject to medical review to ensure that providers are appropriately billing for synthetic, resorbable graft skin substitute products. Finally, we disagree with the commenters who feel that assigning a HCPCS C-code to report synthetic graft skin substitute products may confuse providers who may think synthetic products are receiving pass-through payment. We note that for several years a biological graft skin substitute product, Integra meshed bilayer wound matrix, has been assigned to HCPCS code C9363, and providers are well aware the product is packaged under the OPPS and does not have pass-through status.

Comment: Several commenters stated that if HCPCS code C1849 is not either modified or deleted, then the HCPCS code should be assigned to the low cost skin substitute group by default, similar to how we pay for HCPCS code Q4100 (Skin substitute, not otherwise specified), which is used to report multiple biological skin substitute products that do not have product-specific HCPCS codes. Commenters are concerned that synthetic graft skin substitute products that should receive payment through the low cost skin substitute group would instead receive payment in the high cost skin substitute group and increase overall graft skin substitute costs for Medicare. In addition, two commenters expressed concern about the assignment of HCPCS code C1849 to the high cost skin substitute group because the commenters believed it was an automatic assignment that was not based on OPPS claims data or product pricing data.

Response: We are currently aware of one synthetic graft skin substitute product that is described by HCPCS code C1849. As we mentioned earlier, the manufacturer provided pricing data that showed the cost of the product is above the MUC threshold for graft skin substitute products and therefore HCPCS code C1849 should be assigned to the high cost skin substitute group. We note that we used pricing data to assign HCPCS code C1849 to the high cost group, and the assignment of HCPCS code C1849 to the high cost skin substitute group was not automatic. As more synthetic graft skin substitute products are identified, we will use their pricing data to calculate an average price for the products described by HCPCS code C1849 and compare that average price to the overall MUC threshold to determine whether HCPCS code C1849 should be assigned to the high cost or low cost skin substitute group. We are not in favor of a default assignment of HCPCS code C1849 to the low cost skin substitute group. Instead, we want to rely on pricing data and, when available, claims data to determine the appropriate skin

substitute cost group for HCPCS code C1849. If most of the products described by HCPCS code C1849 have pricing or cost that qualify the products to be assigned to the high cost group, then the HCPCS code should be assigned to the high cost skin substitute group as that group best reflects the costs of the products described by HCPCS code C1849.

Comment: One commenter was concerned that the establishment of a single HCPCS code to describe all synthetic graft skin substitute products is a substantial step towards the establishment of a single category payment system for both synthetic and biological graft skin substitute products.

Response: The creation of HCPCS code C1849 and the scope of its descriptor was not an attempt to promote one of the several payment methodologies discussed in the CY 2019 and CY 2020 comment solicitations regarding alternative payment methodologies for graft skin substitute products over the other payment methodologies. This is made clear by the fact that there are over 100 biological graft skin substitute products with their own product-specific HCPCS codes as compared to one identified synthetic graft skin substitute product. As explained previously, HCPCS code C1849 was created to provide a way for synthetic skin substitute products that have similar function and efficacy to biological skin substitute products to receive comparable payment under the OPPS.

Comment: Multiple commenters expressed their support for our proposal without any suggested changes.

Response: We appreciate the commenters' support for our proposal. After reviewing the public comments, we have decided to implement our proposal for CY 2021 with modification to include synthetic products, in addition to biological products, in our description of skin substitutes. Our new description defines skin substitutes as a category of biological and synthetic products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers. We will retain the additional description of skin substitute products from the CY 2014 OPPS final rule which states that ''skin substitute products do not actually function like human skin that is grafted onto a wound; they are not a substitute for a skin graft. Instead, these products are applied to wounds to aid wound healing and through various mechanisms of action they stimulate the host to regenerate lost tissue'' (78 FR 74930 through 74931). Finally, we note that our definition of skin substitutes does not include bandages or standard dressings and therefore, these items cannot be assigned to either the high cost or low cost skin substitute groups or be reported with either CPT codes 15271 through 15278 or HCPCS codes C5271 through C5278.

VI. Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Background

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for drugs, biologicals, radiopharmaceuticals, and categories of devices for a given year to an ''applicable percentage,'' currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate pro rata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing a proposed estimate of pass-through spending in CY 2021 entails estimating spending for two groups of items. The first group of items consists of device categories that are currently eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2021. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of items that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2020 or beginning in CY 2021. The sum of the proposed CY 2021 pass-through spending estimates for these two groups of device categories equaled the proposed total CY 2021 pass-through spending estimate for device categories with pass-through payment status. We based the device pass-through estimated payments for each device category on the amount of payment as established in section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2014 OPPS/ASC final rule with comment period (78 FR 75034 through 75036). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment methodology for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a natural orifice) use the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), in the proposed rule, we proposed to include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. Similarly, we finalized a policy in CY 2015 that applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology (76 FR 66885 through 66888). Therefore, as we did beginning in CY 2015, for CY 2021, we also proposed to include an estimate of any skin substitutes and similar products in our estimate of pass-through spending for devices.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. Our estimate of drug and biological pass-through payment for CY 2021 for this group of items was $473.4 million, as discussed below, because we proposed that most non pass-through separately payable drugs and biologicals would be paid under the CY 2021 OPPS at ASP+6 percent with the exception of 340B-acquired separately payable drugs, which are paid at ASP minus 22.5

percent, but for which we proposed to pay a net rate of ASP minus 28.7 percent, and because we proposed to pay for CY 2021 pass-through payment drugs and biologicals at ASP+6 percent, as we discussed in section V.A. of this CY 2021 OPPS/ASC proposed rule.

Furthermore, payment for certain drugs, specifically diagnostic radiopharmaceuticals and contrast agents without pass-through payment status, is packaged into payment for the associated procedures, and these products will not be separately paid. In addition, we policy-package all non pass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure and drugs and biologicals that function as supplies when used in a surgical procedure, as discussed in section V.B.1.c. of this CY 2021 OPPS/ASC proposed rule. We proposed that all of these policy-packaged drugs and biologicals with pass-through payment status would be paid at ASP+6 percent, like other pass-through drugs and biologicals, for CY 2020. Therefore, our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2021 was not $0, as discussed below. In section V.A.6. of the CY 2021 OPPS/ASC proposed rule, we discussed our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving pass-through payment, we proposed to offset the amount of pass-through payment for the policy-packaged drug or biological. For these drugs or biologicals, the APC offset amount is the portion of the APC payment for the specific procedure performed with the pass-through drug or biological, which we refer to as the policy-packaged drug APC offset amount. If we determine that an offset is appropriate for a specific policy-packaged drug or biological receiving pass-through payment, we proposed to reduce our estimate of pass-through payments for these drugs or biologicals by this amount.

Similar to pass-through spending estimates for devices, the first group of drugs and biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2021. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible, in the remaining quarters of CY 2020 or beginning in CY 2021. The sum of the CY 2021 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2021 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Estimate of Pass-Through Spending

In the CY 2021 OPPS/ASC proposed rule, we proposed to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2021, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2020 (84 FR 61336 through 61337).

For the first group, consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2021, there are four active categories for CY 2021. The active categories are described by HCPCS codes C1734, C1824, C1982, and C2596. Based on the information from the device manufacturers, we proposed estimates that C1824 will cost $46 million in pass-through expenditures in CY 2021, C1982 will cost $116.3 million in pass-through expenditures in CY 2021, C2596 will cost $11.3 million in pass-through expenditures in CY 2021, and C1734 will cost $37.2 million in pass-through expenditures in CY 2021. Therefore, we proposed an estimate for the first group of devices of $210.8 million. We did not receive any public comments on the proposal. Therefore, we are finalizing the proposed estimate for the first group of devices of $210.8 million for CY 2021.

In estimating our proposed CY 2021 pass-through spending for device categories in the second group, we included: Device categories that we knew at the time of the development of the proposed rule will be newly eligible for pass-through payment in CY 2021; additional device categories that we estimated could be approved for pass-through status after the development of the proposed rule and before January 1, 2021; and contingent projections for new device categories established in the second through fourth quarters of CY 2021. For CY 2021, we proposed to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. The proposed estimate of CY 2021 pass-through spending for this second group of device categories is $99 million.

We did not receive any public comments on this proposal. As stated earlier in this final rule with comment period, we are approving five devices for pass-through payment status in the CY 2021 rulemaking cycle: Barostim NEO® System, Hemospray® Endoscopic Hemostat, EXALT™ Model D Single-Use Duodenoscope, The SpineJack® Expansion Kit, and Customflex® Artificial Iris. The manufacturers of these systems provided utilization and cost data that indicate the spending for the devices would be approximately $4 million for Barostim NEO® System, $40 million for Hemospray® Endoscopic Hemostat, $40 million for EXALT™ Model D Single-Use Duodenoscope, $14 million for SpineJack® Expansion Kit, and $600 thousand for Customflex® Artificial Iris. Therefore, we are finalizing an estimate of $99 million for this second group of devices for CY 2021.

To estimate proposed CY 2021 pass-through spending for drugs and biologicals in the first group, specifically those drugs and biologicals recently made eligible for pass-through payment and continuing on pass-through payment status for at least one quarter in CY 2021, we proposed to use the most recent Medicare hospital outpatient claims data regarding their utilization, information provided in the respective pass-through applications, historical hospital claims data, pharmaceutical industry information, and clinical information regarding those drugs or biologicals to project the CY 2021 OPPS utilization of the products.

For the known drugs and biologicals (excluding policy-packaged diagnostic radiopharmaceuticals, contrast agents, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies when used in a surgical procedure) that will be continuing on pass-through payment status in CY 2021, we estimate the pass-through payment amount as the difference between ASP+6 percent and the payment rate for non pass-through drugs and biologicals that will be separately paid. Separately payable drugs are paid at a rate of ASP+6 percent with the exception of 340B-acquired drugs, for which we currently pay ASP minus 22.5 percent but for which we proposed to pay a net rate of ASP minus 28.7 percent or in the alternative, to continue our current policy of paying ASP minus 22.5 percent. Therefore, the payment rate difference between the pass-through

payment amount and the non pass-through payment amount is $473.4 million for this group of drugs. Because payment for policy-packaged drugs and biologicals is packaged if the product was not paid separately due to its pass-through payment status, we proposed to include in the CY 2021 pass-through estimate the difference between payment for the policy-packaged drug or biological at ASP+6 percent (or WAC+6 percent, or 95 percent of AWP, if ASP or WAC information is not available) and the policy-packaged drug APC offset amount, if we determine that the policy-packaged drug or biological approved for pass-through payment resembles a predecessor drug or biological already included in the costs of the APCs that are associated with the drug receiving pass-through payment, which we estimate for CY 2021 for the first group of policy-packaged drugs to be $0 since there are currently no policy-packaged drugs for which we have cost data that will be on pass-through in CY 2021.

We did not receive any public comments on our proposal. Using our methodology for this final rule with comment period, we calculated a CY 2021 spending estimate for this first group of drugs and biologicals of approximately $449.5 million based on our decision to finalize our alternative proposal to maintain our current policy of paying ASP minus 22.5 percent for 340B-acquired drugs.

To estimate proposed CY 2021 pass-through spending for drugs and biologicals in the second group (that is, drugs and biologicals that we knew at the time of development of the final rule were newly eligible for pass-through payment in CY 2021, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of the final rule and before January 1, 2021 and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2021), we proposed to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2021 pass-through payment estimate. We also proposed to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2021 pass-through payments for this second group of drugs, we calculate a proposed spending estimate for this second group of drugs and biologicals of approximately $10 million.

We did not receive any public comments on our proposal. Therefore, for CY 2021, we are continuing to use the general methodology described above. For this final rule with comment period, we calculated a CY 2021 spending estimate for this second group of drugs and biologicals of approximately $10 million.

We estimate that total pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2021 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2021 would be approximately $769.3 million (approximately $309.8 million for device categories and approximately $459.5 million for drugs and biologicals) which represents 0.92 percent of total projected OPPS payments for CY 2021 (approximately $84 billion). Therefore, we estimate that pass-through spending in CY 2021 will not amount to 2.0 percent of total projected OPPS CY 2021 program spending.

VII. OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2021, we proposed to continue with our current clinic and emergency department (ED) hospital outpatient visits payment policies. For a description of the current clinic and ED hospital outpatient visits policies, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70448). We also proposed to continue our payment policy for critical care services for CY 2020. For a description of the current payment policy for critical care services, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70449), and for the history of the payment policy for critical care services, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75043). In the CY 2021 OPPS/ASC proposed rule, we solicited public comment on any changes to these codes that we should consider for future rulemaking cycles. We encouraged commenters to provide the data and analysis necessary to justify any suggested changes.

The following is a summary of the comments we received and our responses to those comments.

Comment: We received comments suggesting that CMS develop a set of national guidelines for coding hospital emergency department (ED) visits. One commenter cited the June 2019 Medicare Payment Advisory Commission (MedPAC) ''Report to the Congress: Medicare and the Health Care Delivery System,'' which recommended that the Secretary develop and implement a set of national guidelines for coding hospital ED visits under the OPPS by 2022. In this report, MedPAC indicated that national guidelines are necessary in order to improve the accuracy of Medicare payments for ED visits and to regain a distribution of coding frequency that is approximately normal, meaning Level 3 ED visits being the most frequently coded level and Levels 1 and 5 the least frequently coded. MedPAC found that hospitals' coding of ED visits has steadily shifted from the lower levels to the higher levels, and they estimated that 20 to 25 percent of the growth in Medicare spending on ED visits was due to these visits being coded to higher levels. Commenters felt that ''standardized, national guidelines are necessary in order to ensure coding consistency and data comparability across hospitals and to improve payment accuracy.'' Another commenter stated that absent such standards, payers are creating their own criteria and are downgrading higher-level ED evaluation and management services, resulting in a loss of resources and increased administrative burden.

Response: We thank the commenters for their suggestions. As we noted in the CY 2008 OPPS/ASC final rule (72 FR 66579) we understand the interest in promulgating national guidelines but we continue to believe that it is unlikely that national guidelines could apply to the reporting of all ED visits. We may revisit this topic in the future as necessary.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59015), we adopted a method to control unnecessary increases in the volume of covered outpatient department services under section 1833(t)(2)(F) of the Act by utilizing a Medicare Physician Fee Schedule (PFS)-equivalent payment rate for the hospital outpatient clinic visit (HCPCS code G0463) when it is furnished by excepted off-campus provider-based departments (PBDs). As discussed in section X.D of that proposed rule and the CY 2019 OPPS/ASC final rule with comment period (83 FR 58818 through 59179), CY 2020 was the second year of the 2-year transition for this policy and, beginning in CY 2020, these departments are paid the site-specific PFS rate for the clinic visit service. We note that on September 1, 2019, the United States District Court for the District of Columbia (the district court) entered an order vacating the portion of the CY 2019 OPPS/ASC final

rule with comment period that adopted the volume control method for clinic visit services furnished by nonexcepted off-campus PBDs and remanded the matter to the Secretary for further proceedings consistent with the district court's opinion.[87] In the CY 2020 OPPS/ASC final rule with comment period, we acknowledged that the district court vacated the volume control policy for CY 2019 and we stated that we were working to ensure affected 2019 claims for clinic visits were paid consistent with the court's order. We also stated that we did not believe it was appropriate at that time to make a change to the second year of the 2-year phase-in of the clinic visit policy. We explained that we still had appeal rights, and were evaluating the rulings and considering whether to appeal from the final judgment. On July 17, 2020, the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) ruled in favor of CMS, holding that our regulation was a reasonable interpretation of the statutory authority to adopt a method to control for unnecessary increases in the volume of the relevant service. For a full discussion of this policy, we refer readers to the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142).

As detailed later in this section, after consideration of public comments, we are continuing the clinic visit payment policy as adopted in CY 2019 rulemaking. We will continue to take information submitted by the commenters into consideration for future analysis.

The following is a summary of the comments we received and our responses to those comments.

Comment: We received comments supporting CMS' efforts to continue implementing its method to control for unnecessary increases in the volume of outpatient services. Commenters expressed their support for site-neutral payment policies in excepted and non-excepted off-campus PBDs that promote greater payment alignment between physicians and hospitals. One commenter noted, ''Over the last decade, our nation has seen a trend of formerly independent physician practices becoming affiliated with major hospital systems.[88] This movement is part of a larger trend of consolidation among health systems and physicians where health systems are able to use their market power to leverage higher prices for all consumers.[89] The purchasing of physician practices by hospital systems has resulted in costs shifting to outpatient facilities where the costs of care are substantially higher. The drive toward higher-cost hospital-based outpatient services has had a direct negative financial impact on Medicare beneficiaries and overall Medicare expenditures. Medicare beneficiaries pay higher copays at hospital outpatient departments (HOPDs) than they do in physician offices, and HOPDs are paid more than twice as much as physicians are paid under the Medicare physician fee schedule for the same service, thereby contributing to excess Medicare expenditures.'' One commenter recommended CMS continue implementing site-neutral payments not just for off-campus PBDs but also for on-campus PBDs, and freestanding and non-freestanding emergency departments.

Response: We appreciate the commenters' support. As we noted in the CY 2019 OPPS/ASC proposed rule (83 FR 37138 through 37143), ''[a] large source of growth in spending on services furnished in hospital outpatient departments (HOPDs) appears to be the result of the shift of services from (lower cost) physician offices to (higher cost) HOPDs.'' We continue to believe that these shifts in the sites of service are unnecessary if the beneficiary can safely receive the same services in a lower cost setting but instead receives care in a higher cost setting due to payment incentives. In addition to the concern that the difference in payment is leading to unnecessary increases in the volume of covered outpatient department services, we remain concerned that this shift in care setting increases beneficiary cost-sharing liability because Medicare payment rates for the same or similar services are generally higher in hospital outpatient departments than in physician offices. We continue to believe that our method will address the concerns as described in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59005).

Comment: We received numerous comments outlining concerns we contemplated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59005) and in the CY 2020 OPPS/ASC (84 FR 61142) final rule with comment period. Commenters' expressed that the payment cut for hospital outpatient clinic visits threatens access to care, especially in rural and other vulnerable communities, and that CMS has undermined the clear congressional intent of Section 603 of the Bipartisan Budget Act of 2015 and exceeded its legal authority.

Many commenters asserted that the clinic visit policy is an ''adjustment'' subject to budget neutrality. Commenters expressed concern that we did not create sufficient data analytics to support our policy rationales. Commenters stated that there are several factors in the Medicare program (and outside of hospital control) that could influence more services moving to the hospital outpatient setting, including the hospital readmissions reduction program, hospital value-based purchasing, and the 2-midnight rule. Commenters further stated that care provided at PBDs is held to higher quality standards and thus cannot be directly compared to care provided at physician offices.

Commenters reiterated their comments from the CY 2019 OPPS/ASC final rule with comment period (83 FR 59005) that, relative to patients seen in physician offices, patients seen in HOPDs:

- Have more severe chronic conditions;
- Have higher prior utilization of hospitals and EDs;
- Are more likely to live in low-income areas;
- Are 1.8 times more likely to be dually eligible for Medicare and Medicaid;
- Are 1.4 times more likely to be nonwhite;
- Are 1.6 times more likely to be under age 65 and disabled; and
- Are 1.1 times more likely to be over 85 years old.

Response: We continue to believe that section 1833(t)(2)(F) of the Act gives the Secretary authority to develop a method for controlling unnecessary increases in the volume of covered OPD services, including a method that controls unnecessary volume increases by removing a payment differential that is driving a site-of-service decision, and as a result, is unnecessarily increasing service volume.[90] We also continue to believe shifts in the sites of service described in CY 2019 OPPS/ASC final rule with comment period (83 FR

[87] *American Hospital Ass'n, et al.* v. *Azar,* No. 1:18–cv–02841–RMC (D.D.C. Sept. 17, 2019).

[88] Jeff Lagasse, ''Hospitals acquired 5,000 physician practices in a single year,'' Healthcare Finance, March 15, 2018, *https://www.healthcarefinancenews.com/news/hospitals-acquired-5000-physician-practices-single-year.*

[89] Bela Gorman, Don Gorman, Jennifer Smagula, John D. Freedman, Gabriella Lockhart, Rik Ganguly, Alyssa Ursillo, Paul Crespi, and David Kadish, Why Are Hospital Prices Different? An Examination of New York Hospital Reimbursement, New York: New York State Health Foundation, December 2016, *https://nyshealthfoundation.org/wp-content/uploads/2017/11/an-examination-of-new-york-hospital-reimbursement-dec-2016.pdf.*

[90] Available at: *https://www.ssa.gov/OP_Home/ssact/title18/1833.htm.*

59011) are inherently unnecessary if the beneficiary can safely receive the same services in a lower cost setting but instead receives care in a higher cost setting due to the payment incentives created by the difference in payment amounts. While HOPDs may serve unique patient populations and provide services to medically complex beneficiaries, we have not received data from commenters that demonstrates the need for higher payment for clinic visits furnished in excepted off-campus PBDs. As we asserted in the 2019 OPPS/ASC final rule with comment period (83 FR 59011), the fact that the commenters did not supply new or additional data supporting these assertions suggests that the payment differential is likely the main driver for unnecessary volume increases in outpatient department services, particularly clinic visits.

As we noted in the CY 2019 OPPS/ASC final rule comment period (83 FR 59013), we maintain that while section 1833(t)(9)(B) of the Act does require that certain changes made under the OPPS be made in a budget neutral manner, this provision does not apply to the volume control method under section 1833(t)(2)(F) of the Act. Further, as we stated in the CY 2019 OPPS/ASC proposed rule (83 FR 37138 through 37143), we believe that implementing a volume control method in a budget neutral manner would not appropriately reduce the overall unnecessary volume of covered OPD services, and instead would simply shift the volume within the OPPS system in the aggregate.

On July 17, 2020, the D.C. Circuit ruled in favor of CMS, holding that our regulation was a reasonable interpretation of the statutory authority to adopt a method to control for unnecessary increases in the volume of the relevant service.[91] The D.C. Circuit concluded that CMS reasonably read subparagraph (2)(F) to allow a service-specific, non-budget-neutral payment reduction in the circumstances presented in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013).[92] On October 16, 2020, appellees' petition for panel rehearing and petition for rehearing en banc were denied.

Comment: We received comments asserting that our site-neutral policies are based on the flawed assumption that Medicare PFS payment rates are sustainable rates for physicians.

Response: As we noted in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142), Medicare payment rates under the PFS for services furnished by physicians and other suppliers are determined as required by the PFS statute, and the rates for individual services are determined based on the resources involved in furnishing these services relative to other services paid under the PFS. To the extent that commenters believe that the PFS rate for a particular service is misvalued relative to other PFS services, we encourage commenters to nominate the service for review as a potentially misvalued service under the PFS.

Comment: Many commenters referenced the ongoing litigation (described earlier in this section). They noted that the American Hospital Association (AHA) is seeking a rehearing by the full D.C. Circuit of the recent decision overturning the district court's ruling in favor of AHA. Several commenters stated that while this issue remains under consideration by the D.C. Circuit, CMS should delay continuing the policy in CY 2021. Some commenters requested that CMS restore the higher payment rates for off-campus HOPDs. Commenters also requested that CMS make remedial payments to hospitals for underpayments in 2019 and 2020. One commenter stated that CMS should not seek recoupment of previously adjusted claims, given hospitals' current financial situations as a result of the ongoing COVID–19 pandemic. They noted that CMS and HHS have sought opportunities to support hospitals throughout the pandemic and one simple way to do so would be to refrain from recouping prior repayments made to hospitals in response to the district court's decision.

Response: As noted earlier in this section, on July 17, 2020, the D.C. Circuit ruled in favor of CMS, holding that our regulation was a reasonable interpretation of the statutory authority to adopt a method to control for unnecessary increases in the volume of the relevant service. On October 16, 2020, the D.C. Circuit denied the appellees' petitions for a panel rehearing or a rehearing en banc. The appellees have 90 days from the date of the orders denying their petitions to ask the United States Supreme Court to review the case. We are still considering how we may address any over or underpayments for 2019 claims.

Comment: Many commenters characterized the reductions to hospital payments for clinic visits as excessive and harmful, especially during the COVID–19 PHE. One commenter noted that ''Continuing to impose a 60% cut on clinic visit services in 2021, on top of the dire financial impacts on U.S. hospitals and health systems due to COVID–19, would greatly endanger the critical role that HOPDs play in their communities, including providing convenient access to care for the most vulnerable and medically complex beneficiaries.'' Another commenter asked CMS to reconsider its current policy and exempt Medicare-Dependent Hospitals, Small Rural Hospitals, Sole Community Hospitals (urban and rural) and Rural Referral Centers from all applications of the PFS relativity adjuster.

Response: We share commenter's concerns about the financial difficulties brought on by the COVID–19 PHE. We have taken a variety of actions to support hospitals so they can more effectively respond to the COVID–19 PHE, including waiving the provider-based rules and permitting on-campus and excepted off-campus provider-based departments to temporarily relocate and continue to be paid under the OPPS if they submit a temporary extraordinary relocation exception request to their Regional Office. Additionally, we provided for a 2-year phase-in of this policy to help to mitigate the immediate financial impact on providers.

We share the commenters' concerns about access to care, especially in rural areas where access issues may be more pronounced than in other areas of the country. Medicare has long recognized the unique needs of rural communities and the financial challenges rural providers face. Across the various Medicare payment systems, CMS has implemented a number of special payment provisions for rural providers to maintain access and ensure beneficiaries in rural areas receive high quality care. Under the OPPS, section 1833(t)(13) of the Act gives the Secretary authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural sole community hospitals. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural sole community hospitals of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act. We have continued this 7.1 percent payment adjustment since 2006. We will continue to monitor trends for any access to care issues and may consider exemptions from the clinic visit policy for future rulemaking.

[91] *Am. Hosp. Ass'n* v. *Azar,* 964 F.3d 1230, 1244–45 (D.C. Cir. July 17, 2020).

[92] *Id.*

After consideration of public comments we received, we are continuing the clinic visit payment policy for CY 2021 and beyond. We will continue to utilize a PFS-equivalent payment rate for the hospital outpatient clinic visit service described by HCPCS code G0463 when it is furnished by excepted off-campus provider-based departments. The PFS-equivalent rate for CY 2021 is 40 percent of the proposed OPPS payment (that is, 60 percent less than the proposed OPPS rate). Under this policy, these departments will be paid approximately 40 percent of the OPPS rate (100 percent of the OPPS rate minus the 60-percent payment reduction that is applied in CY 2021) for the clinic visit service in CY 2021. Considering the effects of estimated changes in enrollment, utilization, and case-mix, this policy results in an estimated CY 2021 savings of approximately $430 million, with approximately $340 million of the savings accruing to Medicare, and approximately $90 million saved by Medicare beneficiaries in the form of reduced copayments, when compared to estimated expenditures if the policy were not applied. We will continue to monitor the effect of this change in Medicare payment policy, including the volume of these types of OPD services. We also will continue to evaluate this policy as necessary in response to the ongoing litigation.

VIII. Payment for Partial Hospitalization Services

A. Background

A partial hospitalization program (PHP) is an intensive outpatient program of psychiatric services provided as an alternative to inpatient psychiatric care for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and substance use disorders. Section 1861(ff)(1) of the Act defines partial hospitalization services as the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan. Section 1861(ff)(2) of the Act describes the items and services included in partial hospitalization services. Section 1861(ff)(3)(A) of the Act specifies that a PHP is a program furnished by a hospital to its outpatients or by a community mental health center (CMHC), as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting. Section 1861(ff)(3)(B) of the Act defines a CMHC for purposes of this benefit. We refer readers to sections 1833(t)(1)(B)(i), 1833(t)(2)(B), 1833(t)(2)(C), and 1833(t)(9)(A) of the Act and 42 CFR 419.21, for additional guidance regarding PHP.

In CY 2008, we began efforts to strengthen the PHP benefit through extensive data analysis, along with policy and payment changes by implementing two refinements to the methodology for computing the PHP median. For a detailed discussion on these policies, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). In CY 2009, we implemented several regulatory, policy, and payment changes. For a detailed discussion on these policies, we refer readers to the CY 2009 OPPS/ASC final rule (73 FR 68688 through 68697). In CY 2010, we retained the two-tier payment approach for partial hospitalization services and used only hospital-based PHP data in computing the PHP APC per diem costs, upon which PHP APC per diem payment rates are based (74 FR 60556 through 60559). In CY 2011, (75 FR 71994), we established four separate PHP APC per diem payment rates: two for CMHCs (APC 0172 and APC 0173) and two for hospital-based PHPs (APC 0175 and APC 0176) and instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates. For a detailed discussion, we refer readers to section X.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994). In CY 2012, we determined the relative payment weights for partial hospitalization services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for partial hospitalization services provided by hospital-based PHPs based exclusively on hospital data (76 FR 74348 through 74352). In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPPS APCs, including the four PHP APCs (APCs 0172, 0173, 0175, and 0176), on geometric mean costs rather than on the median costs. For a detailed discussion on this policy, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68406 through 68412).

In the CY 2014 OPPS/ASC proposed rule (78 FR 43621 through 43622) and CY 2015 OPPS/ASC final rule with comment period (79 FR 66902 through 66908), we continued to apply our established policies to calculate the four PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims data for each provider type. For a detailed discussion on this policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75047 through 75050). In the CY 2016, we described our extensive analysis of the claims and cost data and ratesetting methodology, corrected a cost inversion that occurred in the final rule data with respect to hospital-based PHP providers and renumbered the PHP APCs. In CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 through 79691), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs and finalized a policy to combine the Level 1 and Level 2 PHP APCs for CMHCs and for hospital-based PHPs. We also implemented an eight-percent outlier cap for CMHCs to mitigate potential outlier billing vulnerabilities. For a comprehensive description of PHP payment policy, including a detailed methodology for determining PHP per diem amounts, we refer readers to the CY 2016 and CY 2017 OPPS/ASC final rules with comment period (80 FR 70453 through 70455 and 81 FR 79678 through 79680).

In the CYs 2018 and 2019 OPPS/ASC final rules with comment period (82 FR 59373 through 59381, and 83 FR 58983 through 58998, respectively), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs, designated a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, and proposed updates to the PHP allowable HCPCS codes. We finalized these proposals in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61352). We refer readers to section VIII.D. of the CY 2021 OPPS/ASC proposed rule for a discussion of the proposed updates and the applicability for CY 2021.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61339 through 61350), we finalized our proposal to use the calculated CY 2020 CMHC geometric mean per diem cost and the calculated CY 2020 hospital-

based PHP geometric mean per diem cost, but with a cost floor equal to the CY 2019 final geometric mean per diem costs as the basis for developing the CY 2020 PHP APC per diem rates. Also, we continued to designate a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS, excluding outlier payments.

In the April 30, 2020 interim final rule with comment (85 FR 27562 through 27566), effective as of March 1, 2020 and for the duration of the COVID–19 Public Health Emergency (PHE), hospital and CMHC staff are permitted to furnish certain outpatient therapy, counseling, and educational services (including certain PHP services), incident to a physician's services, to beneficiaries in temporary expansion locations, including the beneficiary's home, so long as the location meets all conditions of participation to the extent not waived. A hospital or CMHC can furnish such services using telecommunications technology to a beneficiary in a temporary expansion location if that beneficiary is registered as an outpatient. These provisions apply only for the duration of the COVID–19 PHE.

B. PHP APC Update for CY 2021

1. PHP APC Geometric Mean Per Diem Costs

In summary, for CY 2021, we are finalizing our proposal to use the CY 2021 CMHC geometric mean per diem cost calculated in accordance with our existing methodology, using the most recent updated claims and cost data, as the basis for developing the CY 2021 CMHC APC per diem rate. We are also finalizing our proposal for CY 2021 to use the CY 2021 hospital-based geometric mean per diem cost calculated in accordance with our existing methodology, using the most recent updated claims and cost data.

In the CY 2021 OPPS/ASC proposed rule, we proposed to use geometric mean per diem cost for CMHCs and hospital-based PHPs, calculated in accordance with our existing methodology as the basis for calculating the APC per diem rates for CMHCs and hospital-based PHPs respectively, but with a cost floor applicable for each APC. We proposed to use the cost floors calculated last year for CY 2020 ratesetting; that is, a cost floor of $121.62 for CMHCs and a cost floor of $222.76 for hospital-based PHPs. Following this methodology, we proposed to use a cost floor value of $121.62 for CMHCs as the basis for developing the CY 2021 CMHC APC per diem rate. We proposed to use the CY 2021 hospital-based PHP geometric mean per diem cost of $243.94, calculated in accordance with our existing methodology for hospital-based PHPs, as the basis for developing the CY 2021 hospital-based APC per diem rate.

Using the most recent updated claims and cost data as proposed, the final CMHC geometric mean per diem cost is $136.14 and the final hospital-based PHP geometric mean per diem cost is $253.76. The final calculated geometric mean per diem costs for both CMHCs and hospital-based PHPs are significantly higher than each proposed floor, therefore a floor is not necessary at this time and we are not finalizing the proposed cost floors in this CY 2021 OPPS/ASC final rule with comment period at this time.

Lastly, we are finalizing our proposal to continue to use CMHC APC 5853 (Partial Hospitalization (three or More Services Per Day)) and hospital-based PHP APC 5863 (Partial Hospitalization (three or More Services Per Day)). These policies are discussed in more detail below.

2. Development of the PHP APC Geometric Mean Per Diem Costs

In preparation for CY 2021, we followed the PHP ratesetting methodology described in section VIII.B.2. of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 through 70466) to calculate the PHP APCs' geometric mean per diem costs and payment rates for APCs 5853 and 5863, incorporating the modifications made in the CY 2017 OPPS/ASC final rule with comment period. As discussed in section VIII.B.1. of the CY 2017 OPPS/ASC final rule with comment period (81 FR 79680 through 79687), the geometric mean per diem cost for hospital-based PHP APC 5863 is based upon actual hospital-based PHP claims and costs for PHP service days providing three or more services. Similarly, the geometric mean per diem cost for CMHC APC 5853 is based upon actual CMHC claims and costs for CMHC service days providing three or more services. The CMHC or hospital-based PHP APC per diem costs are the provider-type specific costs derived from the most recent claims and cost data. The CMHC or hospital-based PHP APC per diem payment rates are the national unadjusted payment rates calculated from the CMHC or hospital-based PHP APC geometric mean per diem costs, after applying the OPPS budget neutrality adjustments described in section XX of this CY 2021 OPPS/ASC final rule with comment period.

a. CMHC Data Preparation: Data Trims, Exclusions, and CCR Adjustments

For this CY 2021 OPPS/ASC final rule, prior to calculating the proposed geometric mean per diem cost for CMHC APC 5853, we prepared the data by first applying trims and data exclusions, and assessing CCRs as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465), so that ratesetting was not skewed by providers with extreme data. Before any trims or exclusions were applied, there were 40 CMHCs in the PHP claims data file. Under the ±2 standard deviation trim policy, we excluded any data from a CMHC for ratesetting purposes when the CMHC's geometric mean cost per day was more than ±2 standard deviations from the geometric mean cost per day for all CMHCs. In applying this trim for CY 2021 ratesetting, 2 CMHCs had geometric mean costs per day below the trim's lower limit of $33.81 or had geometric mean costs per day above the trim's upper limit of $519.84. Therefore, we excluded these 2 CMHCs from ratesetting because of the ±2 standard deviation trim.

In accordance with our PHP ratesetting methodology (80 FR 70465), we also removed service days with no wage index values, because we used the wage index data to remove the effects of geographic variation in costs prior to APC geometric mean per diem cost calculation. For this CY 2021 OPPS/ASC final rule ratesetting, no CMHC was missing wage index data for all of its service days and, therefore, no CMHC was excluded. We also excluded providers without any days containing 3 or more units of PHP-allowable services. One provider was excluded from ratesetting because it had no days containing 3 or more units of PHP-allowable services. In addition to our trims and data exclusions, before calculating the PHP APC geometric mean per diem costs, we also assess CCRs (80 FR 70463). Our longstanding PHP OPPS ratesetting methodology defaults any CMHC CCR greater than one to the statewide hospital CCR (80 FR 70457). For this CY 2021 OPPS/ASC final rule ratesetting, there were no CMHCs that showed CCRs greater than one. Therefore, it was not necessary to default any CMHC to its statewide hospital CCR for ratesetting.

In summary, these data preparation steps did not adjust the CCR for any CMHCs with a CCR greater than one during our ratesetting process. We excluded one CMHC because it had no

days containing 3 or more services and 2 CMHCs for failing the ±2 standard deviation trim, resulting in the inclusion of 37 CMHCs. We did not exclude any other CMHCs for any other trims or exclusions or for other missing data. There were 439 CMHC claims removed during data preparation steps due to the ±2 standard deviation trim or because they either had no PHP-allowable codes or had zero payment days, leaving 10,495 CMHC claims in our CY 2021 final rule ratesetting modeling. After applying all of the previously listed trims, exclusions, and adjustments, we followed the methodology described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70464 through 70465) and modified in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 through 79688, and 79691) to calculate a CMHC APC geometric mean per diem cost.[93] The calculated CY 2021 geometric mean per diem cost for all CMHCs for providing three or more services per day (CMHC APC 5853) is $136.14, an increase from $121.62 calculated last year for CY 2020 ratesetting (84 FR 61347).

In the CY 2021 proposed rule (85 FR 48902) the CY 2021 calculated CMHC APC was $104.00, which we were concerned would not support ongoing access to PHPs in CMHCs. Therefore, we proposed to extend for CY 2021 and subsequent years the cost floor established in the prior year (84 FR 61339 through 61344). Because the final calculated CMHC geometric mean per diem cost for this final rule with comment period is substantially higher than the cost floor, we believe that the final calculated geometric mean per diem cost for CMHCs will effectively support access to partial hospitalization services and PHPs, and therefore the data no longer supports the need to finalize a cost floor at this time.

The CMHC APC 5853 is described as providing three or more partial hospitalization services per day (81 FR 79680), and 85.7 percent of CMHC paid days in CY 2019 were for providing four or more services per day. To be eligible for a PHP, a patient must need at least 20 hours of therapeutic services per week, as evidenced in the patient's plan of care (42 CFR 410.43(c)(1)). To meet those patient needs, most PHP provider paid days are for providing four or more services per day (we refer readers to Table 45—Percentage of PHP Days by Service Unit Frequency of this final rule with comment period). Therefore, the higher calculated geometric mean per diem cost of $136.14 is in line with our expectations, since the CMHC APC 5853 is actually heavily weighted to the cost of providing four or more services. For context, the per diem costs for CMHC APC 5853 have been calculated as $124.92, $143.22, and $121.62 for CY 2017 (81 FR 79691), CY 2018 (82 FR 59378), and CY 2019 (83 FR 58991), respectively.

In our analysis for the CY 2021 proposed rule, we found that six providers, collectively representing 39.7 percent of all CMHC days, reported lower costs per day than those reported for the CY 2020 final rule ratesetting. These six providers heavily influenced the calculated geometric mean per diem cost for CY 2021. Because these providers had a high number of paid PHP days, and because the CMHC data set was so small (n=38), these providers had a significant influence on the calculated CY 2021 CMHC APC geometric mean per diem cost. Based on updated cost and claims data for this final rule, the geometric mean costs for three of these six providers (collectively representing 15.7 percent of all CMHC days) increased substantially along with the geometric mean costs of a fourth provider, such that the final calculated geometric mean per diem cost for all CMHCs increased to $136.14.

For the CY 2021 OPPS/ASC proposed rule, in crafting our proposal, we also considered a 3-year collective PHP geometric mean per diem cost for each provider type calculated using the cost data from the three most recent years, that is the final cost data from CY 2017 and CY 2018, along with the latest available cost data from CY 2019. We also considered a 4-year collective PHP geometric mean per diem cost for each provider type calculated using the cost data from the four most recent years, which is the final cost data from CY 2016, CY 2017, and CY 2018, along with the latest available cost data from CY 2019. We did not ultimately propose either of these methodologies, and we did not receive any comments on these methodologies. Further discussion of these alternatives that we considered is found in the CY 2021 OPPS/ASC proposed rule (85 FR 48904).

In summary, we are finalizing our proposal to use the current year's CMHC APC geometric mean per diem cost (in this case, the CY 2021 CMHC APC geometric mean per diem cost), calculated in accordance with our existing methodology. Since the final calculated CMHC geometric mean per diem cost for this final rule with comment period is substantially higher than the cost floor, we believe that the final calculated geometric mean per diem cost for CMHCs will effectively support access to partial hospitalization services and PHPs, and therefore the data no longer supports the need to finalize a cost floor at this time. We refer readers to section XXIV. of this CY 2021 OPPS/ASC final rule with comment period for payment impacts, which are budget neutral.

We received 8 comments that addressed CMHC ratesetting, which are summarized as follows:

Comment: Nearly all commenters supported our proposed increase to the CMHC payment rate and the efforts by CMS to mitigate fluctuations in CMHC payments and help protect beneficiary access to PHP services. However, several commenters expressed concern that despite the modest, occasional rate increases proposed and finalized in recent years, the results of the proposed PHP ratesetting methodology are contrary to CMS's efforts to protect access. One commenter suggested that CMS consider incorporating an annual adjustment to the cost floor in order to ensure that it reflects updated cost information and continues to help minimize the impact of significant changes in the median costs. Five commenters stated that the current payment methodology has resulted in reductions in provider access rather than protection of access. Several commenters expressed concern about the decline in the number of CMHCs and the effect that further declines would have on beneficiary access to care. These commenters suggested that declining PHP payment rates have been the cause of the decline in the number of CMHCs. One commenter stated that decreased access to CMHC PHP services could force beneficiaries to use more costly hospital-based PHPs, with higher beneficiary co-payments, or lead to increased use of inpatient psychiatric resources. This commenter stated that the data used for CMHC ratesetting are

[93] Each revenue code on the CMHC claim must have a HCPCS code and charge associated with it. We multiply each claim service line's charges by the CMHC's overall CCR from the OPSF (or statewide CCR, where the overall CCR was greater than 1) to estimate CMHC costs. Only the claims service lines containing PHP allowable HCPCS codes and PHP allowable revenue codes from the CMHC claims remaining after trimming are retained for CMHC cost determination. The costs, payments, and service units for all service lines occurring on the same service date, by the same provider, and for the same beneficiary are summed. CMHC service days must have three or more services provided to be assigned to CMHC APC 5853. The final geometric mean per diem cost for CMHC APC 5853 is calculated by taking the *n*th root of the product of *n* numbers, for days where three or more services were provided. CMHC service days with costs ±3 standard deviations from the geometric mean costs within APC 5853 are deleted and removed from modeling. The remaining PHP service days are used to calculate the final geometric mean per diem cost for each PHP APC by taking the *n*th root of the product of *n* numbers for days where three or more services were provided.

skewed, the calculations are incorrect, and the proposed low payment rates would result in the remaining CMHCs closing. This commenter noted that setting CMHCs' payment rates based on a small number of CMHCs does not reflect the actual cost of providing these services and expressed concern that by using the mean or median costs, more CMHCs would close.

Response: We thank the commenters for their support, and we also share the commenters' concerns about the decline in the number of PHPs, particularly at CMHCs, and the effect on access. However, it does not directly follow that declining per diem payment rates alone have caused the decline in the number of PHPs. As we have noted in prior rulemaking (76 FR 74350 and 79 FR 66906), the closure of PHPs may be due to a number of reasons, such as business management or marketing decisions, competition, oversaturation of certain geographic areas, and federal and state fraud and abuse efforts, among others. Our goal is to ensure accurate and reasonable payment rates for PHP services that protect access to both provider types, so beneficiaries have choices regarding where to receive treatment. We want to ensure that CMHCs remain a viable option as providers of mental health care in the beneficiary's own community. Also, beneficiaries receiving care at a CMHC instead of a hospital-based PHP may incur lower beneficiary copayments. However, we disagree with the assertion that the CMHC data are skewed and that the calculations are incorrect. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70456 to 70459), we implemented a ±2 standard deviation trim on CMHC costs per day to remove aberrant data that could skew costs up or down inappropriately. We recognize that with a small number of providers, such as the 37 CMHCs used for this final rule rate setting, the calculations can be influenced by large providers, however it is important to note that the influence these providers have is appropriate and proportional to their share of PHP days furnished. In this CY 2021 final rule ratesetting, as discussed previously in this section, updated data from three large providers reflected a significant increase in geometric mean per diem costs. Due to the large share of PHP days that these providers furnished, their increased per diem costs influenced the overall CMHC geometric mean per diem cost calculation.

We also recognize that as the number of providers decreases, the ratesetting calculations can be more strongly influenced by the costs of large providers. We are regularly evaluating our rate setting methodology to ensure that it is as accurate as possible, and captures provider cost data fully. However, our rate setting methodology must comply with requirements at sections 1833(t)(2) and 1833(t)(9) of the Act, and depends heavily on provider-reported costs. We strongly encourage CMHCs to review cost reporting instructions to be sure they are reporting their costs correctly. These instructions are available in chapter 45 of the Provider Reimbursement Manual, Part 2, available on the CMS website at *https://www.cms.gov/Regulations-andGuidance/Guidance/Manuals/PaperBased-Manuals.html*. We want to reiterate that it is a requirement for CMHCs, unless they are approved as a low-utilization or no-utilization provider in accordance with PRM–1, chapter 1, section 110 (42 CFR 413.24(g) and (h)), to file full cost reports, to help us capture accurate CMHC costs in rate setting. We furthermore encourage those CMHCs that do not file full cost reports to consider doing so.

We are confident that the per diem costs we calculate follow the methodology discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 to 70466) and in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79691). Those costs are geometric mean per diem costs, rather than arithmetic mean or median per diem costs; in the CY 2013 OPPS final rule (77 FR 68409), we discussed the advantages of using geometric means rather than medians to calculate PHP costs, and noted that the geometric mean more accurately captures the full range of service costs (including outliers) than the median cost and promotes more stability in the payment system. In summary, we believe that providing payment that is based upon actual provider-reported costs supports access to PHP services and does not lead to provider closures; however, as we noted above, we rely on providers to accurately report their costs in a timely and complete manner.

For CY 2021, after reviewing comments and updated cost and claims data, we are finalizing the CY 2021 CMHC geometric mean per diem cost as $136.14, which is above the proposed cost floor amount and based on updated cost and claims data. We believe this calculated geometric mean per diem cost will support access to PHP services. Therefore at this time, we are not finalizing our proposal to extend the cost floor for CY 2021 or subsequent years. Given the higher than expected calculated CMHC geometric mean per diem cost due to updated data, we do not believe our proposal for a cost floor is necessary for CY 2021 and do not believe it is appropriate to apply this cost floor for subsequent years; in response to the concerns raised by several commenters, we will continue to evaluate the effects of our policies and analyze the latest available cost and claims data to look for ways to further mitigate payment fluctuations and protect beneficiary access to PHP services. We appreciate the commenters' suggestions, and will take them into consideration as we explore future policies. We also refer readers to section VII.B.2.b of this final rule with comment period for a similar comment and response related to hospital-based PHPs.

Comment: Three commenters highlighted the importance of PHP services in the current environment and noted that the need for mental health services in general has increased.

Response: We appreciate the work PHPs do to care for a particularly vulnerable population with serious mental illnesses, and we recognize the particular importance of these programs in the current environment. We believe it is crucial to ensure that providers receive accurate payment in order to provide these necessary services to the PHP population. Based on the latest data, the geometric mean per diem cost for CMHCs is significantly higher than the cost floor that we proposed for CY 2021, and therefore the data does not support finalizing floor at this time in this CY 2021 OPPS/ASC final rule. As noted above, we will continue to look for ways to further mitigate payment fluctuations and protect beneficiary access to PHP services.

Comment: One commenter requested that CMS take into account for future rulemaking the effects that the COVID–19 PHE and the subsequent conversion to virtual care may have on PHP services and the payment methodology for such services.

Response: We appreciate the commenter's suggestion and will take this into consideration as we explore policy options for appropriately strengthening the PHP benefit and increasing access to the valuable services provided by CMHCs as well as by hospital-based PHPs. As part of that process, we regularly review our methodology to ensure that it is appropriately capturing the cost of care reported by providers and will give particular attention to effects of the ongoing COVID–19 PHE.

Comment: One commenter stated that CMHCs incur extra costs to meet the CMHC conditions of participation (CoPs) and have experienced an increase in bad debt expense.

Response: Most (if not all) of the costs associated with adhering to CoPs should be captured in the cost report data used in ratesetting and, therefore, are accounted for when computing the geometric mean per diem costs. Finally, the statutory reduction to bad debt reimbursement was a result of provisions of section 3201 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96). The reduction to bad debt reimbursement impacted all providers eligible to receive bad debt reimbursement, as discussed in the CY 2013 End-Stage Renal Disease final rule (77 FR 67518). Medicare currently reimburses bad debt for eligible providers at 65 percent of such debt. Because this percentage was enacted by Congress, CMS does not have the authority to change the percentage. In contrast to the Medicare bad debt reimbursement policy, private sector insurers typically do not reimburse providers for any amounts of enrollees' unpaid deductibles or coinsurance. In light of budgetary constraints and the steady increase in bad debt claims over the years, a reduction in bad debt reimbursement is necessary to protect the Medicare Trust Fund and preserve beneficiary access to care without imposing an undue burden on hospitals.

Comment: One commenter recommended that CMS pay CMHCs the same rate as hospital-based PHPs, since these two provider types provide the same services and have the same qualified clinical staff. This commenter objected to CMS' continuing use of the single-tier payment system for CMHCs, stating that it adversely affects the quality and intensity of PHP services.

Response: The OPPS pays for outpatient services, including partial hospitalization services, based on the costs of providing services using provider data from claims and cost reports, in accordance with statute. Section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services, within a classification system developed by the Secretary for covered OPD services, so that services classified within each group are comparable clinically and with respect to the use of resources. In addition, by statute at Section 1833(t)(2)(C) of the Act, we are required to use data on claims and most recent available cost reports to establish relative payment weights for covered OPD services. Therefore, we calculate a CMHC APC rate based on costs, which providers supply on their cost reports. While CMHCs and hospital-based CMHCs provide the same clinical services, their resource use differs, because these two provider types have different cost structures. In this final rule and in prior rulemaking, commenters and CMS have noted that hospitals tend to have higher costs than CMHCs, particularly higher overhead (83 FR 58986, 82 FR 59377, and 81 FR 79686 to 79687). We see this difference in cost structures reflected when we calculate the geometric mean cost per day for CMHCs versus for hospital-based PHPs, where CMHC costs per day are consistently lower than hospital-based PHP costs per day. For example, for this CY 2021 OPPS/ASC final rule with comment, the calculated geometric mean costs for providing PHP services were $136.14 per day for CMHCs, but were $253.76 per day for hospital-based PHPs. Therefore, we do not believe it is appropriate to pay CMHCs the same APC rate as hospital-based PHPs. We strongly encourage CMHCs to review cost reporting instructions to be sure they are reporting their costs correctly. These instructions are available in chapter 45 of the Provider Reimbursement Manual, Part 2, available on the CMS website at *https://www.cms.gov/Regulations-andGuidance/Guidance/Manuals/PaperBased-Manuals.html*.

We believe our policy to replace the existing Level 1 and Level 2 PHP APCs for both provider types with a single PHP APC, by provider type, is supported by the statute and regulations and will continue to pay for partial hospitalization services appropriately based upon actual provider costs (81 FR 79683). Regarding the commenter's concern about the small number of providers and the use of a single-tier payment system, we refer the commenter to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79682 through 79685), where we discussed our rationale for implementing the single-tier payment system for CMHCs. A key reason behind implementing the single tier for CMHCs was to reduce cost fluctuations and bring more stability to CMHC APC rates, especially given the small number of providers (81 FR 79683). We also noted that the costs of providing a Level 1 CMHC day were nearly the same as the cost of providing a Level 2 CMHC day (81 FR 79684). In accordance with the regulations at 42 CFR 419.31, we could not justify continuing to separate these services into two APCs, but combined clinically similar services with similar resource use into a single APC (81 FR 79683 to 79684).

We do not believe the intensity of PHP services provided in hospitals and in CMHCs has been affected by using a single-tier payment system. Based on the utilization data found in Table 45 of this final rule with comment period, the percentage of paid PHP days which have only three services has been relatively stable over time and has remained consistent for hospital-based PHPs. Even though we identified an increase in 3-service days for CMHCs in 2019, as we note in section VIII.B.3.b of this final rule with comment period, we also identified a noticeable increase in days with 5 or more services. We will continue to monitor the percentage of 3-service days and will also monitor the provision of 20 hours per week of PHP services, to ensure there are no unintended consequences of a single-tier payment system on PHP intensity. We are unable to determine the effects of the single-tier payment on CMHC quality, because there are no quality measures for CMHCs, nor is quality reporting required of CMHCs. However, we do not believe that a single-tier payment system would affect the quality of care provided in a CMHC.

Comment: One commenter suggested that CMS use value-based purchasing for paying CMHCs instead of a cost-based system stating that rewarding providers for higher-quality care, as measured by selected standards is a better way to improve the quality of any service. Other commenters recommended that CMS reconsider its policy positions on PHP services and look for ways to rebuild these services, suggesting that CMS base PHP reimbursement on incentives determined by documented productivity results. These commenters suggested we consider Measurement-based Care and Patient Satisfaction.

Response: We believe ''measurement-based care'' that the commenters cited refers to administering a standardized instrument to measure some aspect of patient symptoms when he or she begins and ends receiving PHP services. This type of measure could inform clinical decision-making and quality improvement activities at minimum, but results could theoretically be used to adjust payment. We also believe that the commenters are asking if CMS could administer patient satisfaction surveys and then reward high-performing PHPs. We responded to a similar public comment in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462) and refer readers to a summary of that comment and our response. Currently, there is no statutory language authorizing incentive payment methodology based on productivity results, patient satisfaction, or value-based purchasing for CMHCs or for outpatient hospital-based PHPs. To reiterate, sections 1833(t)(2) and 1833(t)(9) of the Act set forth the

requirements for establishing and adjusting OPPS payment rates, which are based on costs, and which include PHP payment rates. We note that section 1833(t)(17) of the Act authorizes the Hospital Outpatient Quality Reporting (OQR) Program, which applies a payment reduction to subsection (d) hospitals that fail to meet program requirements. In the CY 2015 OPPS/ASC proposed rule (79 FR 41040), we considered future inclusion of, and requested comments on, the following quality measures addressing PHP issues that would apply in the hospital outpatient setting: (1) 30-Day Readmission; (2) Group Therapy; and (3) No Individual Therapy. We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66957 through 66958) for a more detailed discussion of PHP measures considered for inclusion in the Hospital OQR Program in future years, and of the comments received as a result of the solicitation. CMS also adopted the OAS CAHPS survey in the Hospital OQR Program, beginning with CY 2020 payment determination (2018 data collection) (82 FR 52572 through 52573); however, implementation was delayed until further action in future rulemaking to ensure that the survey measures appropriately account for patient response rates, both aggregate and by survey administration method; reaffirm the reliability of national implementation of OAS CAHPS Survey data; and appropriately account for the burden associated with administering the survey in the outpatient setting of care.

However, the Hospital OQR Program does not apply to CMHCs, and there are no quality measures applied to CMHCs.

After careful consideration of the comments and updated data, we are finalizing our proposal to use the CY 2021 CMHC APC geometric mean per diem cost calculated in accordance with our existing methodology. Because the final calculated CMHC geometric mean per diem cost for this final rule with comment period is substantially higher than the cost floor, we believe that the final calculated geometric mean per diem cost for CMHCs will effectively support access to partial hospitalization services and PHPs. Therefore, the data no longer supports the need to finalize a cost floor at this time. In response to the concerns raised by several commenters, we will continue to look for ways to further mitigate payment fluctuations and protect beneficiary access to PHP services. The final CY 2021 CMHC geometric mean per diem cost is $136.14.

b. Hospital-Based PHP Data Preparation: Data Trims and Exclusions

For this CY 2021 final rule, we prepared data consistent with our policies as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465) for hospital-based PHP providers, which is similar to that used for CMHCs. The CY 2019 PHP claims included data for 449 hospital-based PHP providers for our calculations in this CY 2021 OPPS/ASC proposed rule.

Consistent with our policies as stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465), we prepared the data by applying trims and data exclusions. We applied a trim on hospital service days for hospital-based PHP providers with a CCR greater than 5 at the cost center level. To be clear, the CCR greater than 5 trim is a service day-level trim in contrast to the CMHC ±2 standard deviation trim, which is a provider-level trim. Applying this CCR greater than 5 trim removed affected service days from one hospital-based PHP provider from our final ratesetting. However, 100 percent of the service days for this hospital-based PHP provider had at least one service associated with a CCR greater than 5, so the trim removed this provider entirely from our final ratesetting. In addition, 68 hospital-based PHPs were removed for having no days with PHP payment. Two hospital-based PHPs were removed because none of their days included PHP-allowable HCPCS codes. No hospital-based PHPs were removed for missing wage index data, and a single hospital-based PHP was removed by the OPPS ±3 standard deviation trim on costs per day. (We refer readers to the OPPS Claims Accounting Document, available online at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1717-P-2020-OPPS-Claims-Accounting.pdf*.

Overall, we removed 72 hospital-based PHP providers [(1 with all service days having a CCR greater than 5) + (68 with no PHP payment) + (2 with no PHP-allowable HCPCS codes) + (1 provider with geometric mean costs per day outside the ± 3 SD limits)], resulting in 377 (449 total − 72 excluded) hospital-based PHP providers in the data used for calculating ratesetting. In addition, 6 hospital-based PHP providers were defaulted to their overall hospital ancillary CCRs due to outlier cost center CCR values.

After completing these data preparation steps, we calculated the final CY 2021 geometric mean per diem cost for hospital-based PHP APC 5863 for hospital-based partial hospitalization services by following the methodology described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70464 through 70465) and modified in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 and 79691).[94] The calculated CY 2021 hospital-based PHP APC geometric mean per diem cost for hospital-based PHP providers that provide three or more services per service day (hospital-based PHP APC 5863) is $253.76, which is an increase of 8.7 percent from $233.52 calculated last year for CY 2020 ratesetting (84 FR 61344 through 61348). We believe that a hospital-based PHP APC geometric mean per diem cost of $253.76 best supports ongoing access to hospital-based PHPs.

In the proposed rule (85 FR 48902) we stated that we believe access is better supported when the geometric mean per diem cost does not fluctuate greatly. In addition, while the hospital-based PHP APC 5863 is described as providing payment for the cost of three or more services per day (81 FR 79680), 89.1 percent of hospital-based PHP paid service days in CY 2019 were for providing four or more services per day. To be eligible for a PHP, a patient must need at least 20 hours of therapeutic services per week, as evidenced in the patient's plan of care (42 CFR 410.43(c)(1)). To meet those patient needs, most PHP paid service days provide four or more services (we refer readers to Table 45—Percentage of PHP Days by Service Unit Frequency in this final rule). Therefore, the hospital-based PHP APC 5863 is actually heavily weighted to the cost of providing four or more services. The per diem costs for hospital-based PHP APC 5863 have been

[94] Each revenue code on the hospital-based PHP claim must have a HCPCS code and charge associated with it. We multiply each claim service line's charges by the hospital's department-level CCR; in CY 2020 and subsequent years, that CCR is determined by using the PHP-only revenue-code-to-cost-center crosswalk. Only the claims service lines containing PHP-allowable HCPCS codes and PHP-allowable revenue codes from the hospital-based PHP claims remaining after trimming are retained for hospital-based PHP cost determination. The costs, payments, and service units for all service lines occurring on the same service date, by the same provider, and for the same beneficiary are summed. Hospital-based PHP service days must have three or more services provided to be assigned to hospital-based PHP APC 5863. The final geometric mean per diem cost for hospital-based PHP APC 5863 is calculated by taking the *n*th root of the product of *n* numbers, for days where three or more services were provided. Hospital-based PHP service days with costs ±3 standard deviations from the geometric mean costs within APC 5863 are deleted and removed from modeling. The remaining hospital-based PHP service days are used to calculate the final geometric mean per diem cost for hospital-based PHP APC 5863.

calculated as $213.14, $208.09, and $222.76 for CY 2017 (81 FR 79691), CY 2018 (82 FR 59378), and CY 2019 (83 FR 58991), respectively.

As we noted for CMHCs above, we likewise do not believe that it is likely that the cost of providing hospital-based PHP services would suddenly decline when costs generally increase over time. In order to address concerns about potential fluctuations, which we believed could be influenced by data from a small number of providers with low service costs per day, we proposed to use the CY 2021 hospital-based PHP APC geometric mean per diem cost, calculated in accordance with our existing methodology, but with a cost floor equal to the floor for hospital-based providers of $222.76 calculated last year for CY 2020 ratesetting (84 FR 61344 through 61345), as the basis for developing the CY 2021 hospital-based PHP APC per diem rate. As part of this proposal, we proposed that we would use the most recent updated claims and cost data to calculate CY 2021 geometric mean per diem costs, just as we did for CMHCs. We further proposed that the established hospital-based geometric mean per diem cost floor of $222.76 be extended to CY 2021 and subsequent years and that if the calculated geometric mean per diem cost for a given year is below the floor, then the geometric mean per diem cost that would be used for ratesetting in that year would be equal to the geometric mean per diem cost floor of $222.76. We stated we believed using the CY 2020 hospital-based PHP per diem cost floor as the floor for CY 2021 is appropriate because it is based on very recent hospital-based PHP claims and cost data and would help to protect provider access by preventing wide fluctuation in the per diem costs for hospital-based APC 5863.

While the proposed cost floor would protect hospital-based PHPs if the CY 2021 calculated hospital-based PHP APC geometric mean per diem cost were less than $222.76, the calculated hospital-based PHP geometric mean per diem cost of $243.94 was greater than the floor, and therefore, we proposed this calculated CY 2021 cost for hospital-based PHPs.

For the CY 2021 proposed rule, we also considered a 3-year collective PHP geometric mean per diem cost for each provider type calculated using the cost data from the three most recent years, that is, the final cost data from CY 2017 and CY 2018, along with the latest available cost data from CY 2019. We also considered a 4-year collective PHP geometric mean per diem cost for each provider type calculated using the cost data from the four most recent years, which is the final cost data from CY 2016, CY 2017, and CY 2018, along with the latest available cost data from CY 2019. We did not ultimately propose either of these methodologies, and we did not receive any comments on these methodologies. Further discussion of these alternatives is found in the CY 2021 OPPS proposed rule (85 FR 48904).

In summary, we are finalizing our proposal to use the most recent updated claims and cost data to calculate CY 2021 geometric mean per diem costs, just as we are for CMHCs in the section above. Because the final calculated CY 2021 hospital-based PHP APC geometric mean per diem cost is significantly higher than the proposed floor, we believe that the final calculated geometric mean per diem cost for hospital-based PHPs will effectively support access to partial hospitalization services. The data no longer supports the need to finalize a cost floor at this time, and therefore, we are not finalizing our proposal to extend the established hospital-based geometric mean per diem cost floor of $222.76 to CY 2021 and subsequent years. The final CY 2021 hospital-based PHP geometric mean per diem cost is $253.76. We refer readers to section XXIV of this CY 2021 OPPS/ASC final rule with comment period for a discussion of payment impacts and the budget neutrality adjustment for OPPS rates.

We received 8 comments that addressed hospital-based PHP ratesetting, which are summarized as follows:

Comment: Nearly all commenters supported our proposed increase to the hospital-based PHP payment rate and the efforts by CMS to mitigate fluctuations in hospital-based PHP payments and help protect beneficiary access to PHP services. However, several commenters expressed concern that despite the modest, occasional rate increases proposed and finalized in recent years, the results of the proposed PHP ratesetting methodology are contrary to CMS's efforts to protect access. Several commenters expressed concern about the decline in the number of hospital-based PHPs and the effect that further declines would have on beneficiary access to care. Five of these commenters stated that the current payment methodology has resulted in reductions in provider access rather than protection of access. One commenter suggested that CMS consider incorporating an annual adjustment to the cost floor in order to ensure that it reflects updated cost information and continues to help minimize the impact of significant changes in the median costs.

Response: We thank the commenters for their support, and we also share the commenters' concerns about the decline in the number of PHPs and the effect on access. However, as we stated above, it does not directly follow that declining per diem payment rates alone have caused the decline in the number of PHPs. As we have noted in prior rulemaking (76 FR 74350 and 79 FR 66906), the closure of PHPs may be due to a number of reasons, such as business management or marketing decisions, competition, oversaturation of certain geographic areas, and federal and state fraud and abuse efforts, among others. Our goal is to ensure accurate and reasonable payment rates for PHP services that protect access to both provider types, so beneficiaries have choices regarding where to receive treatment. After reviewing comments and updated costs, for CY 2021, we are finalizing the CY 2021 hospital-based PHP geometric mean per diem cost as $253.76, which is above the cost floor amount and based on updated cost and claims data. We believe this calculated geometric mean per diem cost will support access to hospital-based PHP services. At this time we are not finalizing our proposal to extend the cost floor for CY 2021 or subsequent years. Given the hospital-based PHP geometric mean per diem cost is $253.76, which is above the cost floor, we do not believe our proposal for a cost floor is necessary for CY 2021 and do not believe it is appropriate to apply this cost floor for subsequent years; in response to the concerns raised by several commenters, we will continue evaluate the effects of our policies and analyze the latest available cost and claims data to look for ways to further mitigate payment fluctuations and protect beneficiary access to PHP services. We appreciate the commenters' suggestions, and will take them into consideration as we explore future policies.

We also recognize that as the number of providers decreases, the relative share of PHP days furnished by large providers can increase, such that large providers' costs more strongly influence the ratesetting calculations. We are regularly evaluating our rate setting methodology to ensure that it is as accurate as possible, that it captures provider cost data fully, and that it protects access to PHP services. However, our rate setting methodology must comply with requirements at sections 1833(t)(2) and 1833(t)(9) of the Act, and depends heavily on provider-

reported costs. We strongly encourage hospitals to review cost reporting instructions to be sure they are reporting their costs correctly. These instructions are available in chapter 40 of the Provider Reimbursement Manual, Part 2, available on the CMS website at *https://www.cms.gov/Regulations-andGuidance/Guidance/Manuals/PaperBased-Manuals.html*. We also refer readers to section VIII.B.2.a. for a similar comment and response related to CMHCs.

Comment: Three commenters highlighted the importance of PHP services in the current environment and noted that the need for mental health services in general has increased.

Response: We appreciate the work PHPs do to care for a particularly vulnerable population with serious mental illnesses and believe that having PHPs available to beneficiaries helps prevent patient recidivism and inpatient psychiatric admissions, and we recognize the particular importance of these programs in the current environment. We believe it is crucial to ensure that providers receive accurate payment in order to provide these necessary services to the PHP population. Based on the latest data, the geometric mean per diem cost for hospital-based PHPs is significantly higher than the cost floor that we proposed for CY 2021, and therefore the data does not support finalizing floor at this time in this CY 2021 OPPS/ASC final rule.

Comment: One commenter requested that CMS to take into account for future rulemaking the effects that the COVID–19 PHE and the subsequent conversion to virtual care may have on PHP services and the payment methodology for such services.

Response: As mentioned earlier, we will continue to explore policy options for strengthening the PHP benefit and increasing access to the valuable services provided by CMHCs as well as by hospital-based PHPs with particular attention to effects of this PHE. As part of that process, we regularly review our methodology to ensure that it is appropriately capturing the cost of care reported by providers.

Comment: One commenter suggested that CMS use value-based purchasing for paying hospital-based PHPs instead of a cost-based system stating that rewarding providers for higher-quality care, as measured by selected standards is a better way to improve the quality of any service. Other commenters recommended that CMS reconsider its policy positions on PHP services and look for ways to rebuild these services, suggesting that CMS base PHP reimbursement on incentives determined by documented productivity results. These commenters suggested we consider Measurement-based Care and Patient Satisfaction.

Response: We believe ''measurement-based care'' that the commenters cited refers to administering a standardized instrument to measure some aspect of patient symptoms when he or she begins and ends receiving PHP services. This type of measure could inform clinical decision-making and quality improvement activities at minimum, but results could theoretically be used to adjust payment. We also believe that the commenters are asking if CMS could administer patient satisfaction surveys and then reward high-performing PHPs. We responded to a similar public comment in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462) and refer readers to a summary of that comment and our response. Currently, there is no statutory language authorizing incentive payment methodology based on productivity results, patient satisfaction, or value-based purchasing for CMHCs or for outpatient hospital-based PHPs. To reiterate, sections 1833(t)(2) and 1833(t)(9) of the Act set forth the requirements for establishing and adjusting OPPS payment rates, which are based on costs, and which include PHP payment rates. We note that section 1833(t)(17) of the Act authorizes the Hospital OQR Program, which applies a payment reduction to subsection (d) hospitals that fail to meet program requirements. In the CY 2015 OPPS/ASC proposed rule (79 FR 41040), we considered future inclusion of, and requested comments on, the following quality measures addressing PHP issues that would apply in the hospital outpatient setting: (1) 30-Day Readmission; (2) Group Therapy; and (3) No Individual Therapy. We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66957 through 66958) for a more detailed discussion of PHP measures considered for inclusion in the Hospital OQR Program in future years, and of the comments received as a result of the solicitation. CMS also adopted the OAS CAHPS survey in the Hospital OQR Program, beginning with CY 2020 payment determination (2018 data collection) (82 FR 52572 through 52573); however, implementation was delayed until further action in future rulemaking to ensure that the survey measures appropriately account for patient response rates, both aggregate and by survey administration method; reaffirm the reliability of national implementation of OAS CAHPS Survey data; and appropriately account for the burden associated with administering the survey in the outpatient setting of care.

After careful consideration of all the comments on the proposed rule and updated data, we used the most recent updated claims and cost data to calculate CY 2021 geometric mean per diem costs in this CY 2021 OPPS/ASC final rule with comment period. The final calculated geometric mean per diem costs for CY 2021 are substantially higher than the proposed cost floors for both CMHCs and hospital-based PHPs. We believe that the final calculated geometric mean per diem costs for CMHCs and hospital-based PHPs will effectively protect access to partial hospitalization services. Therefore, the data no longer supports the need to finalize either the proposed CMHC or hospital-based PHP cost floor at this time. In response to the concerns raised by several commenters, we will continue to look for ways to further mitigate payment fluctuations and protect beneficiary access to PHP services. The final CY 2021 hospital-based PHP geometric mean per diem cost is $253.76.

The final CY 2021 PHP geometric mean per diem costs are shown in Table 43 and are used to derive the final CY 2021 PHP APC per diem rates for CMHCs and hospital-based PHPs. The final CY 2021 PHP APC per diem rates are included in Addendum A to the CY 2021 OPPS/ASC proposed rule (which is available on our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*).[95]

[95] As discussed in section XX. of this CY 2021 OPPS/ASC final rule, OPPS APC geometric mean per diem costs (including PHP APC geometric mean per diem costs) are divided by the geometric mean per diem costs for APC 5012 (Clinic Visits and Related Services) to calculate each PHP APC's unscaled relative payment weight. An unscaled relative payment weight is one that is not yet adjusted for budget neutrality. Budget neutrality is required under section 1833(t)(9)(B) of the Act, and ensures that the estimated aggregate weight under the OPPS for a calendar year is neither greater than nor less than the estimated aggregate weight that would have been made without the changes. To adjust for budget neutrality (that is, to scale the weights), we compare the estimated aggregated weight using the scaled relative payment weights from the previous calendar year at issue. We refer readers to the ratesetting procedures described in Part 2 of the OPPS Claims Accounting narrative and in section II. of the CY 2021 OPPS/ASC proposed rule for more information on scaling the weights, and for details on the final steps of the process that leads to final PHP APC per diem payment rates. The OPPS Claims Accounting narrative is available on the CMS website at: *https://www.cms.gov/*

Continued

TABLE 43: CY 2021 PHP APC Geometric Mean Per Diem Costs

CY 2020 APC	Group Title	Proposed PHP APC Geometric Mean Per Diem Costs
5853	Partial Hospitalization (three or more services per day) for CMHCs	$136.14
5863	Partial Hospitalization (three or more services per day) for hospital-based PHPs	$253.76

3. PHP Service Utilization Updates

a. Provision of Individual Therapy

In the CY 2016 OPPS/ASC final rule with comment period (81 FR 79684 through 79685), we expressed concern over the low frequency of individual therapy provided to beneficiaries. The CY 2019 claims data used for the CY 2021 OPPS/ASC proposed rule revealed some changes in the provision of individual therapy compared to CY 2015, CY 2016, CY 2017, and CY 2018 claims data as shown in the Table 44.

TABLE 44: Provision of Individual Therapy, By Provider Type and Claims Year

	Percent of Individual Therapy on Days with 3 Services Only	Percent of Individual Therapy on Days with Four or More Services
CMHCs		
CY 2015 Claims	7.9%	4.4%
CY 2016 Claims	8.5%	5.0%
CY 2017 Claims	4.0%	4.3%
CY 2018 Claims	2.3%	4.5%
CY 2019 Claims	1.1%	4.8%
Hospital-based PHPs		
CY 2015 Claims	4.0%	6.2%
CY 2016 Claims	4.7%	5.8%
CY 2017 Claims	3.9%	5.1%
CY 2018 Claims	3.8%	5.7%
CY 2019 Claims	3.7%	5.7%

As shown in Table 44, the CY 2019 claims show that CMHCs have slightly increased the provision of individual therapy on days with four or more services, compared to CY 2018 claims. However, on CMHC days with three services, the provision of individual therapy decreased sharply from the prior year CY 2018. This appears to follow a downward trend which started in CY 2016 and has continued through CY 2019. In comparing CY 2018 to CY 2019, we see that for CMHCs the provision of 3-service days also sharply increased (this increase is shown in Table 45 in subsection b). The net effect of these two changes is that for all CMHC days with three or more services, the provision of individual therapy decreased from 4.4 percent in CY 2018 to 4.2 percent in CY 2019. We are concerned by this decrease in the provision of individual therapy among CMHCs from CY 2018, and will continue to monitor this trend. As we stated in the CY 2017 final rule with comment period (81 FR 79684 through 79685), the PHP is intensive in nature, and we believe that appropriate treatment for PHP patients includes individual therapy. We continue to encourage providers to examine their provision of individual therapy to PHP patients to ensure that patients are receiving all of the services that they may need.

For hospital-based providers, the CY 2019 claims show that the provision of individual therapy has slightly decreased on days with only 3 services and remained the same on days with four or more services. These very small decreases correspond with a modest increase of less than one tenth of one percent in the provision of individual therapy on all days with three or more services, comparable with fluctuations in prior years.

b. Provision of 3-Service Days

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59378), we stated that we are aware that our single-tier payment policy may influence a change in service provision because providers are able to obtain payment that is heavily weighted to the cost of providing four or more services when they provide only 3 services. We indicated that we are interested in ensuring that providers furnish an appropriate number of services to beneficiaries enrolled in PHPs. Therefore, with the CY 2017 implementation of CMHC APC 5853 and hospital-based PHP APC 5863 for

Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.

providing 3 or more PHP services per day, we are continuing to monitor utilization of days with only 3 PHP services.

For the CY 2021 OPPS/ASC proposed rule, we used the CY 2019 claims data. Table 45 shows the utilization findings based on the 2019 claims data.

TABLE 45: Percentage of PHP Days by Service Unit Frequency

	CY 2016	CY 2017*	CY 2018*	CY 2019*
CMHCs:				
Percent of Days with three services	4.8%	5.6%	6.9%	14.3%
Percent of Days with four services	70.3%	74.0%	71.2%	60.0%
Percent of Days with five or more services	24.9%	20.5%	21.9%	25.7%
Hospital-based PHPs:				
Percent of Days with three services	10.9%	9.8%	12.0%	10.9%
Percent of Days with four services	64.9%	56.4%	64.0%	65.8%
Percent of Days with five or more services	24.1%	33.9%	24.0%	23.4%

*May not sum to 100 percent by provider type due to rounding.

As shown in Table 45, the CY 2019 claims data used for proposed rule show that for CMHCs, utilization of 3 service days is increasing compared to the 3 prior claim years, whereas it is decreasing for hospital-based providers. Compared to CY 2018, in CY 2019 hospital-based PHPs provided fewer days with three services only, more days with four services only, and fewer days with five or more services. Compared to CY 2018, in CY 2019 CMHCs provided substantially more days with three services, fewer days with four services, and more days with five or more services.

The CY 2017 data were the first year of claims data to reflect the change to the single-tier PHP APCs. Since that time, we have observed a steady increase in the percentage of CMHC days with three services only. We are concerned by this increase, because as noted below, the intent of the PHP is for three-service days to be the exception, rather than the norm. As we noted in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79685), we will continue to monitor the provision of days with only three services, particularly now that the single-tier PHP APCs 5853 and 5863 are established for providing three or more services per day for CMHCs and hospital-based PHPs, respectively.

It is important to reiterate our expectation that days with only three services are meant to be an exception and not the typical PHP day. In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68694), we clearly stated that we consider the acceptable minimum units of PHP services required in a PHP day to be 3 and explained that it was never our intention that three units of service represent the number of services to be provided in a typical PHP day. PHP is furnished in lieu of inpatient psychiatric hospitalization and is intended to be more intensive than a half-day program. We further indicated that a typical PHP day should generally consist of 5 to 6 units of service (73 FR 68689). We explained that days with only three units of services may be appropriate to bill in certain limited circumstances, such as when a patient might need to leave early for a medical appointment and, therefore, would be unable to complete a full day of PHP treatment. At that time, we noted that if a PHP were to only provide days with three services, it would be difficult for patients to meet the eligibility requirement in 42 CFR 410.43(c)(1) that patients must require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care (73 FR 68689).

The following is summary of the comments we received and our responses to those comments.

Comment: Four commenters noted that the data in Table 45 (Table 30 of the CY 2021 OPPS/ASC proposed rule) demonstrate commitment by PHPs to comply with and exceed the 20-hour rule. These commenters noted that the vast majority of claim days for CMHCs and hospital-based PHPs have 4 or more services provided. The commenters noted that PHPs are voluntary, and that they cannot force patients to attend every day. They also noted that the typical patient profile includes behaviors that work against attendance and full daily participation. In addition, the commenters wrote that there are other challenges to providing 20 hours of services per week that are beyond providers' control, such as holidays, weather, and other medical appointments.

Response: We appreciate that most PHP days include 4 or more services being provided. The updated data for this final rule with comment period showed an uptick in the percentage of 3-service days among CMHCs, but we also note that there is an increase in the percentage of days with 5 or more services. We will continue to monitor the data over time. The ''20-hour rule'' the commenters mentioned is from our regulations at 42 CFR 410.43(c) (discussed at 73 FR 68694 to 68695), which require that eligible PHP patients need at least 20 hours of therapeutic services per week, as evidenced in their plan of care. PHPs are intended to be intensive programs that are provided in lieu of inpatient hospitalization. We appreciate the efforts providers have

made to increase beneficiary attendance, and also recognize the provider concerns about circumstances beyond their control which can affect the number of hours of services provided each week. We did not make any proposals related to the 20-hour requirement, and are continuing to monitor the claims data regarding the hours per week of services provided, sending providers informational messaging without affecting payment.

C. Outlier Policy for CMHCs

For CY 2021, we proposed to continue to calculate the CMHC outlier percentage, cutoff point and percentage payment amount, outlier reconciliation, outlier payment cap, and fixed-dollar threshold according to previously established policies. These topics are discussed in more detail. We refer readers to section II.G.1 of this CY 2021 OPPS/ASC final rule with comment period for our general policies for hospital outpatient outlier payments.

We did not receive any public comments on our proposal, and are finalizing it as proposed.

1. Background

As discussed in the CY 2004 OPPS final rule with comment period (68 FR 63469 through 63470), we noted a significant difference in the amount of outlier payments made to hospitals and CMHCs for PHP services. Given the difference in PHP charges between hospitals and CMHCs, we did not believe it was appropriate to make outlier payments to CMHCs using the outlier percentage target amount and threshold established for hospitals. Therefore, beginning in CY 2004, we created a separate outlier policy specific to the estimated costs and OPPS payments provided to CMHCs. We designated a portion of the estimated OPPS outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs. This separate outlier threshold for CMHCs resulted in $1.8 million in outlier payments to CMHCs in CY 2004 and $0.5 million in outlier payments to CMHCs in CY 2005 (82 FR 59381). In contrast, in CY 2003, more than $30 million was paid to CMHCs in outlier payments (82 FR 59381).

2. CMHC Outlier Percentage

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 through 59268), we described the current outlier policy for hospital outpatient payments and CMHCs. We note that we also discussed our outlier policy for CMHCs in more detail in section VIII.C. of that same final rule (82 FR 59381). We set our projected target for all OPPS aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS (82 FR 59267). This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996). We estimate CMHC per diem payments and outlier payments by using the most recent available utilization and charges from CMHC claims, updated CCRs, and the updated payment rate for APC 5853. For increased transparency, we are providing a more detailed explanation of the existing calculation process for determining the CMHC outlier percentages. We proposed to continue to calculate the CMHC outlier percentage according to previously established policies, and we did not propose any changes to our current methodology for calculating the CMHC outlier percentage for CY 2021. To calculate the CMHC outlier percentage, we followed three steps:

- *Step 1:* We multiplied the OPPS outlier threshold, which is 1.0 percent, by the total estimated OPPS Medicare payments (before outliers) for the prospective year to calculate the estimated total OPPS outlier payments: (0.01 × Estimated Total OPPS Payments) = Estimated Total OPPS Outlier Payments.
- *Step 2:* We estimated CMHC outlier payments by taking each provider's estimated costs (based on their allowable charges multiplied by the provider's CCR) minus each provider's estimated CMHC outlier multiplier threshold (we refer readers to section VIII.C.3. of the CY 2021 OPPS/ASC proposed rule). That threshold is determined by multiplying the provider's estimated paid days by 3.4 times the CMHC PHP APC payment rate. If the provider's costs exceeded the threshold, we multiplied that excess by 50 percent, as described in section VIII.C.3. of the CY 2021 OPPS/ASC proposed rule, to determine the estimated outlier payments for that provider. CMHC outlier payments are capped at 8 percent of the provider's estimated total per diem payments (including the beneficiary's copayment), as described in section VIII.C.5. of the CY 2021 OPPS/ASC proposed rule, so any provider's costs that exceed the CMHC outlier cap will have its payments adjusted downward. After accounting for the CMHC outlier cap, we summed all of the estimated outlier payments to determine the estimated total CMHC outlier payments.

(Each Provider's Estimated Costs—Each Provider's Estimated Multiplier Threshold) = A. If A is greater than 0, then (A × 0.50) = Estimated CMHC Outlier Payment (before cap) = B. If B is greater than (0.08 × Provider's Total Estimated Per Diem Payments), then cap-adjusted B = (0.08 × Provider's Total Estimated Per Diem Payments); otherwise, B = B. Sum (B or cap-adjusted B) for Each Provider = Total CMHC Outlier Payments.

- *Step 3:* We determined the percentage of all OPPS outlier payments that CMHCs represent by dividing the estimated CMHC outlier payments from Step 2 by the total OPPS outlier payments from Step 1:

(Estimated CMHC Outlier Payments/Total OPPS Outlier Payments).

In CY 2019, we designated approximately 0.01 percent of that estimated 1.0 percent hospital outpatient outlier threshold for CMHCs (83 FR 58996), based on this methodology. For CY 2021, we proposed to continue to use the same methodology as CY 2020. Therefore, based on our CY 2021 payment estimates, CMHCs are projected to receive 0.02 percent of total hospital outpatient payments in CY 2021, excluding outlier payments. We proposed to designate approximately less than 0.01 percent of the estimated 1.0 percent hospital outpatient outlier threshold for CMHCs. This percentage is based upon the formula given in Step 3.

We did not receive any public comments on this proposal, and are finalizing our proposal as proposed.

3. Cutoff Point and Percentage Payment Amount

As described in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59381), our policy has been to pay CMHCs for outliers if the estimated cost of the day exceeds a cutoff point. In CY 2006, we set the cutoff point for outlier payments at 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year (70 FR 68551). For CY 2018, the highest CMHC PHP APC payment rate is the payment rate for CMHC PHP APC 5853. In addition, in CY 2002, the final OPPS outlier payment percentage for costs above the multiplier threshold was set at 50 percent (66 FR 59889). In CY 2018, we continued to apply the same 50 percent outlier payment percentage that applies to hospitals to CMHCs and continued to use the existing cutoff point (82 FR 59381). Therefore, for CY 2018, we continued to pay for partial hospitalization services that exceeded 3.4 times the CMHC PHP APC payment rate at 50 percent of the amount of

CMHC PHP APC geometric mean per diem costs over the cutoff point. For example, for CY 2018, if a CMHC's cost for partial hospitalization services paid under CMHC PHP APC 5853 exceeds 3.4 times the CY 2018 payment rate for CMHC PHP APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.4 times the CY 2018 payment rate for CMHC PHP APC 5853 [0.50 × (CMHC Cost − (3.4 × APC 5853 rate))]. This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996 through 58997) and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351). For CY 2021, we proposed to continue to pay for partial hospitalization services that exceed 3.4 times the proposed CMHC PHP APC payment rate at 50 percent of the CMHC PHP APC geometric mean per diem costs over the cutoff point. That is, for CY 2021, if a CMHC's cost for partial hospitalization services paid under CMHC PHP APC 5853 exceeds 3.4 times the payment rate for CMHC APC 5853, the outlier payment will be calculated as [0.50 × (CMHC Cost − (3.4 × APC 5853 rate))].

We did not receive any public comments on this proposal, and are finalizing our proposal as proposed.

4. Outlier Reconciliation

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599), we established an outlier reconciliation policy to address charging aberrations related to OPPS outlier payments. We addressed vulnerabilities in the OPPS outlier payment system that lead to differences between billed charges and charges included in the overall CCR, which are used to estimate cost and would apply to all hospitals and CMHCs paid under the OPPS. We initiated steps to ensure that outlier payments appropriately account for the financial risk when providing an extraordinarily costly and complex service, but are only being made for services that legitimately qualify for the additional payment.

For a comprehensive description of outlier reconciliation, we refer readers to the CY 2019 OPPS/ASC final rules with comment period (83 FR 58874 through 58875 and 81 FR 79678 through 79680).

We proposed to continue these policies for partial hospitalization services provided through PHPs for CY 2021. The current outlier reconciliation policy requires that providers whose outlier payments meet a specified threshold (currently $500,000 for hospitals and any outlier payments for CMHCs) and whose overall ancillary CCRs change by plus or minus 10 percentage points or more, are subject to outlier reconciliation, pending approval of the CMS Central Office and Regional Office (73 FR 68596 through 68599). The policy also includes provisions related to CCRs and to calculating the time value of money for reconciled outlier payments due to or due from Medicare, as detailed in the CY 2009 OPPS/ASC final rule with comment period and in the Medicare Claims Processing Manual (73 FR 68595 through 68599 and Medicare Claims Processing internet Only Manual, Chapter 4, Section 10.7.2 and its subsections, available online at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf*).

We did not receive any public comments on this proposal, and are finalizing our proposal as proposed.

5. Outlier Payment Cap

In the CY 2017 OPPS/ASC final rule with comment period, we implemented a CMHC outlier payment cap to be applied at the provider level, such that in any given year, an individual CMHC will receive no more than a set percentage of its CMHC total per diem payments in outlier payments (81 FR 79692 through 79695). We finalized the CMHC outlier payment cap to be set at 8 percent of the CMHC's total per diem payments (81 FR 79694 through 79695). This outlier payment cap only affects CMHCs, it does not affect other provider types (that is, hospital-based PHPs), and is in addition to and separate from the current outlier policy and reconciliation policy in effect. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351), we finalized a proposal to continue this policy in CY 2020 and subsequent years.

For CY 2021, we proposed to continue to apply the 8 percent CMHC outlier payment cap to the CMHC's total per diem payments. We did not receive any public comments on this proposal, and are finalizing our proposal as proposed.

6. Fixed-Dollar Threshold

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 through 59268), for the hospital outpatient outlier payment policy, we set a fixed-dollar threshold in addition to an APC multiplier threshold. Fixed-dollar thresholds are typically used to drive outlier payments for very costly items or services, such as cardiac pacemaker insertions. CMHC PHP APC 5853 is the only APC for which CMHCs may receive payment under the OPPS, and is for providing a defined set of services that are relatively low cost when compared to other OPPS services. Because of the relatively low cost of CMHC services that are used to comprise the structure of CMHC PHP APC 5853, it is not necessary to also impose a fixed-dollar threshold on CMHCs. Therefore, in the CY 2018 OPPS/ASC final rule with comment period, we did not set a fixed-dollar threshold for CMHC outlier payments (82 FR 59381). This same policy was also reiterated in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351). We proposed to continue this policy for CY 2021. We did not receive any public comments on this proposal, and are finalizing our proposal as proposed.

IX. Services That Will Be Paid Only as Inpatient Services

A. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352 through 74353) for a full discussion of our longstanding policies for identifying services that are typically provided only in an inpatient setting (referred to as the inpatient only (IPO) list) and, therefore, that will not be paid by Medicare under the OPPS, as well as the criteria we use to review the IPO list each year to determine whether or not any services should be removed from the list. The complete list of codes that describe services that will be paid by Medicare in CY 2021 as inpatient only services is included as Addendum E to this CY 2021 OPPS/ASC proposed rule, which is available via the internet on the CMS website.[96]

B. Proposed Changes to the Inpatient Only (IPO) List

1. Methodology for Identifying Appropriate Changes to IPO List

Currently, there are approximately 1,740 services on the IPO list. Under our current policy, we annually review the IPO list to identify any services that should be removed from or added to the list based on the most recent data and medical evidence available. We have established five criteria to determine whether a procedure should be removed from the IPO list (65 FR 18455). As noted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74353), we utilize these criteria when reviewing services to determine whether

[96] Note, the IPO list is proposed to be eliminated beginning in CY 2021, with all services being removed from the list over the course of a three-year transition period. The CY 2020 IPO List can be found here: Hospital Outpatient PPS, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.*

or not they should be removed from the IPO list and assigned to an APC group for payment under the OPPS when provided in the hospital outpatient setting. We note that a procedure is not required to meet all of the established criteria to be removed from the IPO list. The criteria include the following:

- Most outpatient departments are equipped to provide the services to the Medicare population.
- The simplest procedure described by the code may be furnished in most outpatient departments.
- The procedure is related to codes that we have already removed from the IPO list.
- A determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis.
- A determination is made that the procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has been proposed by us for addition to the ASC list.

2. CY 2021 Proposal To Eliminate the IPO List

The IPO List was established with the implementation of the OPPS in the CY 2000 OPPS/ASC final rule with comment period (65 FR 18455). Using the authority under section 1833(t)(1)(B)(i) of the Act, the IPO List was created to identify services that require inpatient care because of the invasive nature of the procedure, the need for at least 24 hours of postoperative recovery time, or the underlying physical condition of the patient who would require the surgery and, therefore, the service would not be paid by Medicare under the OPPS. For example, the list includes certain surgically invasive services on the brain, heart, and abdomen, such as craniotomies, coronary-artery bypass grafting, and laparotomies.

Since the IPO list was established in 2000, we have stated that regardless of how a procedure is classified for purposes of payment, we expect that in every case the surgeon and the hospital will assess the risk of a procedure or service to the individual patient, taking site of service into account, and will act in that patient's best interests (65 FR 18456). We have reiterated this sentiment in rulemaking several times over the years, including in our discussion of the removal of total knee arthroplasty (TKA) from the IPO list in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59383) and most recently when we discussed removing total hip arthroplasty (THA) from the IPO List in the CY 2020 OPPS/ASC final rule with comment period, where we stated that the decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the beneficiary's individual clinical needs and preferences and on the general coverage rules requiring that any procedure be reasonable and necessary (84 FR 61354).

In previous years, we received several comments from stakeholders who believe that we should eliminate the IPO list entirely and instead defer to the clinical judgment of physicians for decisions regarding site of service. For example, in the CY 2000 final rule with comment period, in response to the establishment of the IPO list, commenters stated that they believed CMS was making decisions, such as the appropriate site of service for a particular medical procedure, that should be left to the discretion of surgeons and their patients (65 FR 18455, 18442). In the CY 2012 OPPS/ASC final rule with comment period, a number of commenters suggested that regulations should not supersede the physician's level of knowledge and assessment of the patient's condition, and that the physician can appropriately determine whether a procedure can be performed in a hospital outpatient setting (76 FR 74354). In the CY 2014 rulemaking, we again noted that some commenters requested that the IPO list be eliminated in its entirety (78 FR 75055). Stakeholders have also commented that the exclusion of services from payment under the OPPS is unnecessary and could have an adverse effect on advances in surgical care (65 FR 18442). Furthermore, some stakeholders have suggested that when a service is removed from the IPO list, it creates an expectation among hospitals that the service must be furnished in the outpatient setting, regardless of the clinical judgment of the physician or needs of the patient.

Other stakeholders have supported maintaining the IPO list and consider it an important tool to indicate which services are appropriate to furnish in the outpatient setting and to ensure that Medicare beneficiaries receive quality care. They have agreed that many of the procedures that we designated as ''inpatient only'' are currently performed appropriately and safely only in the inpatient setting (65 FR 18442). Commenters have expressed concerns that without the IPO list, patient safety and care quality could decline, and have noted the potential for surgical complications in response to allowing specific procedures to be paid under the OPPS when performed in the outpatient setting for the Medicare population, such as TKA and THA.

Stakeholders have also supported the use of the IPO list because services included on the IPO list are an exception to the 2-midnight rule and as such are considered appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay and therefore are not subject to medical review by Beneficiary and Family-Centered Care-Quality Improvement Organizations (BFCC–QIOs) for ''patient status'' (that is, site-of-service). We note that in the CY 2020 OPPS/ASC final rule with comment period, we finalized a policy to exempt procedures that have been removed from the IPO list from certain medical review activities for 2 calendar years following their removal from the IPO list. For CY 2021 and subsequent years, we proposed to continue this 2-year exemption from site-of-service claim denials, BFCC–QIO referrals to Recovery Audit Contractors (RACs), and RAC reviews for ''patient status'' for procedures that are removed from the IPO list under the OPPS beginning on January 1, 2021. We also sought comment on whether a 2-year exemption continues to be appropriate, or if a longer or shorter period may be more warranted. For more information on these policies please refer to section X.B of the CY 2021 OPPS/ASC proposed rule.

While we agreed with commenters in previous rulemakings that the IPO list was necessary, we stated there are many surgical procedures that cannot be safely performed on a typical Medicare beneficiary in the hospital outpatient setting, and that it would be inappropriate for us to establish payment rates for those services under the OPPS (78 FR 75055). However, recently we have reconsidered the various stakeholder comments requesting that we eliminate the IPO list and reevaluated the need for CMS to restrict payment for certain procedures in the hospital outpatient setting. For the proposed rule, we concluded that we no longer believed there was a need for the IPO list in order to identify services that require inpatient care. Instead, we agreed with past commenters that the physician should use his or her clinical knowledge and judgment, together with consideration of the beneficiary's specific needs, to determine whether a procedure can be performed appropriately in a hospital outpatient setting or whether inpatient care is required for the beneficiary, subject to the general coverage rules requiring that any procedure be reasonable and necessary. We believed

that this change would ensure maximum availability of services to beneficiaries in the outpatient setting.

We also believed that since the IPO list was established, there have been significant developments in the practice of medicine that have allowed numerous services to be provided safely and effectively in the outpatient setting. We acknowledged in the CY 2000 OPPS/ASC final rule with comment period that we believed that emerging new technologies and innovative medical practice were blurring the difference between the need for inpatient care and the sufficiency of outpatient care for many services (65 FR 18456). We also stated in the CY 2001 OPPS/ASC interim final rule with comment period that, over time, given advances in technology and surgical technique, many of the procedures that were on the IPO list at the time may eventually be performed safely in a hospital outpatient setting and that we would continue to evaluate services to determine whether they should be removed from the IPO list (65 FR 67826). Specifically, we stated that insofar as advances in medical practice mitigate concerns about these services being furnished on an outpatient basis, we would be prepared to remove them from the IPO list and provide for payment under the OPPS (65 FR 67826). Since that time, there have been many new technologies and advances in surgical techniques and surgical care protocols, including the use of minimally invasive surgical procedures such as laparoscopy, improved perioperative anesthesia, expedited rehabilitation protocols, as well as significant enhancements to postoperative processes, such as improvements in pain management, that have reduced the inpatient length of stay and the need for postoperative care following a surgical service. In consideration of these advancements, we have removed services from the IPO list that were previously considered to require inpatient care, including TKA in CY 2018 (82 FR 59385) and THA in CY 2020 (84 FR 61355). As medical practice continues to develop, we believed that the difference between the need for inpatient care and the appropriateness of outpatient care has become less distinct for many services. Therefore, we believed that the IPO list was no longer necessary to identify services that require inpatient care.

In the CY 2021 OPPS/ASC proposed rule, we acknowledged the seriousness of the concerns regarding patient safety and quality of care that various stakeholders have expressed regarding removing procedures from the IPO list or eliminating the IPO list altogether. However, we stated that we believe that the evolving nature of the practice of medicine, which has allowed more procedures to be performed on an outpatient basis with a shorter recovery time, in addition to physician judgment, state and local licensure requirements, accreditation requirements, hospital conditions of participation (CoPs), medical malpractice laws, and CMS quality and monitoring initiatives and programs will continue to ensure the safety of beneficiaries in both the inpatient and outpatient settings, even in the absence of the IPO list. In the past, we stated that although hospitals must meet minimum safety standards through accreditation or state survey and certification of compliance with the CoPs that ensure a hospital is generally safe and an appropriate environment for providing care, we were concerned that those measures did not determine whether a particular service could be safely provided in the outpatient setting to beneficiaries (76 FR 74355). However, the CoPs are regulations that are focused on protecting the health and safety of all patients receiving services from Medicare enrolled providers. The CoPs are the baseline health and safety requirements for Medicare certification. Accrediting organizations and states and localities, through their licensure authorities, may have more specific and stringent requirements. Often professional organizations or other nonprofit organizations give additional guidance to health care providers to improve patient safety and quality of care. We note that the CoPs already require hospitals to be in compliance with applicable Federal laws related to the health and safety of patients (42 CFR 482.11) Additionally, there are numerous provisions in the hospital CoPs at 42 CFR part 482 that provide extensive patient safeguards and that provide enough flexibility to ensure that hospitals can follow nationally recognized standards of practice and of care, where they are applicable, and can adapt if those standards change over time through innovative new practices.

Additionally, as indicated in the 2020 Quality Strategy,[97] CMS has also continued to develop safety measures and tools, like the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems Survey and the CMS' case management system, to help determine the safety and quality of the performance of procedures in the outpatient setting and to address concerns about the safety and quality of more varied, complex procedures performed in the outpatient setting. We stated in the CY 2021 OPPS/ASC proposed rule that we believe that the aforementioned federally established CoPs, the CMS Quality Strategy and state and local safety requirements help ensure important patient safeguards for all patients, including Medicare beneficiaries. Further, although we believe it was important to pause certain medical contractor reviews for patient status to allow providers time to adjust to the proposed changes to the IPO list, we note that the BFCC–QIO program's beneficiary case review contractors routinely address, and will continue to address any beneficiary quality of care complaints that include concerns about treatment as a hospital inpatient or outpatient, not receiving expected services, early discharge, and discharge planning. CMS' case management system currently allows QIOs and CMS to monitor the frequency and status of beneficiary quality of care complaints and other beneficiary appeals by topic, provider type, and geographic area. These numbers are compiled by the BFCC–QIO national coordinating and oversight review contractor and reported to the QIOs and CMS leadership on a weekly basis for monitoring purposes. As previously noted, although we proposed to continue a 2-year exemption from site-of-service claim denials, BFCC–QIO referrals to Recovery Audit Contractors (RACs), and RAC reviews for ''patient status'' for procedures that are removed from the IPO list under the OPPS beginning on January 1, 2021, BFCC–QIOs will continue to conduct initial medical reviews for both the medical necessity of the services, the medical necessity of the site of service, and will also continue to be permitted and expected to deny claims if the service itself is determined not to be reasonable and medically necessary as noted in the CY 2020 OPPS/ASC final rule (84 FR 61365). Therefore, given CMS' increasing ability to measure the safety of procedures performed in the outpatient setting and to monitor the quality of care, in addition to the other safeguards detailed above, we stated that we believe that quality of care was unlikely to be negatively affected by the elimination of the IPO list. However, we also requested that commenters submit evidence on what effect, if any, they believe eliminating the IPO list would have on the quality of care.

[97] Speech: Remarks by CMS Administrator Seema Verma at the 2020 CMS Quality Conference, *https://www.cms.gov/newsroom/press-releases/speech-remarks-cms-administrator-seema-verma-2020-cms-quality-conference.*

Furthermore, we explained that some stakeholders had previously shared concerns with us that removing procedures from the IPO list and allowing them to be paid under the OPPS when performed in the outpatient setting might result in an increased financial burden for beneficiaries for certain complex services. Under current law, the OPPS cost-sharing for a service is capped at the applicable Part A hospital inpatient deductible amount for that year for each service. However, this cap applies to individual services, so if a Medicare beneficiary receives multiple separately payable OPPS services, it is possible that the aggregate cost-sharing for a beneficiary may be higher for services provided in the outpatient setting than it would be had the services been furnished during an inpatient stay. We emphasized in the CY 2021 OPPS/ASC proposed rule that services included on the IPO list tend to be surgical procedures that would typically be the focus of the hospital outpatient stay and would likely be assigned to a comprehensive APC (C–APC) when they are removed from the IPO list. As such, these services would likely be considered a single episode of care with one payment rate and one copayment amount instead of multiple copayments for each individual service. In most instances, we expect that beneficiaries will not be responsible for multiple copayments for individual ancillary services associated with services removed from the IPO list, since because of their assignment to C–APCs, the inpatient deductible cap will apply to the entire hospital claim which is paid as a comprehensive service or procedure. In the event there are separately payable OPPS services included on a claim with a service assigned to a C–APC, our previously mentioned policy remains applicable, which is that the OPPS cost-sharing for an individual service is capped at the applicable Part A hospital inpatient deductible amount for that year for each service. For further information regarding beneficiary copayments, please refer to section II.I.1. of the CY 2021 OPPS/ASC proposed rule.

After careful consideration of the need for the IPO list and taking into account the feedback that we have received since the OPPS was implemented, we stated in the CY 2021 OPPS/ASC proposed rule that we believe that instead of maintaining a list of services that typically require inpatient care and are not paid under the OPPS, physicians should continue to use their clinical knowledge and judgment to appropriately determine whether a procedure can be performed in a hospital outpatient setting or whether inpatient care is required for the beneficiary based on the beneficiary's specific needs and preferences, subject to the general coverage rules requiring that any procedure be reasonable and necessary, and that payment should be made pursuant to the otherwise applicable payment policies. We also stated that we believe that developments in surgical technique and technological advances in the delivery of services may obviate the need for the IPO list. Finally, we also stated that we believe physician judgment, state and local regulations, accreditation requirements, hospital conditions of participation (CoPs), medical malpractice laws, and other CMS quality and monitoring initiatives would continue to ensure the safety of beneficiaries in both the inpatient and outpatient settings in the absence of the IPO list. Therefore, we proposed to eliminate the IPO list over a transitional period beginning in CY 2021. We also stated that while we believe that the list could be eliminated in its entirety at this point, as explained in further detail below, we proposed a transitional period.

Given the significant number of services on the list and that they would be newly priced under the OPPS, we recognized that stakeholders may need time to adjust to the removal of procedures from the list. Providers may need time to prepare, update their billing systems, and gain experience with newly removed procedures eligible to be paid under either the inpatient prospective payment system or outpatient prospective payment system. Therefore, we proposed to transition services off the IPO list over a 3-year period, with the list completely eliminated by 2024. In accordance with this proposal, we proposed to amend 42 CFR 419.22(n) to state that effective beginning on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition, with the full list eliminated in its entirety by January 1, 2024.

For CY 2021, we proposed that musculoskeletal services would be the first group of services that would be removed from the IPO list. We stated that we believe it is appropriate to remove this group of services first for several reasons. In recent years, due to new technologies and advances in surgical care protocols, expedited rehabilitation protocols, and significant enhancements to postoperative processes we have removed TKA and THA, which are both musculoskeletal services, from the IPO list. During the process of proposing and finalizing removing TKA and THA from the IPO list, stakeholders have continuously requested that CMS remove other musculoskeletal services from the IPO list as well, citing shortened length of stay times, advancements in technologies and surgical techniques, and improved postoperative processes. Additionally, we noted that, more often than not, stakeholders' historical requests for removals were for musculoskeletal services. We also recognized that there is already a set of comprehensive APCs for musculoskeletal services for payment in the outpatient setting, which facilitates the removal of these types of services for CY 2021. Specifically, because we have previously removed codes from the IPO list that are similar clinically and in terms of resource cost and assigned them to these comprehensive APCs, these APCs generally describe appropriate ranges and placements for these musculoskeletal codes being proposed for removal in CY 2021, which will allow for appropriate payment. We identified 266 musculoskeletal services that we proposed to remove from the IPO list for CY 2021.

Comment: Numerous commenters, including some medical specialty societies, health systems, and individual physicians, supported our proposal to eliminate the IPO list and defer to physicians' judgment on site of service decisions. These commenters stated that CMS' efforts to remove regulatory barriers would provide patients with more choices for where to receive affordable care. The commenters also believed the proposed change could potentially decrease overall healthcare costs and improve clinical outcomes for patients. These commenters stated that there is no clinical difference between a surgery performed in an inpatient setting and an outpatient setting, and that eliminating the IPO list would create more flexibility for physicians and beneficiaries.

Response: We thank the commenters for their support.

Comment: Many commenters, including hospital associations, health systems, medical specialty societies and professional organizations, and advocacy groups opposed the elimination of the IPO list due to patient safety concerns, stating that the IPO list serves as an important programmatic safeguard and maintains a common standard in the Medicare program. These commenters stated that the high-risk, invasive procedures that require post-operative monitoring that are currently included on the IPO list

would not be safe to perform on Medicare beneficiaries in the outpatient setting. These commenters also stated that CMS should retain its current process for evaluating and removing procedures from the IPO list through rulemaking. Alternatively, several commenters requested that instead of eliminating the IPO list, CMS maintain the list specifically for a smaller number of procedures that are complex, surgically invasive, and should never be performed in the outpatient setting. Other commenters requested that specific CPT codes proposed to be removed from the IPO list for CY 2021 remain payable in the inpatient setting only, including CPT codes 27280 (Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed) and 22857 (Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar).

Response: We acknowledge the commenters' important concerns regarding the elimination of the IPO list and the potential for safety risks for Medicare beneficiaries. We continue to believe that physicians can and should use their clinical knowledge and judgment to appropriately determine whether a procedure can be performed in a hospital outpatient setting or whether inpatient care is required for the beneficiary based on the beneficiary's specific needs and preferences, subject to the general coverage rules requiring that any procedure be reasonable and necessary, and that payment should be made pursuant to the otherwise applicable payment policies. We believe that patient safety and quality of care will be safeguarded by the physician's assessment of the risk of a procedure or service to the individual beneficiary and their selection of the most appropriate setting of care based on this risk in addition to state and local licensure requirements, accreditation requirements, hospital conditions of participation (CoPs), medical malpractice laws, and CMS quality and monitoring initiatives and programs. In addition, as we have stated in previous rulemaking, the removal of a service from the IPO list does not require the service to be performed only on an outpatient basis. Rather, it allows for payment under the OPPS when the service is performed on a registered hospital outpatient (82 FR 59384; 84 FR 61354). Services that are removed from the IPO list can and are performed on individuals who are admitted as inpatients (as well as individuals who are registered hospital outpatients). We also continue to believe that there have been significant developments in the practice of medicine that have allowed numerous services to now be provided safely and effectively in the outpatient setting. Therefore, at this time, we do not believe it is necessary for CMS to maintain a list of services that typically require inpatient care and are not paid under the OPPS nor do we currently believe that it is necessary to require specific HCPCS codes to remain payable only when furnished in the inpatient setting.

Comment: We received comments from physicians and medical specialty societies who stated that, while they agreed that physicians should be the primary arbiters regarding the clinically appropriate site of service for a procedure, a physician's medical judgment is not always paramount in this decision-making. These commenters noted that when procedures are removed from the IPO list, many hospitals and commercial payors make rules establishing outpatient status as the assumed baseline site of service for these procedures, regardless of patient characteristics or the physician's clinical assessment. Commenters noted various reasons for this action on the part of hospitals and commercial payors, including concerns regarding the application of the 2-midnight benchmark to services that are removed from the IPO list and the potential for claim denials if this benchmark is not met and/or excessive administrative burden to support the case-by-case exception to the 2-midnight rule, misinterpretation of CMS' rulemaking guidance, or the desire to have the procedure performed in a lower cost setting. According to commenters, physicians must, at times, convince a hospital or payor that a particular patient should receive a given procedure in an inpatient setting due to patient safety concerns. Commenters requested that CMS issue clear guidance that encourages consideration of and deference to the judgment of the physician, professional societies, and hospital associations regarding the procedures that are appropriate to be performed in the HOPD.

Response: CMS has repeatedly recognized that the decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the beneficiary's individual clinical needs and on the general coverage rules requiring that any procedure be reasonable and necessary. We continue to believe that deference should be given to physicians and medical professionals in these determinations. In accordance with section 1801 of the Act, CMS does not control or supervise the practice of medicine or the manner in which medical services are provided. We also reiterate that we do not require services that are no longer included on the IPO list to be performed solely in the outpatient setting and that following elimination of the IPO list, services that were previously identified as inpatient-only can continue to be performed in the inpatient setting. It is not CMS' policy to require services that are removed from the IPO list to only be performed in the outpatient setting. Instead, we aim to offer providers enhanced flexibility and choice in determining the safest, most efficient setting of care for Medicare beneficiaries, whether that is the inpatient or outpatient setting. It is a misinterpretation of CMS payment policy for providers to create policies or guidelines that establish the outpatient setting as the baseline or default site of service for a procedure based on its removal from the IPO list or the elimination of the IPO list. As stated in previous rulemaking, services that are no longer included on the IPO list are payable in either the inpatient or outpatient setting subject to the general coverage rules requiring that any procedure be reasonable and necessary, and payment should be made pursuant to the otherwise applicable payment policies (84 FR 61354; 82 FR 59384; 81 FR 79697).

As discussed in detail in previous rulemaking (84 FR 61363 through 61365) as well as in section X.B. of this final rule with comment period, the 2-midnight benchmark, which provides that an inpatient admission is considered reasonable and necessary for purposes of Medicare Part A payment when the physician expects the patient to require hospital care that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation, is applicable to services that have been removed from the IPO list. Additionally, as we have detailed in previous rulemaking (80 FR 70538 through 70549), we allow for case-by-case exceptions to the 2-midnight benchmark, whereby Medicare Part A payment may be made for inpatient admissions where the admitting physician does not expect the patient to require hospital care spanning 2 midnights, if the documentation in the medical record supports the physician's

determination that the patient nonetheless requires inpatient hospital care. We acknowledge commenters' concerns regarding the application of the 2-midnight benchmark to services that are removed from the IPO list. While services removed from the IPO list are no longer subject to the blanket IPO list exception from the 2-midnight rule at 42 CFR 412.3(d)(2), such services may be payable under Part A pursuant to either the 2-midnight benchmark at § 412.3(d)(1) or the case-by-case exception at § 412.3(d)(3). In addition, beginning in CY 2020, we have allowed an exemption from certain medical review activities related to the 2-midnight rule for procedures that have been recently removed from the IPO list. Specifically, while inpatient claims for procedures that have been removed from the IPO list may be reviewed by the BFCC–QIOs for purposes of providing education to practitioners and providers on compliance with the 2-midnight rule, those claims identified as noncompliant will not be denied for such noncompliance within the first 2 calendar years of their removal from the IPO list. Additionally, these procedures are not considered by the BFCC–QIOs in determining whether a provider exhibits persistent noncompliance with the 2-midnight rule for purposes of referral to the RAC nor are these procedures reviewed by RACs for ''patient status.'' As discussed further in section X.B of this final rule, for CY 2021, we are finalizing a proposal to extend the medical review exemption period indefinitely for a service newly removed from the IPO list beginning in CY 2021, until there is data indicating that the procedure removed is more commonly performed in the outpatient setting than in the inpatient setting. We believe this exemption from certain medical review activities in combination with the fact that many inpatient admissions for procedures formerly on the IPO list are likely to meet either the 2-midnight benchmark or the case-by-case exception to that benchmark mitigates the concerns regarding denial of payment under Medicare Part A for procedures no longer included on the IPO list. Lastly, with regard to the behavior of commercial insurance providers and site selection for outpatient services, while we believe that these comments are outside the scope of the proposed rule, we note that commercial providers establish their own rules regarding payment for services.

Comment: Several commenters requested that if the proposal to eliminate the IPO list is finalized, CMS provide baseline criteria or guidance for providers to consider when determining which services would be appropriate to furnish in the outpatient setting based upon peer-reviewed evidence, patient factors including age, co-morbidities, social determinants, and other factors relevant to positive patient outcomes. Commenters urged CMS to develop national guidelines outlining beneficiaries who are appropriate candidates for the inpatient vs outpatient setting, particularly for services that generally have a short length of stay (*i.e.* do not meet the 2-midnight benchmark).

Response: We again emphasize that the decision about the most appropriate care setting for a given surgical procedure is a complex medical judgment and we believe this decision should be based on the beneficiary's individual clinical needs and on the general coverage rules requiring that any procedure be reasonable and necessary. However, we understand that with over 1,700 services currently included on the IPO list, the elimination of the list over the three-year period will vastly increase the number of services that are newly payable in the outpatient setting. It will take time for clinical staff and providers to gain experience furnishing these services to the appropriate Medicare beneficiaries in the HOPD in order to develop comprehensive patient selection criteria and other protocols to identify whether a beneficiary can safely have these procedures performed in the outpatient setting. We agree with the commenters that, in the near term, in light of the elimination of the IPO list over a three-year period, physicians and providers could benefit from having access to general considerations for physicians regarding the types of services that may continue to be more appropriately performed in the inpatient setting for Medicare beneficiaries. Therefore, in the future, we plan to provide information on appropriate site of service selection to support physicians' decision-making. We note that these considerations will be for informational or educational purposes only and will not supersede physicians' medical judgment about whether a procedure should be performed in the inpatient or outpatient hospital setting.

Comment: Some commenters also noted the potential for negative financial impacts for both providers and beneficiaries with the elimination of the IPO list. Commenters stated that beneficiaries who require more than one outpatient hospital procedure delivered in separate episodes of care could be subject to multiple co-payments that may, when combined, exceed the inpatient deductible. Other commenters, particularly hospital associations and health systems, stated that a shift in site of service from the inpatient setting to the outpatient setting for numerous procedures could be financially disadvantageous for providers because the patients who would continue to receive these services as inpatients would likely be the more complex cases and more costly to treat. These commenters stated that this financial impact would be particularly significant in light of the COVID–19 pandemic.

Response: As stated in the CY 2021 OPPS/ASC proposed rule (85 FR 48911), services included on the IPO list tend to be surgical procedures that, if performed on an outpatient basis, would typically be the focus of the hospital outpatient stay and would likely be assigned to a comprehensive APC (C–APC) when they are removed from the IPO list. As such, these services would likely be considered a single episode of care with one payment rate and one copayment amount. In most instances, we expect that beneficiaries will not be responsible for multiple copayments for individual ancillary services associated with services removed from the IPO list, because the primary service will be assigned to a C–APC and the inpatient deductible cap will apply to the entire hospital claim, which is paid as a comprehensive service. All 298 services that are being removed from the IPO list beginning in CY 2021 are assigned status indicator ''J1'' and will receive payment through C–APCs, except for 34 services that are assigned status indicator ''N'', which indicates that payment for the service is packaged into payment for other services and there is no separate APC payment, and two services assigned status indicator ''Q1'' which indicates conditionally packaged payment. CPT code 44314 (Revision of ileostomy; complicated (reconstruction in-depth) (separate procedure)), is the only code to be removed from the IPO list that is assigned status indicator ''T'', indicating that it is a separately paid procedure. The vast majority of the procedures being removed from the IPO list for CY 2021 are assigned to C–APCs or packaged into payment for other services, which will result in beneficiaries paying one copayment amount. Therefore, we do not believe that beneficiaries will be significantly impacted through increased cost sharing for services that were on the IPO list and are furnished in the hospital outpatient department setting.

In the event there are separately payable OPPS services included on a claim with a service assigned to a C–APC, our previously mentioned policy

remains applicable; that is, the OPPS cost-sharing for an individual service is capped at the applicable Part A hospital inpatient deductible amount for that year for each service. For further information regarding beneficiary copayments, please refer to section II.I.1. of this final rule.

With regard to stakeholder concerns about providers experiencing negative financial effects because of services transitioning from the inpatient setting to the lower cost outpatient setting, we understand the numerous challenges that providers are facing due to the COVID–19 public health emergency. We reiterate that providers retain the flexibility to provide services that are no longer included on the IPO list in the inpatient setting and that these services will remain payable under Medicare Part A when appropriate in accordance with the 2-midnight rule and general coverage rules. We also refer readers to the discussion of exemption from certain medical review activities for services removed from the IPO list in section X.B. of this final rule with comment period. Similar to other services that have been removed from the IPO list in previous years, we expect that the volume of services currently being performed in the inpatient setting that can be appropriately performed in the outpatient setting will gradually shift as physicians and providers gain experience furnishing these services to the appropriate Medicare beneficiaries in the HOPD. Therefore, we do not expect that providers will experience a significant financial impact due to the elimination of the IPO list.

Comment: Commenters expressed concerns regarding the proposed APC assignments for procedures proposed to be removed from the IPO list and stated that CMS did not provide sufficient detail as to how the proposed APC placements were determined. Some commenters also believed that the proposed APC payments did not adequately reflect the costs associated with providing the procedure in the outpatient setting and that there was a significant differential between MS–DRG payment and APC payment for some procedures. One commenter also disagreed with the proposed APC assignment of APC 5115 (Level 5 Musculoskeletal Procedures) for the following HCPCS codes: 27702 (Arthroplasty, ankle; with implant (total ankle)), 27703 (Arthroplasty; revision, total ankle), 23472 (Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (*e.g.,* total shoulder))) and 23473 (Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component), stating that the geometric mean costs of these procedures is more similar to the geometric mean costs of procedures assigned to APC 5116 (Level 6 Musculoskeletal Procedures). The commenter noted the assignment of HCPCS code 27702 to APC 5115 would have created a 2 times rule violation within this APC based on geometric mean costs; however, the procedure did not have enough claims volume to be considered a significant procedure and therefore was not considered in the evaluation of 2 times rule violations. The commenter requested that all these procedures be assigned to C–APC 5116 for CY 2021.

Response: We assign services payable under the OPPS, including services removed from the IPO list, to APCs based on their similarity to other codes within the APC in terms of clinical characteristics and resource use. Based on the claims data currently available for procedures removed from the IPO list and the clinical characteristics of the procedures, we believe that the 266 musculoskeletal procedures being removed from the IPO list for CY 2021, including HCPCS codes 27702, 27703, 23472, and 23473, are appropriately assigned to the C–APCs identified in Table 48—Services Removed from the Inpatient Only (IPO) List for CY 2021. We will continue to monitor these procedures and claims data as they become available to determine if assignment to other APCs is appropriate. We refer readers to Section III.D.17 of this final rule with comment period for a discussion of the musculoskeletal procedure APC series (APCs 5111 through 5116).

Comment: Commenters raised concerns about the effect of the elimination of the IPO list on the target pricing of payment models administered by the Center for Medicare and Medicaid Innovation (CMS Innovation Center), such as the Bundled Payments for Care Initiatives, the Bundled Payments for Care Initiatives (BPCI) Advanced Model, and the Comprehensive Care for Joint Replacement Model and requested that CMS ensure that any changes to the IPO list do not unfairly penalize model participants.

Response: As we have stated in previous rulemaking (82 FR 59384 and 84 FR 61355) when commenters raised similar concerns when total knee arthroplasty and total hip arthroplasty were removed from the IPO list, the CMS Innovation Center will monitor the overall volume and complexity of cases performed in hospital outpatient departments to determine whether any future refinements to the CJR, BPCI, and BPCI Advanced Models are warranted. The Innovation Center may consider making future changes to these models to address the elimination of the IPO list and subsequent performance of procedures previously identified as inpatient-only in the outpatient hospital setting.

Comment: Commenters also raised concerns about the impact of this policy on the 3-day stay requirement for skilled nursing facility care. By statute, beneficiaries must have a prior inpatient hospital stay of no fewer than three consecutive days to be eligible for Medicare coverage of inpatient SNF care. Specifically, commenters stated that the elimination of the IPO list may have a significant impact on Medicare beneficiaries' ability to obtain a three day inpatient stay to qualify for SNF care.

Response: We reiterate that removal of procedures from the IPO list does not require the procedures to be performed only on an outpatient basis. Removal of procedures from the IPO list allows for payment of the procedure in either the inpatient setting or the outpatient setting. A prior 3-day inpatient hospital stay remains a statutory requirement for SNF coverage. However, as stated in the CY 2018 final rule with comment period (82 FR 59384), in our discussion of the removal of TKA from the IPO list, we would expect that Medicare beneficiaries who are identified as appropriate candidates to receive a surgical procedure in the outpatient setting instead of being admitted as an inpatient, would not be expected to require SNF care following surgery. Instead, we expect that many of these beneficiaries would be appropriate for discharge to home (with outpatient therapy) or home health care.

Comment: Commenters noted that there are anesthesia codes related to some of the musculoskeletal procedures proposed to be removed from the IPO list for CY 2021 that were not proposed to be removed from the list. These commenters requested that these related anesthesia services also be removed from the IPO list for CY 2021. In addition to these requests, at the August 31, 2020 meeting, the Advisory Panel on Hospital Outpatient Payment (HOP Panel) recommended that we remove the 16 additional procedures in Table 47 from the IPO list and assign these procedures to C–APCs.

Response: We appreciate the comments. We reviewed the IPO list for CPT codes describing anesthesia services that are related to the musculoskeletal procedures that we have proposed to remove from the IPO

list beginning in CY 2021. After our analysis, we agree with the commenters that the anesthesia codes that are billed with services that were proposed to be removed from the IPO list for CY 2021 should also be removed from the IPO list for CY 2021. Therefore, we are removing the 16 anesthesia codes from the IPO list for CY 2021.

We also accept the HOP panel recommendation to remove 16 additional procedures from the IPO list. The anesthesia services are included in Table 46 below. The CPT codes recommended for removal from the IPO list by the HOP panel are included in Table 47 below. We refer readers to Table 48 for the final list of all procedures we are removing from the IPO list for CY 2021.

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TABLE 46. – Anesthesia Services Removed from IPO List Beginning in CY 2021

CPT Code	Long Descriptor	CY 2021 OPPS Status Indicator
00192	Anesthesia for procedures on facial bones or skull; radical surgery (including prognathism)	N
00474	Anesthesia for partial rib resection; radical procedures (eg, pectus excavatum)	N
00604	Anesthesia for procedures on cervical spine and cord; procedures with patient in the sitting position	N
00904	Anesthesia for; radical perineal procedure	N
01140	Anesthesia for interpelviabdominal (hindquarter) amputation	N
01150	Anesthesia for radical procedures for tumor of pelvis, except hindquarter amputation	N
01212	Anesthesia for open procedures involving hip joint; hip disarticulation	N
01232	Anesthesia for open procedures involving upper two-thirds of femur; amputation	N
01234	Anesthesia for open procedures involving upper two-thirds of femur; radical resection	N
01274	Anesthesia for procedures involving arteries of upper leg, including bypass graft; femoral artery embolectomy	N
01404	Anesthesia for open or surgical arthroscopic procedures on knee joint; disarticulation at knee	N
01486	Anesthesia for open procedures on bones of lower leg, ankle, and foot; total ankle replacement	N
01634	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; shoulder disarticulation	N
01636	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; interthoracoscapular (forequarter) amputation	N
01638	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; total shoulder replacement	N
01756	Anesthesia for open or surgical arthroscopic procedures of the elbow; radical procedures	N

TABLE 47. – HOP Panel-Recommended Procedures Removed from the IPO List Beginning in CY 2021

CPT Code	Long Descriptor	Related Services	CY 2021 OPPS Status Indicator	CY 2021 OPPS APC Assignment
35372	Thromboendarterectomy, including patch graft, if performed; deep (profunda) femoral	35321	J1	5184
35800	Exploration for postoperative hemorrhage, thrombosis or infection; neck	35800	J1	5184
37182	Insertion of transvenous intrahepatic portosystemic shunt(s) (tips) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract formation/dilatation, stent placement and all associated imaging guidance and documentation)	37183	J1	5193
37617	Ligation, major artery (eg, post-traumatic, rupture); abdomen	37615	J1	5183
38562	Limited lymphadenectomy for staging (separate procedure); pelvic and para-aortic	38571	J1	5362
43840	Gastrorrhaphy, suture of perforated duodenal or gastric ulcer, wound, or injury	43830	J1	5331
44300	Placement, enterostomy or cecostomy, tube open (eg, for feeding or decompression) (separate procedure)	43246	J1	5302
44314	Revision of ileostomy; complicated (reconstruction in-depth) (separate procedure)	44340	T	5055
44345	Revision of colostomy; complicated (reconstruction in-depth) (separate procedure)	47536	J1	5341
44346	Revision of colostomy; with repair of paracolostomy hernia (separate procedure)	47533	J1	5341
44602	Suture of small intestine (enterorrhaphy) for perforated ulcer, diverticulum, wound, injury or rupture; single perforation	43870	J1	5303
49010	Exploration, retroperitoneal area with or without biopsy(s) (separate procedure)	44950	J1	5341

49255	Omentectomy, epiploectomy, resection of omentum (separate procedure)	44950	J1	5341
51840	Anterior vesicourethropexy, or urethropexy (eg, marshall-marchetti-krantz, burch); simple	51845	J1	5341
56630	Vulvectomy, radical, partial;	57530	J1	5415
61624	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; central nervous system (intracranial, spinal cord)	93581	J1	5194

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3. Comment Solicitation on Order of Removal of Additional Clinical Families From the IPO List During the Transition To Complete Elimination of the IPO List

As stated above, we proposed to eliminate the current IPO list of 1,740 services, starting with the 266 musculoskeletal-related services, which were listed in Table 31 of the CY 2021 OPPS/ASC proposed rule (85 FR 48912). We requested comments from the public on whether three years was an appropriate time frame for the transition, whether there are other services that would be ideal candidates for removal from the IPO list in the near term given known technological advancements and other advances in care, and the order of removal of additional clinical families and/or specific services for each of the CY 2022 and CY 2023 rulemakings until the IPO list is completely eliminated. Additionally, we sought comment on whether we should restructure or create any new APCs to allow for OPPS payment for services that are removed from the IPO list. We also solicited public comments on whether any of the musculoskeletal codes proposed for removal from the IPO list for CY 2021 may meet the criteria to be added to the ASC Covered Procedures List. We refer readers to section XIII.C.1.c. of the CY 2021 OPPS/ASC proposed rule for a complete discussion of the ASC Covered Procedures List.

Comment: Several commenters, including several hospital associations, medical specialty societies, and MedPAC requested we delay the elimination of the IPO list until a comprehensive evaluation of the procedures on the list has occurred. They felt a more thorough review of the services proposed for removal is appropriate due to the large number of services on the IPO list across a range of medical specialties. Commenters suggested various time frames for eliminating the IPO list that ranged from three years to seven years. Several hospital associations recommended we delay eliminating the list until we address patient safety concerns and provide national guidelines outlining patients who are appropriate candidates for care in the inpatient hospital versus outpatient hospital setting. One commenter suggested that we remove the proposed musculoskeletal services from the IPO list, and then monitor the transition of those services to the outpatient hospital setting and the effect on beneficiary outcomes for a period of time before removing any additional procedures. Some hospital systems also requested a delay, noting that the timing of the proposed change is particularly difficult in light of the COVID–19 pandemic.

Response: We thank commenters for their feedback. However, we do not believe it is necessary to delay eliminating the IPO list over the course of a three-year transition beginning in CY 2021. We are finalizing a three-year transition for removing procedures from the IPO list and enabling them to be paid under the OPPS, with the list eliminated in its entirety by 2024. In the CY 2021 OPPS/ASC proposed rule (85 FR 48911), we proposed to eliminate the IPO list over 3 years to provide a gradual transition that gives the public the opportunity to comment on the sequence in which services should be removed from the IPO list. In addition, as we previously discussed in the CY 2021 OPPS/ASC proposed rule (85 FR 48911), we recognized that stakeholders would need time to adjust to the significant number of services removed from the IPO list and newly priced under the OPPS. We believe that longer transition periods would prevent providers who are ready to perform services in the outpatient department from doing so, and it is equally important to note that providers are not required to perform services in the outpatient department as services are eliminated from the IPO list if they are not ready. While we still believe that 3 years will offer providers an adequate time period to prepare, update their billing systems, and gain experience with newly removed procedures eligible to be paid when furnished in both the inpatient hospital and outpatient hospital settings, we also realize that providers will have varying time frames for completing the transition.

In the CY 2021 OPPS/ASC proposed rule (85 FR 48909 through 48912) we discussed patient safety concerns stakeholders expressed regarding removing procedures from the IPO list or eliminating the IPO list. We continue to believe that the evolving nature of the practice of medicine, which has allowed more procedures to be performed on an outpatient basis with a shorter recovery time, in addition to physician judgment, state and local licensure requirements, accreditation requirements, hospital conditions of participation (CoPs), medical malpractice laws, and CMS quality and monitoring initiatives and programs will continue to ensure the safety of beneficiaries in both the inpatient and outpatient settings, even in the absence of the IPO list (85 FR 48910). In prior rulemaking, we have

stated that regardless of how a procedure is classified for purposes of payment, we expect that in every case the surgeon and the hospital will assess the risk of a procedure or service to the individual patient, taking site of service into account, and will act in that patient's best interests (65 FR 18456). As we transition procedures off of the IPO list, we will continue to actively monitor for impacts on patient safety and quality through analyzing claims and other relevant data; throughout this transition, CMS will take necessary steps to address any changes in patient safety or quality that may emerge.

Comment: Two medical specialty societies recommended that cardiothoracic procedures and spine-related procedures be the last procedures removed from the IPO list due to clinical and resource intensity these procedures require.

Response: We appreciate the commenter's feedback. We will consider these comments for future rulemaking.

Comment: A few commenters suggested that procedures removed from the IPO list receive an interim assignment to a new technology APC to help collect claims data and subsequently assign the procedures to clinical APCs. These commenters suggested that we assign a default 31 percent device offset for procedures removed from the IPO list that are low-volume and are assigned to a device-intensive APC. They felt that current APCs may need to be restructured due to the lack of appropriate comparison procedures to those procedures being removed from the IPO list. In addition, the commenter argued that we did not provide an analysis to support our proposal to assign a given HCPCS/CPT code to a proposed APC or C–APC from the perspective of clinical or resource use similarity. They stated that in Table 31 of the proposed rule, we referenced related services for the musculoskeletal services proposed for removal from the IPO list for 2021; however, we proposed to assign these codes to different APCs than the APCs to which the comparator services are assigned. The commenter also stated that we did not provide information on proposed device offset amounts or how complexity adjustments were considered for procedures proposed for IPO List removal.

Response: As specified in our regulation at 42 CFR 419.31(a)(1), CMS classifies outpatient services and procedures that are comparable clinically and in terms of resource use into APC groups. As we stated in the CY 2012 OPPS/ASC final rule (76 FR 74224), the OPPS is a prospective payment system that provides payment for groups of services that share clinical and resource use characteristics. It should be noted that for all codes newly paid under the OPPS, including codes removed from the IPO list, our policy has been to assign the service or procedure to an APC based on feedback from a variety of sources, including but not limited to, review of the clinical similarity of the service to existing procedures; advice from CMS medical advisors; information from interested specialty societies; and review of all other information available to us, including information provided to us by the public, whether through meetings with stakeholders or additional information that is mailed or otherwise communicated to us (84 FR 61229). Therefore, we believe assigning procedures removed from the IPO list to existing clinical APCs that are similar in clinical characteristics and resource costs is appropriate. We note that procedures assigned to new technology APCs do not fit into existing APC groups, unlike the procedures transitioning from the IPO list. For further information on new technology APCs, we refer readers to Section III.C. We note that we will reevaluate the APC assignments for procedures removed from the IPO list once we have hospital outpatient claims data and, if appropriate, reassign and/or restructure APC assignments. For procedures that we are removing from the IPO list in CY 2021, we will apply offset calculations and assessment in determining device intensive status at the HCPCS/CPT code level (81 FR 79657). We refer readers to Section IV.B for more information on device-intensive assignments for procedures.

In summary, after consideration of the public comments, we are finalizing our proposal with modification to eliminate the IPO list over the course of the next 3 years, starting with the proposed removal of 266 musculoskeletal-related services and 16 HOP Panel recommended services and related anesthesia codes, for a total of 298 services, as provided in Table 48 in CY 2021. We plan to provide considerations for physicians and other health care providers when determining whether a service may be more appropriately performed in the inpatient or outpatient setting for a beneficiary, but again we emphasize that decisions regarding appropriate care setting are complex medical judgments. We are also finalizing our proposal, without modification, to amend 42 CFR 419.22(n) to state that effective beginning on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition, with the full list eliminated in its entirety by January 1, 2024. We believe that the developments in surgical technique and technological advances in the practice of medicine, as well as the various safeguards discussed above, including, but not limited to, physician clinical judgment, state and local regulations, accreditation requirements, medical malpractice laws, hospital conditions of participation, and other CMS initiatives will ensure that procedures removed from the IPO list and provided in the outpatient setting will be done so safely.

Table 48 lists the final procedures, including long descriptors and CPT/HCPCS codes and status indicators (if applicable) that are removed from the IPO list for CY 2021. These services are included in Addendum B to the CY 2021 OPPS/ASC final rule as well.

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TABLE 48: SERVICES REMOVED FROM THE INPATIENT ONLY (IPO) LIST FOR CY 2021 (N=298)

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2021 OPPS Status Indicator	CY 2021 OPPS APC Assignment
00192	Anesthesia for procedures on facial bones or skull; radical surgery (including prognathism)	N	N/A
00474	Anesthesia for partial rib resection; radical procedures (eg, pectus excavatum)	N	N/A
00604	Anesthesia for procedures on cervical spine and cord; procedures with patient in the sitting position	N	N/A
00904	Anesthesia for; radical perineal procedure	N	N/A
0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)	N	N/A
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)	N	N/A
01140	Anesthesia for interpelviabdominal (hindquarter) amputation	N	N/A
01150	Anesthesia for radical procedures for tumor of pelvis, except hindquarter amputation	N	N/A
01212	Anesthesia for open procedures involving hip joint; hip disarticulation	N	N/A
01232	Anesthesia for open procedures involving upper two-thirds of femur; amputation	N	N/A
01234	Anesthesia for open procedures involving upper two-thirds of femur; radical resection	N	N/A
01274	Anesthesia for procedures involving arteries of upper leg, including bypass graft; femoral artery embolectomy	N	N/A
01404	Anesthesia for open or surgical arthroscopic procedures on knee joint; disarticulation at knee	N	N/A
01486	Anesthesia for open procedures on bones of lower leg, ankle, and foot; total ankle replacement	N	N/A
0163T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (list separately in addition to code for primary procedure)	N	N/A
01634	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; shoulder disarticulation	N	N/A

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2021 OPPS Status Indicator	CY 2021 OPPS APC Assignment
01636	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; interthoracoscapular (forequarter) amputation	N	N/A
01638	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; total shoulder replacement	N	N/A
0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (list separately in addition to code for primary procedure)	N	N/A
0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (list separately in addition to code for primary procedure)	N	N/A
01756	Anesthesia for open or surgical arthroscopic procedures of the elbow; radical procedures	N	N/A
0202T	Posterior vertebral joint(s) arthroplasty (for example, facet joint[s] replacement), including facetectomy, laminectomy, foraminotomy, and vertebral column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine	J1	5115
0219T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical	J1	5115
0220T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; thoracic	J1	5115
20661	Application of halo, including removal; cranial	Q1	5113
20664	Application of halo, including removal, cranial, 6 or more pins placed, for thin skull osteology (eg, pediatric patients, hydrocephalus, osteogenesis imperfecta)	Q1	5113
20802	Replantation, arm (includes surgical neck of humerus through elbow joint), complete amputation	J1	5116
20805	Replantation, forearm (includes radius and ulna to radial carpal joint), complete amputation	J1	5116
20808	Replantation, hand (includes hand through metacarpophalangeal joints), complete amputation	J1	5116
20816	Replantation, digit, excluding thumb (includes metacarpophalangeal joint to insertion of flexor sublimis tendon), complete amputation	J1	5114
20824	Replantation, thumb (includes carpometacarpal joint to MP joint), complete amputation	J1	5114
20827	Replantation, thumb (includes distal tip to MP joint), complete amputation	J1	5114

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2021 OPPS Status Indicator	CY 2021 OPPS APC Assignment
20838	Replantation, foot, complete amputation	J1	5116
20955	Bone graft with microvascular anastomosis; fibula	J1	5114
20956	Bone graft with microvascular anastomosis; iliac crest	J1	5114
20957	Bone graft with microvascular anastomosis; metatarsal	J1	5114
20962	Bone graft with microvascular anastomosis; other than fibula, iliac crest, or metatarsal	J1	5114
20969	Free osteocutaneous flap with microvascular anastomosis; other than iliac crest, metatarsal, or great toe	J1	5114
20970	Free osteocutaneous flap with microvascular anastomosis; iliac crest	J1	5114
21045	Excision of malignant tumor of mandible; radical resection	J1	5165
21141	Reconstruction midface, lefort i; single piece, segment movement in any direction (for example, for long face syndrome), without bone graft	J1	5165
21142	Reconstruction midface, lefort i; 2 pieces, segment movement in any direction, without bone graft	J1	5165
21143	Reconstruction midface, lefort i; 3 or more pieces, segment movement in any direction, without bone graft	J1	5165
21145	Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	J1	5165
21146	Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	J1	5165
21147	Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	J1	5165
21151	Reconstruction midface, LeFort II; any direction, requiring bone grafts (includes obtaining autografts)	J1	5165
21154	Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); without LeFort I	J1	5165
21155	Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); with LeFort I	J1	5165
21159	Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (for example, mono bloc), requiring bone grafts (includes obtaining autografts); without LeFort I	J1	5165
21160	Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (for example, mono bloc), requiring bone grafts (includes obtaining autografts); with LeFort I	J1	5165

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21179	Reconstruction, entire or majority of forehead and/or supraorbital rims; with grafts (allograft or prosthetic material)	J1	5165
21180	Reconstruction, entire or majority of forehead and/or supraorbital rims; with autograft (includes obtaining grafts)	J1	5165
21182	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (for example, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting less than 40 sq cm	J1	5165
21183	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (for example, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting greater than 40 sq cm but less than 80 sq cm	J1	5165
21184	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (for example, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting greater than 80 sq cm	J1	5165
21188	Reconstruction midface, osteotomies (other than lefort type) and bone grafts (includes obtaining autografts)	J1	5165
21194	Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; with bone graft (includes obtaining graft)	J1	5165
21196	Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation	J1	5165
21247	Reconstruction of mandibular condyle with bone and cartilage autografts (includes obtaining grafts) (for example, for hemifacial microsomia)	J1	5165
21255	Reconstruction of zygomatic arch and glenoid fossa with bone and cartilage (includes obtaining autografts)	J1	5165
21268	Orbital repositioning, periorbital osteotomies, unilateral, with bone grafts; combined intra- and extracranial approach	J1	5165
21343	Open treatment of depressed frontal sinus fracture	J1	5165
21344	Open treatment of complicated (for example, comminuted or involving posterior wall) frontal sinus fracture, via coronal or multiple approaches	J1	5165
21347	Open treatment of nasomaxillary complex fracture (lefort ii type); requiring multiple open approaches	J1	5165

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21348	Open treatment of nasomaxillary complex fracture (lefort ii type); with bone grafting (includes obtaining graft)	J1	5165
21366	Open treatment of complicated (for example, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with bone grafting (includes obtaining graft)	J1	5165
21422	Open treatment of palatal or maxillary fracture (lefort i type);	J1	5165
21423	Open treatment of palatal or maxillary fracture (lefort i type); complicated (comminuted or involving cranial nerve foramina), multiple approaches	J1	5165
21431	Closed treatment of craniofacial separation (lefort iii type) using interdental wire fixation of denture or splint	J1	5165
21432	Open treatment of craniofacial separation (lefort iii type); with wiring and/or internal fixation	J1	5165
21433	Open treatment of craniofacial separation (lefort iii type); complicated (for example, comminuted or involving cranial nerve foramina), multiple surgical approaches	J1	5165
21435	Open treatment of craniofacial separation (lefort iii type); complicated, utilizing internal and/or external fixation techniques (for example, head cap, halo device, and/or intermaxillary fixation)	J1	5165
21436	Open treatment of craniofacial separation (lefort iii type); complicated, multiple surgical approaches, internal fixation, with bone grafting (includes obtaining graft)	J1	5165
21510	Incision, deep, with opening of bone cortex (for example, for osteomyelitis or bone abscess), thorax	J1	5114
21602	Excision of chest wall tumor involving rib(s), with plastic reconstruction; without mediastinal lymphadenectomy	J1	5114
21603	Excision of chest wall tumor involving rib(s), with plastic reconstruction; with mediastinal lymphadenectomy	J1	5114
21615	Excision first and/or cervical rib;	J1	5114
21616	Excision first and/or cervical rib; with sympathectomy	J1	5114
21620	Ostectomy of sternum, partial	J1	5114
21627	Sternal debridement	J1	5114
21630	Radical resection of sternum;	J1	5114
21632	Radical resection of sternum; with mediastinal lymphadenectomy	J1	5114
21705	Division of scalenus anticus; with resection of cervical rib	J1	5114

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21740	Reconstructive repair of pectus excavatum or carinatum; open	J1	5114
21750	Closure of median sternotomy separation with or without debridement (separate procedure)	J1	5114
21825	Open treatment of sternum fracture with or without skeletal fixation	J1	5114
22010	Incision and drainage, open, of deep abscess (subfascial), posterior spine; cervical, thoracic, or cervicothoracic	J1	5114
22015	Incision and drainage, open, of deep abscess (subfascial), posterior spine; lumbar, sacral, or lumbosacral	J1	5114
22110	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; cervical	J1	5114
22112	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; thoracic	J1	5114
22114	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; lumbar	J1	5114
22116	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; each additional vertebral segment (list separately in addition to code for primary procedure)	N	N/A
22206	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (for example, pedicle/vertebral body subtraction); thoracic	J1	5114
22207	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (for example, pedicle/vertebral body subtraction); lumbar	J1	5114
22208	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (for example, pedicle/vertebral body subtraction); each additional vertebral segment (list separately in addition to code for primary procedure)	N	N/A
22210	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; cervical	J1	5114
22212	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; thoracic	J1	5114
22214	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; lumbar	J1	5114
22216	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; each additional vertebral segment (list separately in addition to primary procedure)	N	N/A

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22220	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; cervical	J1	5114
22222	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; thoracic	J1	5114
22224	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; lumbar	J1	5114
22226	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; each additional vertebral segment (list separately in addition to code for primary procedure)	N	N/A
22318	Open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation; without grafting	J1	5115
22319	Open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation; with grafting	J1	5115
22325	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; lumbar	J1	5115
22326	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; cervical	J1	5115
22327	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; thoracic	J1	5115
22328	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; each additional fractured vertebra or dislocated segment (list separately in addition to code for primary procedure)	N	N/A
22532	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic	J1	5116
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	J1	5116
22534	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic or lumbar, each additional vertebral segment (list separately in addition to code for primary procedure)	N	N/A
22548	Arthrodesis, anterior transoral or extraoral technique, clivus-c1-c2 (atlas-axis), with or without excision of odontoid process	J1	5116

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22556	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic	J1	5116
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	J1	5116
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, l5-s1 interspace	J1	5116
22590	Arthrodesis, posterior technique, craniocervical (occiput-c2)	J1	5116
22595	Arthrodesis, posterior technique, atlas-axis (c1-c2)	J1	5116
22600	Arthrodesis, posterior or posterolateral technique, single level; cervical below c2 segment	J1	5116
22610	Arthrodesis, posterior or posterolateral technique, single level; thoracic (with lateral transverse technique, when performed)	J1	5116
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar	J1	5116
22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (list separately in addition to code for primary procedure)	N	N/A
22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments	J1	5116
22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments	J1	5116
22804	Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments	J1	5116
22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments	J1	5116
22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments	J1	5116
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments	J1	5116
22818	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); single or 2 segments	J1	5116
22819	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); 3 or more segments	J1	5116

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22830	Exploration of spinal fusion	J1	5115
22841	Internal spinal fixation by wiring of spinous processes (list separately in addition to code for primary procedure)	N	N/A
22843	Posterior segmental instrumentation (for example, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments (list separately in addition to code for primary procedure)	N	N/A
22844	Posterior segmental instrumentation (for example, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 13 or more vertebral segments (list separately in addition to code for primary procedure)	N	N/A
22846	Anterior instrumentation; 4 to 7 vertebral segments (list separately in addition to code for primary procedure)	N	N/A
22847	Anterior instrumentation; 8 or more vertebral segments (list separately in addition to code for primary procedure)	N	N/A
22848	Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum (list separately in addition to code for primary procedure)	N	N/A
22849	Reinsertion of spinal fixation device	J1	5116
22850	Removal of posterior nonsegmental instrumentation (for example, harrington rod)	J1	5115
22852	Removal of posterior segmental instrumentation	J1	5115
22855	Removal of anterior instrumentation	J1	5115
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar	J1	5116
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	J1	5116
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar	J1	5116
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	J1	5115
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar	J1	5115
23200	Radical resection of tumor; clavicle	J1	5114
23210	Radical resection of tumor; scapula	J1	5114
23220	Radical resection of tumor, proximal humerus	J1	5114

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23335	Removal of prosthesis, includes debridement and synovectomy when performed; humeral and glenoid components (for example, total shoulder)	J1	5073
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (for example, total shoulder))	J1	5115
23474	Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component	J1	5115
23900	Interthoracoscapular amputation (forequarter)	J1	5115
23920	Disarticulation of shoulder;	J1	5115
24900	Amputation, arm through humerus; with primary closure	J1	5115
24920	Amputation, arm through humerus; open, circular (guillotine)	J1	5115
24930	Amputation, arm through humerus; re-amputation	J1	5114
24931	Amputation, arm through humerus; with implant	J1	5115
24940	Cineplasty, upper extremity, complete procedure	J1	5115
25900	Amputation, forearm, through radius and ulna;	J1	5115
25905	Amputation, forearm, through radius and ulna; open, circular (guillotine)	J1	5115
25915	Krukenberg procedure	J1	5114
25920	Disarticulation through wrist;	J1	5114
25924	Disarticulation through wrist; re-amputation	J1	5114
25927	Transmetacarpal amputation;	J1	5113
26551	Transfer, toe-to-hand with microvascular anastomosis; great toe wrap-around with bone graft	J1	5114
26553	Transfer, toe-to-hand with microvascular anastomosis; other than great toe, single	J1	5114
26554	Transfer, toe-to-hand with microvascular anastomosis; other than great toe, double	J1	5114
26556	Transfer, free toe joint, with microvascular anastomosis	J1	5114
26992	Incision, bone cortex, pelvis and/or hip joint (for example, osteomyelitis or bone abscess)	J1	5114
27005	Tenotomy, hip flexor(s), open (separate procedure)	J1	5114
27025	Fasciotomy, hip or thigh, any type	J1	5114
27030	Arthrotomy, hip, with drainage (for example, infection)	J1	5114
27036	Capsulectomy or capsulotomy, hip, with or without excision of heterotopic bone, with release of hip flexor muscles (ie, gluteus medius, gluteus minimus, tensor fascia latae, rectus femoris, sartorius, iliopsoas)	J1	5114
27054	Arthrotomy with synovectomy, hip joint	J1	5113
27070	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (for example, osteomyelitis or bone abscess); superficial	J1	5114

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27071	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (for example, osteomyelitis or bone abscess); deep (subfascial or intramuscular)	J1	5114
27075	Radical resection of tumor; wing of ilium, 1 pubic or ischial ramus or symphysis pubis	J1	5114
27076	Radical resection of tumor; ilium, including acetabulum, both pubic rami, or ischium and acetabulum	J1	5114
27077	Radical resection of tumor; innominate bone, total	J1	5115
27078	Radical resection of tumor; ischial tuberosity and greater trochanter of femur	J1	5115
27090	Removal of hip prosthesis; (separate procedure)	J1	5073
27091	Removal of hip prosthesis; complicated, including total hip prosthesis, methylmethacrylate with or without insertion of spacer	J1	5073
27120	Acetabuloplasty; (for example, whitman, colonna, haygroves, or cup type)	J1	5115
27122	Acetabuloplasty; resection, femoral head (for example, girdlestone procedure)	J1	5115
27125	Hemiarthroplasty, hip, partial (for example, femoral stem prosthesis, bipolar arthroplasty)	J1	5115
27132	Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft	J1	5115
27134	Revision of total hip arthroplasty; both components, with or without autograft or allograft	J1	5115
27137	Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft	J1	5115
27138	Revision of total hip arthroplasty; femoral component only, with or without allograft	J1	5115
27140	Osteotomy and transfer of greater trochanter of femur (separate procedure)	J1	5115
27146	Osteotomy, iliac, acetabular or innominate bone;	J1	5114
27147	Osteotomy, iliac, acetabular or innominate bone; with open reduction of hip	J1	5114
27151	Osteotomy, iliac, acetabular or innominate bone; with femoral osteotomy	J1	5114
27156	Osteotomy, iliac, acetabular or innominate bone; with femoral osteotomy and with open reduction of hip	J1	5114
27158	Osteotomy, pelvis, bilateral (for example, congenital malformation)	J1	5114
27161	Osteotomy, femoral neck (separate procedure)	J1	5114
27165	Osteotomy, intertrochanteric or subtrochanteric including internal or external fixation and/or cast	J1	5114
27170	Bone graft, femoral head, neck, intertrochanteric or subtrochanteric area (includes obtaining bone graft)	J1	5114

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27175	Treatment of slipped femoral epiphysis; by traction, without reduction	J1	5114
27176	Treatment of slipped femoral epiphysis; by single or multiple pinning, in situ	J1	5115
27177	Open treatment of slipped femoral epiphysis; single or multiple pinning or bone graft (includes obtaining graft)	J1	5114
27178	Open treatment of slipped femoral epiphysis; closed manipulation with single or multiple pinning	J1	5114
27181	Open treatment of slipped femoral epiphysis; osteotomy and internal fixation	J1	5114
27185	Epiphyseal arrest by epiphysiodesis or stapling, greater trochanter of femur	J1	5114
27187	Prophylactic treatment (nailing, pinning, plating or wiring) with or without methylmethacrylate, femoral neck and proximal femur	J1	5114
27222	Closed treatment of acetabulum (hip socket) fracture(s); with manipulation, with or without skeletal traction	J1	5111
27226	Open treatment of posterior or anterior acetabular wall fracture, with internal fixation	J1	5114
27227	Open treatment of acetabular fracture(s) involving anterior or posterior (one) column, or a fracture running transversely across the acetabulum, with internal fixation	J1	5114
27228	Open treatment of acetabular fracture(s) involving anterior and posterior (two) columns, includes t-fracture and both column fracture with complete articular detachment, or single column or transverse fracture with associated acetabular wall fracture, with internal fixation	J1	5114
27232	Closed treatment of femoral fracture, proximal end, neck; with manipulation, with or without skeletal traction	J1	5112
27236	Open treatment of femoral fracture, proximal end, neck, internal fixation or prosthetic replacement	J1	5114
27240	Closed treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with manipulation, with or without skin or skeletal traction	J1	5112
27244	Treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with plate/screw type implant, with or without cerclage	J1	5114
27245	Treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with intramedullary implant, with or without interlocking screws and/or cerclage	J1	5114
27248	Open treatment of greater trochanteric fracture, includes internal fixation, when performed	J1	5114

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27253	Open treatment of hip dislocation, traumatic, without internal fixation	J1	5113
27254	Open treatment of hip dislocation, traumatic, with acetabular wall and femoral head fracture, with or without internal or external fixation	J1	5113
27258	Open treatment of spontaneous hip dislocation (developmental, including congenital or pathological), replacement of femoral head in acetabulum (including tenotomy, etc);	J1	5113
27259	Open treatment of spontaneous hip dislocation (developmental, including congenital or pathological), replacement of femoral head in acetabulum (including tenotomy, etc); with femoral shaft shortening	J1	5113
27268	Closed treatment of femoral fracture, proximal end, head; with manipulation	J1	5113
27269	Open treatment of femoral fracture, proximal end, head, includes internal fixation, when performed	J1	5112
27280	Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed	J1	5116
27282	Arthrodesis, symphysis pubis (including obtaining graft)	J1	5115
27284	Arthrodesis, hip joint (including obtaining graft);	J1	5116
27286	Arthrodesis, hip joint (including obtaining graft); with subtrochanteric osteotomy	J1	5116
27290	Interpelviabdominal amputation (hindquarter amputation)	J1	5116
27295	Detachment of hip joint	J1	5116
27303	Incision, deep, with opening of bone cortex, femur or knee (for example, osteomyelitis or bone abscess)	J1	5114
27365	Radical resection of tumor, femur or knee	J1	5114
27445	Arthroplasty, knee, hinge prosthesis (for example, walldius type)	J1	5115
27448	Osteotomy, femur, shaft or supracondylar; without fixation	J1	5114
27450	Osteotomy, femur, shaft or supracondylar; with fixation	J1	5114
27454	Osteotomy, multiple, with realignment on intramedullary rod, femoral shaft (for example, sofield type procedure)	J1	5114
27455	Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus [bowleg] or genu valgus [knock-knee]); before epiphyseal closure	J1	5114
27457	Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus [bowleg] or genu valgus [knock-knee]); after epiphyseal closure	J1	5114
27465	Osteoplasty, femur; shortening (excluding 64876)	J1	5114
27466	Osteoplasty, femur; lengthening	J1	5114

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27468	Osteoplasty, femur; combined, lengthening and shortening with femoral segment transfer	J1	5114
27470	Repair, nonunion or malunion, femur, distal to head and neck; without graft (for example, compression technique)	J1	5114
27472	Repair, nonunion or malunion, femur, distal to head and neck; with iliac or other autogenous bone graft (includes obtaining graft)	J1	5114
27486	Repair, nonunion or malunion, femur, distal to head and neck; with iliac or other autogenous bone graft (includes obtaining graft)	J1	5115
27487	Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component	J1	5115
27488	Removal of prosthesis, including total knee prosthesis, methylmethacrylate with or without insertion of spacer, knee	J1	5114
27495	Prophylactic treatment (nailing, pinning, plating, or wiring) with or without methylmethacrylate, femur	J1	5114
27506	Open treatment of femoral shaft fracture, with or without external fixation, with insertion of intramedullary implant, with or without cerclage and/or locking screws	J1	5114
27507	Open treatment of femoral shaft fracture with plate/screws, with or without cerclage	J1	5114
27511	Open treatment of femoral supracondylar or transcondylar fracture without intercondylar extension, includes internal fixation, when performed	J1	5114
27513	Open treatment of femoral supracondylar or transcondylar fracture with intercondylar extension, includes internal fixation, when performed	J1	5114
27514	Open treatment of femoral fracture, distal end, medial or lateral condyle, includes internal fixation, when performed	J1	5114
27519	Open treatment of femoral fracture, distal end, medial or lateral condyle, includes internal fixation, when performed	J1	5114
27535	Open treatment of tibial fracture, proximal (plateau); unicondylar, includes internal fixation, when performed	J1	5114
27536	Open treatment of tibial fracture, proximal (plateau); bicondylar, with or without internal fixation	J1	5114
27540	Open treatment of intercondylar spine(s) and/or tuberosity fracture(s) of the knee, includes internal fixation, when performed	J1	5114
27556	Open treatment of knee dislocation, includes internal fixation, when performed; without primary ligamentous repair or augmentation/reconstruction	J1	5114

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27557	Open treatment of knee dislocation, includes internal fixation, when performed; with primary ligamentous repair	J1	5114
27558	Open treatment of knee dislocation, includes internal fixation, when performed; with primary ligamentous repair	J1	5114
27580	Arthrodesis, knee, any technique	J1	5115
27590	Amputation, thigh, through femur, any level;	J1	5116
27591	Amputation, thigh, through femur, any level; immediate fitting technique including first cast	J1	5116
27592	Amputation, thigh, through femur, any level; open, circular (guillotine)	J1	5116
27596	Amputation, thigh, through femur, any level; re-amputation	J1	5114
27598	Disarticulation at knee	J1	5115
27645	Radical resection of tumor; tibia	J1	5114
27646	Radical resection of tumor; fibula	J1	5114
27702	Arthroplasty, ankle; with implant (total ankle)	J1	5115
27703	Arthroplasty, ankle; revision, total ankle	J1	5115
27712	Osteotomy; multiple, with realignment on intramedullary rod (for example, sofield type procedure)	J1	5115
27715	Osteoplasty, tibia and fibula, lengthening or shortening	J1	5115
27724	Repair of nonunion or malunion, tibia; with iliac or other autograft (includes obtaining graft)	J1	5114
27725	Repair of nonunion or malunion, tibia; by synostosis, with fibula, any method	J1	5114
27727	Repair of congenital pseudarthrosis, tibia	J1	5114
27880	Amputation, leg, through tibia and fibula;	J1	5116
27881	Amputation, leg, through tibia and fibula; with immediate fitting technique including application of first cast	J1	5114
27882	Amputation, leg, through tibia and fibula; open, circular (guillotine)	J1	5114
27886	Amputation, leg, through tibia and fibula; re-amputation	J1	5114
27888	Amputation, ankle, through malleoli of tibia and fibula (for example, syme, pirogoff type procedures), with plastic closure and resection of nerves	J1	5115
28800	Amputation, foot; midtarsal (for example, chopart type procedure)	J1	5113
G0412	Open treatment of iliac spine(s), tuberosity avulsion, or iliac wing fracture(s), unilateral or bilateral for pelvic bone fracture patterns which do not disrupt the pelvic ring includes internal fixation, when performed	J1	5114

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2021 OPPS Status Indicator	CY 2021 OPPS APC Assignment
G0414	Open treatment of anterior pelvic bone fracture and/or dislocation for fracture patterns which disrupt the pelvic ring, unilateral or bilateral, includes internal fixation when performed (includes pubic symphysis and/or superior/inferior rami)	J1	5115
G0415	Open treatment of posterior pelvic bone fracture and/or dislocation, for fracture patterns which disrupt the pelvic ring, unilateral or bilateral, includes internal fixation, when performed (includes ilium, sacroiliac joint and/or sacrum)	J1	5115
35372	Thromboendarterectomy, including patch graft, if performed; deep (profunda) femoral	J1	5184
35800	Exploration for postoperative hemorrhage, thrombosis or infection; neck	J1	5184
37182	Insertion of transvenous intrahepatic portosystemic shunt(s) (tips) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract formation/dilatation, stent placement and all associated imaging guidance and documentation)	J1	5193
37617	Ligation, major artery (eg, post-traumatic, rupture); abdomen	J1	5183
38562	Limited lymphadenectomy for staging (separate procedure); pelvic and para-aortic	J1	5362
43840	Gastrorrhaphy, suture of perforated duodenal or gastric ulcer, wound, or injury	J1	5331
44300	Placement, enterostomy or cecostomy, tube open (eg, for feeding or decompression) (separate procedure)	J1	5302
44314	Revision of ileostomy; complicated (reconstruction in-depth) (separate procedure)	T	5055
44345	Revision of colostomy; complicated (reconstruction in-depth) (separate procedure)	J1	5341
44346	Revision of colostomy; with repair of paracolostomy hernia (separate procedure)	J1	5341
44602	Suture of small intestine (enterorrhaphy) for perforated ulcer, diverticulum, wound, injury or rupture; single perforation	J1	5303
49010	Exploration, retroperitoneal area with or without biopsy(s) (separate procedure)	J1	5341
49255	Omentectomy, epiploectomy, resection of omentum (separate procedure)	J1	5341
51840	Anterior vesicourethropexy, or urethropexy (eg, marshall-marchetti-krantz, burch); simple	J1	5415
56630	Vulvectomy, radical, partial;	J1	5415

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2021 OPPS Status Indicator	CY 2021 OPPS APC Assignment
61624	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; central nervous system (intracranial, spinal cord)	J1	5194

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X. Nonrecurring Policy Changes

A. Changes in the Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals (CAHs)

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61359 through 61363), we implemented a policy for CY 2020 and subsequent years to change the generally applicable minimum required level of supervision for most hospital outpatient therapeutic services from direct supervision to general supervision for services furnished by all hospitals and CAHs. However, some groups of services were not subject to the change in the required supervision level and those services continue to have a minimum default level of supervision that is higher than general supervision.

On January 31, 2020, Health and Human Services Secretary Alex M. Azar II determined that a PHE exists retroactive to January 27, 2020 [98] under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID–19, and on April 21, 2020, Secretary Azar renewed, effective April 26, 2020, and again effective July 25, 2020, the determination that a PHE exists.[99] On March 13, 2020, the President of the U.S. declared the COVID–19 outbreak in the U.S. constitutes a national emergency,[100] beginning March 1, 2020. On March 31, 2020, we issued an interim final rule with comment period (IFC) to give individuals and entities that provide services to Medicare beneficiaries needed flexibilities to respond effectively to the serious public health threats posed by the spread of COVID–19. The goal of the IFC issued on March 31, 2020, was to provide the necessary flexibility for Medicare beneficiaries to be able to receive medically necessary services without jeopardizing their health or the health of those who are providing those services, while minimizing the overall risk to public health (85 FR 19232).

In the IFC issued March 31, 2020, we adopted a policy to reduce, on an interim basis for the duration of the PHE, the minimum default level of supervision for non-surgical extended duration therapeutic services (NSEDTS) to general supervision for the entire service, including the initiation portion of the service, for which we had previously required direct supervision. We also specified in the IFC issued March 31, 2020, that, for the duration of the PHE for the COVID–19 pandemic, the requirement for direct physician supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services includes virtual presence of the physician through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider.

These policies were adopted on an interim final basis for the duration of the PHE. However, in the CY 2021 OPPS/ASC proposed rule, we stated that we believed these policies are appropriate outside of the PHE and should apply permanently. Therefore, we proposed to adopt these policies for CY 2021 and beyond as described in more detail below.

1. General Supervision of Outpatient Hospital Therapeutic Services Currently Assigned to the Non-Surgical Extended Duration Therapeutic Services (NSEDTS) Level of Supervision

NSEDTS describe services that have a significant monitoring component that can extend for a lengthy period of time, that are not surgical, and that typically have a low risk of complications after the assessment at the beginning of the service. The minimum default supervision level of NSEDTS was established in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72003 through 72013) as being direct supervision during the initiation of the service, which may be followed by general supervision at the discretion of the supervising physician or the appropriate nonphysician practitioner (§ 410.27(a)(1)(iv)(E)). In this case, initiation means the beginning portion of the NSEDTS, which ends when the patient is stable and the supervising physician or the appropriate nonphysician practitioner determines that the remainder of the service can be delivered safely under general supervision. We originally established general supervision as the appropriate level of supervision after the initiation of the service because it is challenging for hospitals to ensure direct supervision for services with an extended duration and a significant monitoring component, particularly for CAHs and small rural hospitals.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61359 through 61363), we changed the generally applicable minimum required level of supervision for most hospital outpatient therapeutic services from direct supervision to general supervision for hospitals and CAHs. We made this change because we believe it is critical that hospitals have the flexibility to provide the services Medicare beneficiaries need while minimizing provider burden. In the IFC issued March 31, 2020 (85 FR 19266), we assigned, on an interim basis, a minimum required supervision level of general supervision for NSEDTS services, including during the initiation portion of the service, during the PHE. Changing the minimum level of supervision to general supervision during the PHE gives providers additional flexibility to handle the burdens created by the COVID–19 PHE.

We believe changing the level of supervision for NSEDTS permanently for the duration of the service would be beneficial to patients and outpatient hospital providers as it would allow greater flexibility in providing these services and reduce provider burden, and thus, improve access to these

[98] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[99] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.aspx.*

[100] *https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.*

services in cases where the direct supervision requirement may have otherwise prevented some services from being furnished due to lack of availability of the supervising physician or nonphysician practitioner. In addition, as we explained in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61360), our experience indicates that Medicare providers will provide a similar quality of hospital outpatient therapeutic services, including NSEDTS, regardless of whether the minimum level of supervision required under the Medicare program is direct or general. We note that the requirement for general supervision for an entire NSEDTS does not preclude these hospitals from providing direct supervision for any part of a NSEDTS when the practitioners administering the medical procedures decide that it is appropriate to do so. Many outpatient therapeutic services, including NSEDTS, may involve a level of complexity and risk such that direct supervision would be warranted even though only general supervision is required.

In addition, CAHs and hospitals in general continue to be subject to conditions of participation (CoPs) that complement the general supervision requirements for hospital outpatient therapeutic services, including NSEDTS, to ensure that the medical services Medicare patients receive are properly supervised. CoPs for hospitals require Medicare patients to be under the care of a physician (42 CFR 482.12(c)(4)), and for the hospital to ''have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by the hospital'' (42 CFR 482.22). The CoPs for CAHs (42 CFR 485.631(b)(1)(i)) require physicians to provide medical direction for the CAHs' health care activities, consultation for, and medical supervision of the health care staff. The physicians' responsibilities in hospitals and CAHs include supervision of all services performed at those facilities. In addition, physicians must also follow state laws regarding scope of practice.

Therefore, we proposed to establish general supervision as the minimum required supervision level for all NSEDTS that are furnished on or after January 1, 2021. This would be consistent with the minimum required level of general supervision that currently applies for most outpatient hospital therapeutic services. General supervision, as defined in our regulation at § 410.32(b)(3)(i), means that the procedure is furnished under the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure; and as provided under § 410.27(a)(1)(iv)(C), certain non-physician practitioners can provide the required supervision of services that they can personally furnish in accordance with state law and all other applicable requirements. Because we proposed a minimum required level of general supervision for NSEDTS, including during the initiation of the service, we proposed to delete paragraph (a)(1)(iv)(E) from the regulations at § 410.27. We sought public comment on this proposal.

Comment: All commenters supported our proposal to change the minimum required level of supervision to general supervision for all NSEDTS that are furnished on or after January 1, 2021. Several commenters appreciated the additional flexibility to deliver care while acknowledging that practitioners administering individual medical procedures continue to have the discretion to increase the level of supervision when necessary. Commenters similarly acknowledged that CoPs for hospitals and CAHs and state scope of practice requirements also might lead to higher level of supervision for a part or all of an NSEDTS. One commenter, MedPAC, supported our proposal, but encouraged CMS to be diligent in monitoring NSEDTS performed under general supervision, especially services that involve risk of serious complications.

Response: We appreciate the support for our proposal from the commenters. We will monitor NSEDTS for safety or service quality issues that may arise from the change to general supervision as the minimum default level of supervision for the initiation period of these services.

After reviewing the public comments we received, we are finalizing our proposal without modification to establish general supervision as the minimum required supervision level for all NSEDTS that are furnished on or after January 1, 2021. In addition, we are finalizing our proposal to delete paragraph (a)(1)(iv)(E) from the regulations at § 410.27, which will reflect that, starting in CY 2021, the entirety of NSEDTS has a minimum required supervision level of general supervision.

2. Direct Supervision of Pulmonary Rehabilitation Services, Cardiac Rehabilitation Services, and Intensive Cardiac Rehabilitation Services Using Interactive Telecommunications Technology

Direct physician supervision was the standard set forth in the April 7, 2000 OPPS final rule with comment period (68 FR 18524 through 18526) for supervision of hospital outpatient therapeutic services covered and paid by Medicare in hospitals and provider-based departments of hospitals, including for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation services provided to hospital outpatients. As we explained in the CY 2011 OPPS/ASC final rule with comment period, the statutory language of sections 1861(eee)(2)(B) and (eee)(4)(A) and section 1861(fff)(1) of the Act (as added by section 144(a)(1) of Pub. L. 110–275) defines cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation programs as ''physician supervised.'' More specifically, section 1861(eee)(2)(B) of the Act establishes that, for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation programs, ''a physician is immediately available and accessible for consultation and medical emergencies at all times items and services are being furnished under the program, except that, in the case of items and services furnished under such a program in a hospital, such availability shall be presumed.'' As we explained in the CY 2009 OPPS/ASC proposed rule and final rule with comment period (73 FR 41518 through 41519 and 73 FR 68702 through 68704, referencing the April 7, 2000 OPPS final rule (65 FR 18525)), the ''presumption'' or ''assumption'' of direct supervision means that direct physician supervision is the standard for all hospital outpatient therapeutic services. We have assumed this requirement is met on hospital premises because staff physicians would always be nearby in the hospital. In other words, the requirement is not negated by a presumption that the requirement is being met. Recently, some stakeholders suggested we have the authority to change the default minimum level of supervision for pulmonary rehabilitation services, cardiac rehabilitation services, and intensive cardiac rehabilitation services to general supervision because of the policy we adopted in CY 2020 to change the generally applicable minimum required level of supervision for most other hospital outpatient therapeutic services from direct supervision to

general supervision (84 FR 61359 through 61363). For the reasons explained above, we disagree that we can change the default level of supervision for these services to general supervision under current law.

In the IFC issued March 31, 2020 (85 FR 19246), we implemented a policy for the duration of the PHE that allows the direct supervision requirement for cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation services to be met by the virtual presence of the supervising physician through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks to COVID–19 for the beneficiary or health care provider. While we adopted this policy to help improve the availability of rehabilitation services during the PHE and reduce the burden for providers, we also believed the policy to allow direct supervision provided by the virtual presence of the physician could continue to improve access for patients and reduce burden for providers after the end of the PHE. In some cases, depending upon the circumstances of individual patients and supervising physicians, we believed that telecommunications technology could be used in a manner that would facilitate the physician's immediate availability to furnish assistance and direction without necessarily requiring the physician's physical presence in the location where the service is being furnished. For example, use of real-time audio and video telecommunications technology could allow a supervising physician to observe the patient during treatment as they interact with or respond to the in-person clinical staff. Thus, the supervising physician's immediate availability to furnish assistance and direction during the service could be met virtually without requiring the physician's physical presence in that location.

Therefore for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, we proposed to change our regulation at § 410.27(a)(1)(iv)(D) to specify that, beginning on or after January 1, 2021, direct supervision for these services includes virtual presence of the physician through audio/video real-time communications technology subject to the clinical judgment of the supervising physician. We clarify that the virtual presence required for direct supervision using audio/video real-time communications technology would not be limited to mere availability of the physician, but rather real-time presence via interactive audio and video technology throughout the performance of the procedure. We sought public comment on this proposal.

Comment: Many commenters wanted more clarity on our proposal to meet the direct supervision requirement for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services through virtual presence. Commenters were unsure what the phrase ''real-time presence via interactive audio and video technology throughout the performance of the procedure'' meant. Some commenters were concerned that our proposal would require the supervising practitioner to observe a rehabilitation service during the entire time the service is being administered, which would be comparable to personal supervision. That type of standard, according to the commenters, would actually be more burdensome than the current direct supervision requirement through physical presence.

Other commenters stated that, while they were generally in favor of permitting direct physician supervision through virtual presence for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, they would prefer that we require the supervising practitioner simply be ''immediately available'' through audio/visual real-time communications technology, and not be required to provide real-time presence or observation of the service via interactive audio and video technology throughout the performance of the procedure. A few commenters also encouraged us to align our proposal on direct supervision through virtual presence with what had been proposed in the CY 2021 PFS proposed rule (85 FR 50115 through 50116), which discussed requiring only immediate availability to engage using audio/visual technology to provide direct supervision.

Response: We believe the commenters have made some important points about our proposal. CMS continues to work to reduce burden on providers under the Medicare program, and we want to ensure that while expanding access to medical care and promoting patient safety, we do not implement policies that increase provider burden. In this case, our proposal appears to have required a higher level of participation by the physician providing direct supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services through virtual presence than would be required if they were providing direct supervision of the services in person. In addition, our proposal was not aligned with the proposal in the CY 2021 PFS proposed rule to permit direct supervision requirements to be met through virtual presence through the later of the end of the year in which the PHE ends or December 31, 2021; and to specify that the direct supervision requirement could be met by the supervising practitioner being immediately available to engage via interactive real-time audio/video communications technology, without requiring real-time presence or observation of the service via interactive audio/video technology throughout the performance of the procedure. This lack of alignment could lead to additional burden for providers having to accommodate different levels of virtual engagement depending on whether a rehabilitation service is furnished as an outpatient hospital service or a physicians' service.

Comment: A few commenters either opposed the proposal or wanted to place substantial limits on when direct supervision through virtual presence could be used to furnish pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services. One commenter, MedPAC, opposed the proposal because they believe it is unclear whether telehealth is beneficial or harmful to the quality of care received for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services. MedPAC encouraged us to study the policy further before implementing our proposal. Another commenter expressed support for permitting the direct supervision of rehabilitation services through virtual presence, but only if the supervising practitioner has first seen both the patient and the site of service in person, initiated the treatment, and provides subsequent services that show active participation in, and management of, the course of treatment. A third commenter did not explicitly state that they were against allowing direct supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services through virtual presence, and the commenter expressed support for permitting direct supervision through virtual presence during the current PHE to avoid the risks associated with COVID–19. However, the commenter believes that the policy to allow direct supervision through virtual presence should end for all medical services including pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services at the end of the PHE. The commenter felt that practitioners cannot adequately

supervise procedures, especially complex and high-risk procedures, and meet all of a patient's clinical needs, unless they are physically available to participate in the administration of the medical service. Furthermore, the commenter suggested that we adopt limits on the number of clinical staff members a supervising practitioner may engage with simultaneously through audio and visual technology, and limits on a supervising practitioner's incident to relationships with outpatient hospital providers that are fulfilled primarily through the use of audio and visual technology before allowing direct supervision through virtual presence after the end of the PHE. This request was for all outpatient hospital services, and not just for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services.

Response: We appreciate the concerns expressed by some commenters about the potential risks of allowing direct supervision using virtual presence. We note that, during the PHE, virtual presence of the supervising physician using interactive audio/video real-time communications technology is an available option for direct supervision, but it is not a requirement. Providers and physicians are free to use their own judgment to determine whether direct supervision through virtual presence is appropriate for the rehabilitation services being administered, or if the supervising physician should provide direct supervision in person. Also, providers will need to meet conditions of participation and state scope of work requirements in the location where the service is administered. Finally, we will monitor the use of interactive audio/video real-time communications technology to meet the direct supervision requirement to determine whether there is a negative impact on the quality of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services.

Comment: Several commenters supported our proposal to allow the use of virtual presence to meet the direct physician supervision requirements for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services as proposed and they did not request modifications to our proposal.

Response: We thank the commenters for their support of our proposal.

After consideration of the public comments received for our proposal, we have decided to modify the proposal in the CY 2021 OPPS/ASC proposed rule. We believe we need to continue to explore the appropriateness of permitting direct supervision through virtual presence before extending this policy permanently beyond the end of the PHE. The public comments we received, along with feedback we have received since the implementation of the policy in IFC–1 allowing for direct supervision through virtual presence (85 FR 19246) have convinced us that we need more information on the issues involved with direct supervision through virtual presence before implementing this policy permanently. Therefore, we are finalizing our proposed policy to permit direct supervision of these services using virtual presence only until the later of the end of the calendar year in which the PHE ends or December 31, 2021. Specifically, the required direct physician supervision can be provided through virtual presence using audio/video real-time communications technology (excluding audio-only) subject to the clinical judgement of the supervising practitioner, as discussed in IFC–1 (85 FR 19246).

When the policy to permit direct supervision through virtual presence ends, we will resume our current policy to require direct physician supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, and that the supervising practitioner must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. This does not mean that the supervising practitioner must be present in the room when the procedure is performed.

In response to questions received since we issued our interim policy for the PHE, we are clarifying that, to the extent our policy allows direct supervision through virtual presence using audio/video real-time communications technology during the PHE, the requirement could be met by the supervising practitioner being immediately available to engage via audio/video technology (excluding audio-only), and would not require real-time presence or observation of the service via interactive audio and video technology throughout the performance of the procedure. We intend our policy to permit direct physician supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services to be consistent with the policy to permit direct supervision through virtual presence in section II.D.9. of the CY 2021 PFS final rule, which we cross reference here. We also are revising the regulatory text in 42 CFR 410.27(a)(1)(iv)(D) to reflect our revised policy, and to align the regulation with similar language describing direct supervision through virtual presence in the physician office setting in 42 CFR 410.32(b)(3)(ii).

B. Medical Review of Certain Inpatient Hospital Admissions Under Medicare Part A for CY 2021 and Subsequent Years

1. Background on the 2-Midnight Rule

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50913 through 50954), we clarified our policy regarding when an inpatient admission is considered reasonable and necessary for purposes of Medicare Part A payment. Under this policy, we established a benchmark providing that surgical procedures, diagnostic tests, and other treatments would be generally considered appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation. Conversely, when a beneficiary enters a hospital for a surgical procedure not designated as an inpatient-only (IPO) procedure as described in 42 CFR 419.22(n), a diagnostic test, or any other treatment, and the physician expects to keep the beneficiary in the hospital for only a limited period of time that does not cross 2 midnights, the services would be generally inappropriate for payment under Medicare Part A, regardless of the hour that the beneficiary came to the hospital or whether the beneficiary used a bed. With respect to services designated under the OPPS as IPO procedures, we explained that because of the intrinsic risks, recovery impacts, or complexities associated with such services, these procedures would continue to be appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay. We also indicated that there might be further ''rare and unusual'' exceptions to the application of the benchmark, which would be detailed in subregulatory guidance.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50913 through 50954), we also finalized the 2-Midnight presumption, which is related to the 2-Midnight benchmark but is a separate medical review policy. The 2-Midnight benchmark represents guidance to reviewers to identify when an inpatient admission is generally reasonable and necessary for purposes of Medicare Part A payment, while the 2-Midnight presumption relates to instructions to medical reviewers regarding the

selection of claims for medical review. Specifically, under the 2-Midnight presumption, inpatient hospital claims with lengths of stay greater than 2 midnights after the formal admission following the order are presumed to be appropriate for Medicare Part A payment and are not the focus of medical review efforts, absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2-Midnight presumption. Thus, for purposes of the 2-Midnight *presumption,* the ''clock'' starts at the point of admission as an inpatient.

With respect to the 2-Midnight *benchmark,* however, the starting point is when the beneficiary begins receiving hospital care either as a registered outpatient or after inpatient admission. That is, for purposes of determining whether the 2-Midnight benchmark is met and, therefore, whether an inpatient admission is appropriate for Medicare Part A payment, we consider the physician's expectation including the total time spent receiving hospital care—not only the expected duration of care after inpatient admission, but also any time the beneficiary has spent (before inpatient admission) receiving outpatient services, such as observation services, treatments in the emergency department, and procedures provided in the operating room or other treatment area. From the medical review perspective, while the time the beneficiary spent as an outpatient before the admission order is written is not considered inpatient time, it is considered during the medical review process for purposes of determining whether the 2-Midnight benchmark was met and, therefore, whether payment is appropriate under Medicare Part A. For beneficiaries who do not arrive through the emergency department or are directly receiving inpatient services (for example, inpatient admission order written prior to admission for an elective admission), the starting point for medical review purposes is when the beneficiary starts receiving medically responsive services following arrival at the hospital. For Medicare payment purposes, both the decision to keep the patient at the hospital and the expectation of needed duration of the stay must be supported by documentation in the medical record based on factors such as beneficiary medical history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event during hospitalization.

With respect to inpatient stays spanning less than 2 midnights after admission, we instructed contractors that, although such claims would not be subject to the presumption, the admission may still be appropriate for Medicare Part A payment because time spent as an outpatient should be considered in determining whether there was a reasonable expectation that the hospital care would span 2 or more midnights. In other words, even if an inpatient admission was for only 1 Medicare utilization day, medical reviewers are instructed to consider the total duration of hospital care, both pre- and post-inpatient admission, as well as the reasonable expectations of the admitting physician regarding duration of hospital care, when making the determination of whether the inpatient stay was reasonable and necessary for purposes of Medicare Part A payment.

We continue to believe that use of the 2-Midnight benchmark gives appropriate consideration to the medical judgment of physicians and furthers the goal of clearly identifying when an inpatient admission is appropriate for payment under Medicare Part A. More specifically, as we described in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50943 through 50954), factors such as the procedures being performed and the beneficiary's condition and comorbidities apply when the physician formulates his or her expectation regarding the need for hospital care, while the determination of whether an admission is appropriately billed and paid under Medicare Part A or Part B is generally based upon the physician's medical judgment regarding the beneficiary's expected length of stay. We have not identified any circumstances where the 2-Midnight benchmark restricts the physician to a specific pattern of care, because the 2-Midnight benchmark does not prevent the physician from ordering or providing any service at any hospital, regardless of the expected duration of the service. Rather, this policy provides guidance on when the hospitalized beneficiary's care is appropriate for coverage and payment under Medicare Part A as an inpatient, and when the beneficiary's care is reasonable and necessary for payment under Medicare Part B as an outpatient.

2. Current Policy for Medical Review of Inpatient Hospital Admissions Under Medicare Part A

As mentioned previously, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50943 through 50954), we provided guidance for payment purposes that specified that, generally, a hospital inpatient admission is considered reasonable and necessary if a physician or other qualified practitioner (collectively, ''physician'') orders such admission based on the expectation that the beneficiary's length of stay will exceed 2 midnights or if the beneficiary requires a procedure specified as inpatient-only under § 419.22 of the regulations. We finalized at § 412.3 of the regulations that services designated under the OPPS as inpatient only procedures would continue to be appropriate for inpatient hospital admission and payment under Medicare Part A. In addition, we finalized a benchmark providing that surgical procedures, diagnostic tests, and other treatments would be generally considered appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation.

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70538 through 70549), we revisited the previous rare and unusual exceptions policy and finalized a proposal to allow for case-by-case exceptions to the 2-Midnight benchmark, whereby Medicare Part A payment may be made for inpatient admissions where the admitting physician does not expect the patient to require hospital care spanning 2 midnights, if the documentation in the medical record supports the physician's determination that the patient nonetheless requires inpatient hospital care.

We note that, in the CY 2016 OPPS/ASC final rule with comment period, we reiterated our position that the 2-Midnight benchmark provides clear guidance on when a hospital inpatient admission is appropriate for Medicare Part A payment, while respecting the role of physician judgment. We stated that the following criteria will be relevant to determining whether an inpatient admission with an expected length of stay of less than 2 midnights is nonetheless appropriate for Medicare Part A payment:

- Complex medical factors such as history and comorbidities;
- The severity of signs and symptoms;
- Current medical needs; and
- The risk of an adverse event.

In other words, for purposes of Medicare payment, an inpatient admission is payable under Part A if the documentation in the medical record supports either the admitting physician's reasonable expectation that the patient will require hospital care spanning at least 2 midnights, or the physician's determination based on factors such as those identified previously that the patient nonetheless

requires care on an inpatient basis. The exceptions for procedures on the IPO list and for ''rare and unusual'' circumstances designated by CMS as national exceptions were unchanged by the CY 2016 OPPS/ASC final rule with comment period.

As we stated in the CY 2016 OPPS/ASC final rule with comment period, the decision to formally admit a patient to the hospital is subject to medical review. For instance, for cases where the medical record does not support a reasonable expectation of the need for hospital care crossing at least 2 midnights, and for inpatient admissions not related to a surgical procedure specified by Medicare as an IPO procedure under 42 CFR 419.22(n) or for which there was not a national exception, payment of the claim under Medicare Part A is subject to the clinical judgment of the medical reviewer. The medical reviewer's clinical judgment involves the synthesis of all submitted medical record information (for example, progress notes, diagnostic findings, medications, nursing notes, and other supporting documentation) to make a medical review determination on whether the clinical requirements in the relevant policy have been met. In addition, Medicare review contractors must abide by CMS' policies in conducting payment determinations, but are permitted to take into account evidence-based guidelines or commercial utilization tools that may aid such a decision. While Medicare review contractors may continue to use commercial screening tools to help evaluate the inpatient admission decision for purposes of payment under Medicare Part A, such tools are not binding on the hospital, CMS, or its review contractors. This type of information also may be appropriately considered by the physician as part of the complex medical judgment that guides their decision to keep a beneficiary in the hospital and formulation of the expected length of stay.

In the CY 2020 OPPS/ASC final rule with comment period we finalized a policy to exempt procedures that have been removed from the IPO list from certain medical review activities to assess compliance with the 2-Midnight rule within the 2-calendar years following their removal from the IPO list. We stated that these procedures will not be considered by the Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC–QIOs) in determining whether a provider exhibits persistent noncompliance with the 2-Midnight rule for purposes of referral to the RAC nor will these procedures be reviewed by RACs for ''patient status.'' We explained that during this 2-year period, BFCC–QIOs will have the opportunity to review such claims in order to provide education for practitioners and providers regarding compliance with the 2-Midnight rule, but claims identified as noncompliant will not be denied with respect to the site-of-service under Medicare Part A.

3. Medical Review of Certain Inpatient Hospital Admissions Under Medicare Part A for CY 2021 and Subsequent Years

As stated earlier in this section, services on the IPO list are not subject to the 2-Midnight rule for purposes of determining whether payment is appropriate under Medicare Part A. However, the 2-Midnight rule is applicable once services have been removed from the IPO list. Outside of the exemption period discussed above, services that have been removed from the IPO list are subject to initial medical reviews of claims for short-stay inpatient admissions conducted by BFCC–QIOs.

BFCC–QIOs may also refer providers to the RACs for further medical review due to exhibiting persistent noncompliance with Medicare payment policies, including, but not limited to:

- Having high denial rates;
- Consistently failing to adhere to the 2-Midnight rule; or
- Failing to improve their performance after QIO educational intervention.

However, as finalized in the CY 2020 OPPS/ASC final rule with comment period, procedures that have been removed from the IPO list are exempt from claim denial by the BFCC–QIOs based on site-of-service and from eligibility for referral to RACs for noncompliance with the 2-Midnight rule within the 2-calendar years following their removal from the IPO list.

As stated in section IX. of this final rule with comment period, we are finalizing our policy to eliminate the IPO list in CY 2021 with a transitional period of 3 years. For CY 2021, we are finalizing our proposal to remove all musculoskeletal procedures from the IPO list. The elimination of the IPO list will mean that procedures currently on the IPO list will be subject to the 2-Midnight rule (both the 2-Midnight benchmark and 2-Midnight presumption).

We believe that with the elimination of the IPO list, the 2-Midnight benchmark will remain an important metric to help guide when Part A payment for inpatient hospital admissions is appropriate. With more services available to be paid in the hospital outpatient setting, it will be increasingly important for physicians to exercise their clinical judgment in determining the generally appropriate clinical setting for their patient to receive a procedure, whether that be as an inpatient or on an outpatient basis. Importantly, removal of a service from the IPO list has never meant that a beneficiary cannot receive the service as a hospital inpatient—as always, the physician should use his or her complex medical judgment to determine the appropriate setting on a case by case basis.

As stated previously, our current policy regarding IPO list procedures is that they are appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay. With the elimination of the IPO list, this policy will no longer be applicable. Instead, just as for services removed from the IPO list, the elimination of the IPO list will mean that any service that was once on the IPO list will be subject to the 2-Midnight benchmark and 2-Midnight presumption. This means that for services removed from the IPO list, under the 2-Midnight presumption, inpatient hospital claims with lengths of stay greater than 2 midnights after admission will be presumed to be appropriate for Medicare Part A payment and would not be the focus of medical review efforts, absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2-Midnight presumption. Additionally, under the 2-Midnight benchmark, services formerly on the IPO list will be generally considered appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation.

As finalized in the CY 2020 OPPS/ASC final rule with comment period, procedures that have been removed from the IPO list are exempt from certain medical review activities to assess compliance with the 2-Midnight rule within the first 2 calendar years of their removal from the IPO list. These procedures are not considered by the BFCC–QIOs in determining whether a provider exhibits persistent noncompliance with the 2-midnight rule for purposes of referral to the RAC nor will claims for these procedures be reviewed by RACs for ''patient status.'' During the 2-year period, BFCC–QIOs

have the opportunity to review such claims in order to provide education for practitioners and providers regarding compliance with the 2-Midnight rule, but claims identified as noncompliant are not denied with respect to the site-of-service under Medicare Part A. Again, information gathered by the BFCC–QIO when reviewing procedures as they are newly removed from the IPO list can be used for educational purposes and does not result in a claim denial during the 2-year exemption period.

We explained in the CY 2021 OPPS/ASC proposed rule that, based on the information available to us as the time, we continued to believe that in order to facilitate compliance with our payment policy for inpatient admissions, the 2-year exemption from certain medical review activities by the BFCC–QIOs for services removed from the IPO list under the OPPS in CY 2021 and subsequent years was appropriate. Accordingly, we proposed to retain the existing 2-year exemption even in the event that we finalized the proposal to eliminate the IPO list. However, given that a large number of services would be removed from the IPO list at once during the proposed transition to eliminate the list, we sought comment on whether this 2-year period was appropriate or whether a longer or shorter period would be more appropriate in order for providers to gain experience with applying the 2-Midnight rule to these services.

We also explained that we continued to believe that a 2-year exemption from BFCC–QIO referral to RACs and RAC ''patient status'' review of the setting for procedures removed from the IPO list under the OPPS and performed in the inpatient setting would be an adequate amount of time to allow providers to gain experience with application of the 2-Midnight rule to these procedures and the documentation necessary for Part A payment for those patients for which the admitting physician determines that the procedures should be furnished in an inpatient setting. Furthermore, it was our belief that the 2-year exemption from referrals to RACs, RAC patient status review, and claims denials would be sufficient to allow providers time to update their billing systems and gain experience with respect to newly removed procedures eligible to be paid under either the IPPS or the OPPS, while avoiding potential adverse site-of-service determinations. Nonetheless, we solicited public comments regarding the appropriate period of time for this exemption. Commenters could indicate whether and why they believed the 2-year period was appropriate, or whether they believed a longer or shorter exemption period would be more appropriate.

In summary, for CY 2021 and subsequent years, we proposed to continue the 2-year exemption from site-of-service claim denials, BFCC–QIO referrals to RACs, and RAC reviews for ''patient status'' (that is, site-of-service) for procedures that are removed from the IPO list under the OPPS beginning on January 1, 2021. We encouraged BFCC–QIOs to review these cases for medical necessity in order to educate themselves and the provider community on appropriate documentation for Part A payment when the admitting physician determines that it is medically reasonable and necessary to conduct these procedures on an inpatient basis. We noted that we would monitor changes in site-of-service to determine whether changes may be necessary to certain CMS Innovation Center models. Finally, while we proposed to retain the current 2-year exemption period, given that a large number of services would be removed from the IPO as part of the transition towards the elimination of the list, we sought comment on whether that time period remained appropriate, or if a longer or shorter period may be more warranted.

Many commenters offered suggestions on the appropriate length of time for exemptions from site-of-service claim denials, BFCC–QIO referrals to RACs, and RAC reviews for ''patient status'' (that is, site-of-service) for procedures that are removed from the IPO list under the OPPS beginning on January 1, 2021. These comments are summarized below.

Comment: Numerous stakeholders including medical professional societies, health systems, and hospital associations supported the proposal to continue the 2-year exemption from site-of-service claim denials under Medicare Part A, eligibility for BFCC–QIO referrals to RACs for noncompliance with the 2-Midnight rule, and RAC reviews for ''patient status'' (that is, site-of-service) for procedures that are removed from the IPO list under the OPPS beginning on January 1, 2021. While these commenters expressed their support for continuing the 2-year exemption, they further stated that a longer exemption period would be more appropriate. Some commenters suggested that anywhere between 3 to 6 years or indefinitely would be appropriate. Commenters felt that increasing the length of the exemption would be necessary to allow hospitals and practitioners sufficient time to adjust their billing and clinical systems, as well as processes used to determine the appropriate setting of care. One commenter noted that because providers have no experience assessing procedures on the IPO list against the 2-Midnight benchmark, they will require time to update their processes to make appropriate decisions about whether to admit patients for the large numbers of procedures being removed from the IPO list. Commenters stressed that providers need time without the fear of audits to update their procedures so they can make appropriate decisions about admitting patients based on their specific conditions and recovery needs. They further noted that having an extension of the exemption period would provide stability to the healthcare systems and ensure that clinician judgment, shared decision-making with the patient, and a focus on high quality outcomes drive the selection of the appropriate site-of-service for care.

Response: We thank these commenters for their support of our proposal to continue the 2-year exemption from site-of-service claim denials under Medicare Part A, eligibility for BFCC–QIO referrals to RACs for noncompliance with the 2-Midnight rule, and RAC reviews for ''patient status'' (that is, site-of-service) for procedures that are removed from the IPO list under the OPPS beginning on January 1, 2021. We understand that the 2-year exemption might not be sufficient given the magnitude of the change for providers. We agree that additional time would be more appropriate for hospitals and practitioners to adjust their billing and clinical systems, as well as develop their own internal processes to determine the appropriate setting of care for their patients. We recognize that providers may not be experienced with assessing procedures on the IPO list against the 2-Midnight benchmark and that a longer exemption would allow them ample time to update their processes to make appropriate decisions about whether to admit patients for the large numbers of procedures being removed from the IPO list. We are mindful of the important role medical review plays in maintaining the integrity of the Medicare program but understand why providers might be anxious about balancing a new landscape for services with their concerns about claim denials or RAC referrals. Accordingly, as discussed more fully below, we are finalizing an indefinite exemption period rather than the 2-year period proposed.

Comment: We heard from many commenters that the two-year

exemption was appropriate when CMS was removing a smaller volume of procedures from the IPO list. However, commenters felt that the unprecedented volume of procedures becoming subject to the 2-Midnight rule would necessitate a longer exemption period. Many commenters believe that the extra time would allow for the education of hospital staff and physician/non-physician practitioners and operational processes to be established and refined.

Response: We agree that the two-year exemption was appropriate when CMS was removing a smaller, more targeted population of procedures from the IPO. We also agree that since the agency is changing the landscape in where procedures can be performed that a longer exemption would be more appropriate. Accordingly, as discussed more fully below, we are finalizing an indefinite exemption period for procedures removed from the IPO list due to the elimination of that list.

Comment: A large contingent of commenters felt that CMS should extend the exemption indefinitely. Some expressed that 2 years is not enough time for adequate evidence and research to be conducted to demonstrate that procedures removed from the IPO list can be performed safely for Medicare beneficiaries in hospital outpatient settings. As such, they commented that CMS should extend the medical review exemption period until such evidence is widely available and there is data indicating that the procedure removed from the IPO list is more commonly performed on an outpatient basis. One commenter specified that procedures that have an average length of stay of 2 days or more or are performed on an inpatient basis more than a threshold percentage of the time (for example, 70 or more percent) should be exempted from the medical review activities outlined earlier in this section. Another commenter noted that procedures should be removed from exemption from medical review under the 2-Midnight rule as medical technology practice changes, inpatient length of stay declines, and procedures become more commonly performed on an outpatient basis. Another commenter suggested that CMS should use claims data from several payers (that is, Medicare, commercial payers, Veterans Affairs hospitals, etc.) in order to determine when procedures removed from the IPO list are routinely and safely performed in the outpatient setting and no longer require an indefinite exemption.

Most commenters that suggested the indefinite exemption stressed it was appropriate because even with the elimination of the IPO list it will still be medically necessary for a large number of these procedures to be performed in the inpatient setting. A commenter stated that applying the 2-Midnight rule to some of these procedures was not practical, as they are either exclusively performed on an inpatient basis or have an average length of stay of two days or longer. Another commenter noted that complex medical decisions are not always straightforward, and while CMS claims its intent is to defer to physician judgement on the appropriate site-of-service, this deference is not always incentivized during medical reviews and thus reflected in the RAC's review practices. Many commenters were concerned about the compliance burden on hospitals and health care providers as they seek to navigate providing care in the appropriate setting while balancing 2-Midnight enforcement.

Response: We agree with the commenters' suggestions that an indefinite exemption period is appropriate. Further, we are convinced that the medical review exemption should apply until evidence is widely available and there is data indicating that the procedure removed from the IPO list is more commonly performed on an outpatient basis. Accordingly, we are finalizing an indefinite exemption from the specified medical review activities for procedures removed from the IPO list as a result of the elimination of that list. This exemption will apply to each procedure until such time as the procedure is more commonly performed on an outpatient basis. We will use Medicare claims data to determine when a procedure is more commonly performed on an outpatient basis. We will compare on a yearly basis the number of times a given procedure is performed inpatient versus outpatient. We will define ''more commonly performed'' as being done more than fifty percent of the time in the outpatient setting. As with the 2-Midnight presumption, we will still maintain the ability to conduct medical reviews where there is evidence of systemic fraud or abuse.

We would like to emphasize that the 2-Midnight rule does not prohibit procedures from being performed or billed on an inpatient basis. Whether a procedure has an exemption or not, does not change what site-of-service is medically necessary or appropriate for an individual beneficiary. Providers are still expected to bill in compliance with the 2-Midnight rule. The exemption is not from the 2-Midnight rule but from certain medical review procedures and certain site-of-service claim denials. We do not believe that there will be any significant additional burden in complying with the 2-Midnight rule. It is standard practice for providers to sufficiently document medically necessity in medical records. Providers are expected to do this whether the 2-Midnight rule or any associated exemption applies or not.

Comment: Commenters suggested that CMS could reevaluate the exemption once there is sufficient data indicating that the procedure is being more commonly performed in the outpatient setting. One commenter recommended that CMS only remove the exemption once sufficient evidence exists that the procedure is being performed routinely and safely in the outpatient setting, which they believed is unlikely to develop within two years. They added that without an extension of the exemption period providers might not receive payment for care for inpatient settings even when it is the appropriate site of care. Many commenters stated that ending the exemption too early could create pressure on providers to perform a medical service in the outpatient setting despite medical judgement suggesting otherwise.

Response: We agree with commenters and will be finalizing a policy that indefinitely extends the exemption for all procedures removed from the IPO list after January 1, 2021. We will consider removing the exemption for a procedure once we have claims data that indicates it is being performed more in the outpatient setting than the inpatient setting. We do not agree with commenters that the exemption, whether it be indefinite, shorter or longer would create any hindrance to providers receiving the appropriate payment for care in the inpatient setting when the documentation in the medical record supports the inpatient setting as the appropriate site of care. In such a scenario, the claim would generally be payable under Part A pursuant to either the 2-Midnight rule at 42 CFR. 412.3(d)(1) or the case-by-case exception at § 412.3(d)(3). We also believe it is important for CMS to be able to continue to conduct medical reviews in situations in which there is evidence of systemic fraud or abuse.

Comment: We received comments suggesting that CMS establish a list of procedures that would be exempt from medical review under the 2-Midnight rule permanently. One commenter suggested that CMS provide an explicit exception to the 2-Midnight rule for procedures that are removed from the IPO list where the beneficiary is at higher risk as identified by factors such as age, dual-eligible status, presence of certain comorbidities, social factors,

environmental factors, and patient body mass index. Another commenter stated that certain procedures with high average length of stay, such as organ transplants, are likely to never be performed outpatient absent significant improvements in technology. They added that, based on criteria similar to that of the current IPO list, CMS could use average length of stay information and site-of-service patterns to determine whether the exemption would continue for a given procedure and deference provided to the physician.

Response: We thank the commenters for their suggestions and will consider additional metrics for determining whether a procedure requires a 2-Midnight medical review exemption in the future.

Comment: We received many comments suggesting that if the elimination of the IPO list is being driven by the belief that the physician should determine the correct level of care based upon individual patient needs and comorbidities and the physician certifies this need, these level of care audits should be discontinued. Many commenters felt that physicians should be able to select the appropriate site-of-service without having that decision questioned by subjecting the procedure to medical review for site-of-service under the 2-Midnight rule. Some commenters expressed that site-of-service claim denials, BFCC–QIO referrals to RACs, and RAC reviews for ''patient status'' (that is, site-of-service) constituted a barrier to payment for procedures performed in the inpatient setting. Moreover, if site-of-service determinations are based on a physician's clinical judgment regarding the care setting that is best suited to meet a given patient's medical needs that decision should not be subject to any review.

Response: As stated earlier in this section, we continue to believe that use of the 2-Midnight benchmark gives appropriate consideration to the medical judgment of physicians and furthers the goal of clearly identifying when an inpatient admission is appropriate for payment under Medicare Part A. More specifically, as we described in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50943 through 50954), factors such as the procedures being performed and the beneficiary's condition and comorbidities apply when the physician formulates his or her expectation regarding the need for hospital care, while the determination of whether an admission is appropriately billed and paid under Medicare Part A or Part B is generally based upon the physician's medical judgment regarding the beneficiary's expected length of stay. We have not identified any circumstances where the 2-Midnight benchmark restricts the physician to a specific pattern of care, because the 2-Midnight benchmark does not prevent the physician from ordering or providing any service at any hospital, regardless of the expected duration of the service. Rather, this policy provides guidance on when the hospitalized beneficiary's care is appropriate for coverage and payment under Medicare Part A as an inpatient, and when the beneficiary's care is reasonable and necessary for payment under Medicare Part B as an outpatient. Further, as we stated in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70545), section 1154(a)(1) of the Act authorizes BFCC–QIOs to review whether services and items billed under Medicare are reasonable and medically necessary and whether services that are provided on an inpatient basis could be appropriately and effectively provided on an outpatient basis.

BFCC–QIOs will continue to conduct initial medical reviews for both the medical necessity of the services, and the medical necessity of the site-of-service. BFCC–QIOs will continue to be permitted and expected to deny claims if the service itself is determined not to be reasonable and medically necessary. For procedures removed from the IPO list on or after January 1, 2021, BFCC–QIOs will not make referrals to RACs for noncompliance with the 2-Midnight rule for such procedures until the procedure is no longer subject to the medical review exemption because it is more commonly performed in the outpatient setting then the inpatient setting. RACs will not conduct reviews for ''patient status'' (that is, site-of-service) for procedures that are removed from the IPO list until they are no longer subject to the medical review exemption, and claims for procedures that are removed from the IPO list that are identified as noncompliant with the 2-Midnight rule will not be denied with respect to the site-of-service under Medicare Part A until they are no longer subject to the medical review exemption. Providers are still expected to bill in compliance with the 2-Midnight rule even if the procedure is exempt from medical review activities. The BFCC–QIOs will continue to review claims and provide education when providers submit noncompliant claims, despite the fact that they will not be denying such claims during the exemption period. CMS may also still conduct medical review where there is evidence of systemic fraud or abuse.

We continue to believe that the 2-Midnight rule plays a useful role in providing clarity to hospitals and physicians while addressing the program integrity concerns surrounding appropriate inpatient admissions. We believe that extending the exemption while providing education to providers when they submit noncompliant claims will alleviate providers' concerns about adjusting to new procedures being subject to the 2-Midnight rule.

Comment: Some commenters approached the policy concerns more broadly and implored CMS to reevaluate the meaningfulness of the 2-Midnight rule considering the agency's shift toward site-neutrality. A few commenters went as far to suggest that CMS rescind the 2-Midnight rule in its entirety.

Response: We thank the commenters for their suggestions, but note that they are outside the scope of the proposed rule. Moreover, we believe that with more choices in site-of-service the 2-Midnight rule continues to be meaningful and necessary. It continues to be important to determine whether an inpatient admission is appropriate for Medicare Part A payment. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50913 through 50954), in which we clarified our policy regarding when an inpatient admission is considered reasonable and necessary for purposes of Medicare Part A payment. Eliminating the IPO list does not change the agency's stance on the 2-Midnight rule.

Comment: Some commenters expressed concern that the elimination of the IPO list along with the continued application of the 2-Midnight rule would increase paperwork and administrative burden. Commenters were particularly concerned about the documentation required when a patient is admitted for a short stay to undergo a procedure that should only be performed on an inpatient basis. Many commenters were concerned that the burden will fall on physicians to provide appropriate documentation for Part A payment when the physician determines that it is medically reasonable and necessary to conduct these procedures on an inpatient basis. Commenters stressed that subjecting these procedures to the 2-Midnight rule would significantly increase provider documentation burden, which is counter to CMS' recent stated efforts to reduce physicians' administrative burden. Many commenters felt that subjecting additional procedures to the 2-Midnight rule would result in increased documentation and audit

burden, both of which would increase the administrative cost of procedures.

Response: The decision to eliminate the IPO list is based upon CMS's determination that it is no longer appropriate to categorically specify that Medicare only pays for certain procedures when they are performed in an inpatient hospital setting. Instead, as with other procedures, the determination of the appropriate site-of-service is a complex medical decision to be made on a case-by-case basis. We continue to expect providers and physicians to document the medical necessity of any inpatient admission.

We believe that exempting procedures that are removed from the IPO list from site-of-service claim denials under Medicare Part A, eligibility for BFCC–QIO referrals to RACs for noncompliance with the 2-Midnight rule, and RAC reviews for ''patient status'' (that is, site-of-service) until the procedure is more commonly performed in the outpatient setting then the inpatient setting will give providers the requisite time to adjust to any additional changes associated with the elimination of the IPO list. As we indicated in the CY 2016 OPPS/ASC Final Rule (80 FR 70543), we believe that the documentation requirements for admitting physicians are not overly burdensome because they are consistent with Medicare's longstanding documentation requirements, which predate the adoption of the 2-Midnight rule.

Comment: We heard from many commenters that CMS has an essential role to play in the education of stakeholders on the 2-Midnight rule, its exceptions, and outpatient selection criteria. Some commenters felt that not enough providers are aware that CMS policy allows for case-by-case exceptions to the 2-Midnight rule based on patient history, co-morbidities and risk of adverse events. Many commenters requested that CMS provide additional education on the case-by-case exceptions to the 2-Midnight rule. One commenter felt that such education would help ensure that concerns about audits are not unduly influencing the selection of an outpatient setting unless it is medically appropriate. One commenter specifically requested that CMS issue educational guidance to providers and Medicare contractors, similar to MLN Matters articles, reinforcing that surgeons determine whether a particular procedure should be performed on an inpatient or outpatient basis, and there is no presumption that procedures should be performed on an outpatient basis. Other commenters felt that providing hospitals and clinicians with clear and consistent standards against which they can perform will alleviate some of the administrative and financial burden otherwise associated with this kind of substantial policy overhaul.

Response: We understand the importance of education and guidance when implementing policy changes. Therefore, in the future, we plan to provide considerations for the selection of site-of-service for a procedure to support physicians' decision-making. We note that these guidelines will be for informational or educational purposes only and will not be intended to prohibit payment of procedures that were previously included on the IPO list in the outpatient setting.

CMS is finalizing a policy to exempt procedures removed from the IPO list as part of its elimination from certain medical review activities associated with the 2-Midnight rule. As noted previously, however, these procedures are not an exception to the 2-Midnight rule. Providers are still expected to comply with the 2-Midnight rule even if the procedure is exempt from medical review activities. The BFCC–QIOs will continue to review claims and provide education when providers submit noncompliant claims, despite the fact that they will not be denying such claims during the exemption period. This is different from the case-by-case exceptions to the 2-Midnight benchmark, whereby Medicare Part A payment may be made for inpatient admissions where the admitting physician does not expect the patient to require hospital care spanning 2-Midnights, if the documentation in the medical record supports the physician's determination that the patient nonetheless requires inpatient hospital care.

Comment: Numerous commenters were concerned about how the Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC–QIOs) and Recovery Audit Contractors (RACs) would handle the rapid influx of procedures now subject to review. Many commenters felt that it was essential for CMS to begin outreach to the BFCC–QIOs to ensure that best practices for audits and education to providers regarding compliance with short-stay admission policies are universally adopted and communicated prior to the start of CY 2021. Commenters further asserted that this will help mitigate some of the administrative burden for outpatient hospitals and surgeons performing services previously flagged as inpatient-only procedures. One commenter noted that BFCC–QIOs contract awards are being delayed by vendor protests. They were concerned that few hospitals have actually had the opportunity to engage with the BFCC–QIOs to review cases recently removed from the IPO list, such as TKAs and THAs. They felt it will be important to ensure that these discussion sessions can occur so that the exemption can serve its intended purpose.

Response: We understand commenters' concerns and will work with the BFCC–QIOs as appropriate to address any issues as they arise. The BFCC–QIOs will continue to review claims even while procedures are exempt from denial based on site-of-service in order to provide education for practitioners and providers regarding compliance with the 2-Midnight rule.

We appreciate the stakeholders' feedback regarding the appropriate period of time for this exemption. After considering the concerns, suggestions, and recommendations from commenters, we have decided to finalize our proposal with modifications. Instead of the 2-year exemption, procedures removed from the IPO list on or after January 1, 2021 will be indefinitely exempted from site-of-service claim denials under Medicare Part A, eligibility for BFCC–QIO referrals to RACs for noncompliance with the 2-Midnight rule, and RAC reviews for ''patient status'' (that is, site-of-service) indefinitely, until the procedure is more commonly performed in the outpatient setting then the inpatient setting. As a result, in order for the exemption to end for a specific procedure, we will require claims data for the service indicating that the procedure is performed more commonly on an outpatient rather than inpatient basis in a given year. Thus, for the exemption to end for a specific procedure, in a single calendar year we would need to have Medicare claims data indicating that procedure was performed more than 50 percent of the time in the outpatient setting. We will revisit in rulemaking whether and when an exemption for a procedure should be ended. Thus, for each procedure removed from the IPO list on or after January 1, 2021, the exemption will continue until terminated in future rulemaking. We may consider additional metrics in the future that could assist us in determining when the exemption period should end for a procedure. This will only apply to procedures removed from the IPO list beginning in CY 2021. We may revisit procedures that were removed from the IPO list prior to January 1, 2021 and extend their exemption if we deem it necessary. Conversely, we may shorten

the exemption period for a procedure if necessary. In the future, we may examine the exemption status of any procedure that was formerly on the IPO list and lengthen, shorten or end their exemption.

As we stated earlier, procedures removed from the IPO list in prior years were targeted and selected in small numbers. In those cases, 2-years was an appropriate time frame to allow providers to become more comfortable with how to comply with the 2-Midnight rule. Eliminating the IPO list is a larger scale change that creates brand new considerations in determining site-of-service for providers and beneficiaries. This is a significant change, and based upon feedback from commenters, we have reevaluated our stance on the exemption period for procedures removed from the IPO list. We now feel that the magnitude of this change calls for an indefinite exemption, with CMS reevaluating that exemption once procedures are more commonly performed in the outpatient setting.

We agree with the commenters who suggested that an indefinite exemption period from certain medical review activities for procedures removed from the IPO list would be necessary to allow providers to become more familiar with how to comply with the 2-Midnight rule. The indefinite exemption will help hospitals and clinicians become used to the availability of payment under both the hospital inpatient and outpatient setting for procedures removed from the IPO list. Further, we are persuaded by the comments asserting that an indefinite exemption period will allow providers time to gather information on procedures newly removed from the IPO list to help inform education and guidance for the broader provider community, develop patient selection criteria to identify which patients are, and are not, appropriate candidates for outpatient procedures, and to develop related policy protocols. We also believe that an extended exemption period will further facilitate compliance with our payment policy for inpatient admissions.

We believe that extending the exemption period until procedures are more commonly performed in the outpatient setting than the inpatient setting will let providers comfortably gain experience with the application of the 2-Midnight rule to these procedures. While these procedures will be exempt from certain medical review activities related to the 2-Midnight rule, providers are not excepted from compliance with the 2-Midnight rule. That is an important distinction. As we stated earlier, providers are still expected to bill in compliance with the 2-Midnight rule. It is standard practice that the factors supporting the determination that inpatient care is required will be documented in the medical records. The BFCC–QIOs will still have the opportunity to review claims for exempt procedures in order to provide education for practitioners and providers regarding compliance with the 2-Midnight rule, but claims identified as noncompliant will not be denied with respect to the site-of-service under Medicare Part A until the procedure is no longer subject to the exemption. We believe that the longer exemption from the medical review for procedures removed from the IPO list will give providers and BFCC–QIOs time to understand the documentation necessary to support Part A payment for those patients for which the admitting physician determines that the procedures should be furnished in an inpatient setting.

Additionally, CMS may still conduct medical review in cases in which there is evidence of systemic fraud or abuse occurring. Finally, we are amending 42 CFR 412.3 to clarify when a procedure removed from the IPO is exempt from certain medical review activities. For those services and procedures removed between January 1 and December 31, 2020, this exemption will last for 2 years from the date of such removal. For those services and procedures removed on or after January 1, 2021, this exemption will last until the Secretary determines that the service or procedure is more commonly performed in the outpatient setting.

XI. CY 2021 OPPS Payment Status and Comment Indicators

A. CY 2021 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system, and also whether particular OPPS policies apply to the code.

For CY 2021, we did not propose to make any changes to the existing definitions of status indicators that were listed in Addendum D1 to the CY 2020 OPPS/ASC final rule with comment period available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*.

We did not receive any public comments on the proposed definitions of the OPPS status indicators for CY 2021. We believe that the existing definitions of the OPPS status indicators will continue to be appropriate for CY 2021. Therefore, we are finalizing our proposed policy without modifications.

The complete list of the payment status indicators and their definitions that would apply for CY 2021 is displayed in Addendum D1 to the CY 2021 OPPS/ASC final rule with comment period, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

CY 2021 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to the CY 2021 OPPS/ASC final rule with comment period, which are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

B. CY 2021 OPPS Comment Indicator Definitions

In the CY 2021 OPPS/ASC proposed rule, we proposed to use four comment indicators for the CY 2021 OPPS. These comment indicators, ''CH'', ''NC'', ''NI'', and ''NP'', are in effect for CY 2020 and we proposed to continue their use in CY 2021. The CY 2021 OPPS comment indicators are as follows:

- ''CH''—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.
- ''NC''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year for which we requested comments in the proposed rule, final APC assignment; comments will *not* be accepted on the final APC assignment for the new code.
- ''NI''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.
- ''NP''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, proposed APC assignment; comments

will be accepted on the proposed APC assignment for the new code.

The definitions of the OPPS comment indicators for CY 2021 are listed in Addendum D2 to the CY 2021 OPPS/ASC final rule with comment period, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

We did not receive any public comments on the proposed definitions of the OPPS comment indicators for CY 2021.

We believe that the existing CY 2020 definitions of the OPPS comment indicators continue to be appropriate for CY 2021. Therefore, we are using those definitions without modification for CY 2021.

XII. MedPAC Recommendations

The Medicare Payment Advisory Commission (MedPAC) was established under section 1805 of the Act in large part to advise the U.S. Congress on issues affecting the Medicare program. As required under the statute, MedPAC submits reports to the Congress no later than March and June of each year that present its Medicare payment policy recommendations. The March report typically provides discussion of Medicare payment policy across different payment systems and the June report typically discusses selected Medicare issues. We are including this section to make stakeholders aware of certain MedPAC recommendations for the OPPS and ASC payment systems as discussed in its March 2020 report.

A. OPPS Payment Rates Update

The March 2020 MedPAC ''Report to the Congress: Medicare Payment Policy,'' recommended that Congress update Medicare OPPS payment rates by 2 percent, with the difference between this and the update amount specified in current law to be used to increase payments in a new suggested Medicare quality program, the ''Hospital Value Incentive Program (HVIP).'' We refer readers to the March 2020 report for a complete discussion of these recommendations.[101] We appreciate MedPAC's recommendations, but as MedPAC acknowledged in its March 2020 report, the Congress would need to change current law to enable us to implement its recommendations. Comments received from MedPAC for other OPPS policies are discussed in the applicable sections of this rule.

B. ASC Conversion Factor Update

In the March 2020 MedPAC ''Report to the Congress: Medicare Payment Policy,'' MedPAC found that, based on its analysis of indicators of payment adequacy, the number of ASCs had increased, beneficiaries' use of ASCs had increased, and ASC access to capital has been adequate.[102] As a result, for CY 2021, MedPAC stated that payments to ASCs are adequate and recommended that in the absence of cost report data no payment update should be given for CY 2021 (that is, the update factor would be zero percent).

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59079), we adopted a policy, which we codified at 42 CFR 416.171(a)(2), to apply the MFP-adjusted hospital market basket update to ASC payment system rates for an interim period of 5 years. We refer readers to the CY 2019 OPPS/ASC final rule with comment period for complete details regarding our policy to use the MFP-adjusted hospital market basket update for the ASC payment system for CY 2019 through CY 2023. Therefore, consistent with our policy for the ASC payment system, as discussed in section XIII.G. of the CY 2021 OPPS/ASC proposed rule, we proposed to apply the MFP-adjusted hospital market basket update factor to the CY 2020 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2021 ASC payment amounts.

C. ASC Cost Data

In the March 2020 MedPAC ''Report to the Congress: Medicare Payment Policy,'' MedPAC recommended that Congress require ASCs to report cost data to enable the Commission to examine the growth of ASCs' costs over time and analyze Medicare payments relative to the costs of efficient providers, and that CMS could use ASC cost data to examine whether an existing Medicare price index is an appropriate proxy for ASC costs or an ASC specific market basket should be developed. Further, MedPAC suggested that CMS could limit the scope of the cost reporting system to minimize administrative burden on ASCs and the program.[103]

We recognize that the submission of cost data could place additional administrative burden on most ASCs. We are interested in methods that would mitigate the burden of reporting costs on ASCs while also collecting enough data to reliably use such data in the determination of ASC costs. We did not propose any cost reporting requirements for ASCs in the CY 2021 OPPS/ASC proposed rule.

Comments received from MedPAC for other ASC payment system policies are discussed in the applicable sections of this rule. The full March 2020 MedPAC Report to Congress can be downloaded from MedPAC's website at: *http://www.medpac.gov.*

XIII. Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background

1. Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

For a detailed discussion of the legislative history and statutory authority related to payments to ASCs under Medicare, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74377 through 74378) and the June 12, 1998 proposed rule (63 FR 32291 through 32292). For a discussion of prior rulemaking on the ASC payment system, we refer readers to the CYs 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019 and 2020 OPPS/ASC final rules with comment period (76 FR 74378 through 74379; 77 FR 68434 through 68467; 78 FR 75064 through 75090; 79 FR 66915 through 66940; 80 FR 70474 through 70502; 81 FR 79732 through 79753; 82 FR 59401 through 59424; 83 FR 59028 through 59080, and 84 FR 61370 through 61410, respectively).

2. Policies Governing Changes to the Lists of Codes and Payment Rates for ASC Covered Surgical Procedures and Covered Ancillary Services

Under 42 CFR 416.2 and 416.166 of the Medicare regulations, subject to certain exclusions, covered surgical procedures in an ASC are surgical procedures that are separately paid under the OPPS, that would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the

[101] Medicare Payment Advisory Committee. March 2020 Report to the Congress. Chapter 5: Ambulatory surgical center services, pp.94–95. Available at: *http://www.medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf?sfvrsn=0.*

[102] Medicare Payment Advisory Committee. March 2020 Report to the Congress. Chapter 5: Ambulatory surgical center services, p.147. Available at: *http://www.medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf?sfvrsn=0.*

[103] Medicare Payment Advisory Committee. March 2020 Report to the Congress. Chapter 5: Ambulatory surgical center services. Available at: *http://www.medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf?sfvrsn=0.*

procedure (''overnight stay''). We adopted this standard for defining which surgical procedures are covered under the ASC payment system as an indicator of the complexity of the procedure and its appropriateness for Medicare payment in ASCs. We use this standard only for purposes of evaluating procedures to determine whether or not they are appropriate to be furnished to Medicare beneficiaries in ASCs. As discussed in detail in Section XIII.C.1.d of this final rule with comment period, we are finalizing changes to the way procedures are added to the CPL.

Historically, we have defined surgical procedures as those described by Category I CPT codes in the surgical range from 10000 through 69999 as well as those Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined do not pose a significant safety risk, that we would not expect to require an overnight stay when performed in ASCs, and that are separately paid under the OPPS (72 FR 42478).

In the August 2, 2007 final rule (72 FR 42495), we also established our policy to make separate ASC payments for the following ancillary items and services when they are provided integral to ASC covered surgical procedures: (1) Brachytherapy sources; (2) certain implantable items that have pass-through payment status under the OPPS; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPS; and (5) certain radiology services for which separate payment is allowed under the OPPS. In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66932 through 66934), we expanded the scope of ASC covered ancillary services to include certain diagnostic tests within the medicine range of Current Procedural Terminology (CPT) codes for which separate payment is allowed under the OPPS when they are provided integral to an ASC covered surgical procedure. Covered ancillary services are specified in 42 CFR 416.164(b) and, as stated previously, are eligible for separate ASC payment. Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

We update the lists of, and payment rates for, covered surgical procedures and covered ancillary services in ASCs in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment system (42 CFR 416.173; 72 FR 42535). We base ASC payment and policies for most covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies, and we use quarterly change requests (CRs) to update services covered under the OPPS. We also provide quarterly update CRs for ASC covered surgical procedures and covered ancillary services throughout the year (January, April, July, and October). We release new and revised Level II HCPCS codes and recognize the release of new and revised CPT codes by the American Medical Association (AMA) and make these codes effective (that is, the codes are recognized on Medicare claims) via these ASC quarterly update CRs. We recognize the release of new and revised Category III CPT codes in the July and January CRs. These updates implement newly created and revised Level II HCPCS and Category III CPT codes for ASC payments and update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New and revised Category I CPT codes, except vaccine codes, are released only once a year, and are implemented only through the January quarterly CR update. New and revised Category I CPT vaccine codes are released twice a year and are implemented through the January and July quarterly CR updates. We refer readers to Table 41 in the CY 2012 OPPS/ASC proposed rule for an example of how this process is used to update HCPCS and CPT codes, which we finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 42291; 76 FR 74380 through 74384).

In our annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures, new codes, and codes with revised descriptors, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of ASC covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of many covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

3. Definition of ASC Covered Surgical Procedures

Since the implementation of the ASC prospective payment system, we have historically defined a ''surgical'' procedure under the payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the AMA defines as ''surgery'' (CPT codes 10000 through 69999) (72 FR 42478). We also have included as ''surgical,'' procedures that are described by Level II HCPCS codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined do not pose a significant safety risk, would not expect to require an overnight stay when performed in an ASC, and that are separately paid under the OPPS (72 FR 42478).

As we noted in the August 7, 2007 final rule that implemented the revised ASC payment system, using this definition of surgery would exclude from ASC payment certain invasive, ''surgery-like'' procedures, such as cardiac catheterization or certain radiation treatment services that are assigned codes outside the CPT surgical range (72 FR 42477). We stated in that final rule that we believed continuing to rely on the CPT definition of surgery is administratively straightforward, is logically related to the categorization of services by physician experts who both establish the codes and perform the procedures, and is consistent with a policy to allow ASC payment for all outpatient surgical procedures.

However, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59029 through 59030), after consideration of public comments received in response to the CY 2019 OPPS/ASC proposed rule and earlier OPPS/ASC rulemaking cycles, we revised our definition of a surgical procedure under the ASC payment system. We now define a surgical procedure under the ASC payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the AMA defines as ''surgery'' (CPT codes 10000 through 69999) (72 FR 42476), as well as procedures that are described by Level II HCPCS codes or by Category I CPT codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we have determined are not expected to pose a significant risk to beneficiary safety when performed in an ASC, for which

standard medical practice dictates that the beneficiary would not typically be expected to require an overnight stay following the procedure, and are separately paid under the OPPS.

B. ASC Treatment of New and Revised Codes

1. Background on Current Process for Recognizing New and Revised HCPCS Codes

Payment for ASC procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on ASC claims. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system maintained by the American Medical Association (AMA), and includes Category I, II, and III CPT codes. Level II of the HCPCS, which is maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. Together, Level I and II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims:

- Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes (also known as alpha-numeric codes), which are used primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 final rule (72 FR 42533 through 42535) to evaluate each year all new and revised Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures. In addition, we identify new and revised codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. In prior rulemakings, we refer to this process as recognizing new codes. However, this process has always involved the recognition of new and revised codes. We consider revised codes to be new when they have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator. To clarify, we refer to these codes as new and revised in this CY 2021 OPPS/ASC proposed rule.

We have separated our discussion below based on when the codes are released and whether we proposed to solicit public comments in the CY 2021 OPPS/ASC proposed rule (and respond to those comments in this final rule with comment period) or whether we are soliciting public comments in this final rule with comment period (and responding to those comments in the CY 2022 OPPS/ASC final rule with comment period).

We note that we sought public comments in the CY 2020 OPPS/ASC final rule with comment period (84 FR 62375) on the new and revised Level II HCPCS codes effective October 1, 2019 or January 1, 2020. These new and revised codes were flagged with comment indicator ''NI'' in Addenda AA and BB to the CY 2020 OPPS/ASC final rule with comment period to indicate that we were assigning them an interim payment status and payment rate, if applicable, which were subject to public comment following publication of the CY 2020 OPPS/ASC final rule with comment period. In the CY 2021 OPPS/ASC proposed rule, we stated that we will finalize the treatment of these codes under the ASC payment system in this CY 2021 OPPS/ASC final rule with comment period.

2. April 2020 HCPCS Codes for Which We Solicited Public Comments in the Proposed Rule

For the April 2020 update, there were no new CPT codes, however, there were several new Level II HCPCS codes. In the April 2020 ASC quarterly update (Transmittal 10046, CR 11694, dated April 13, 2020), we added four new Level II HCPCS codes to the list of covered ancillary services. Table 32 of the CY 2021 OPPS/ASC proposed rule displayed the new Level II HCPCS codes that were implemented on April 1, 2020, along with their proposed payment indicators for CY 2021.

We invited public comments on the proposed payment indicators and payment rates for the new HCPCS codes that were recognized as ASC ancillary services in April 2020 through the quarterly update CRs, as listed in Table 32 of the CY 2021 OPPS/ASC proposed rule. We proposed to finalize their payment indicators in this CY 2021 OPPS/ASC final rule with comment period.

We did not receive any public comments on the proposed ASC payment indicator assignments for the new Level II HCPCS codes implemented in April 2020. Therefore, we are finalizing the proposed ASC payment indicator assignments for these codes, as indicated in Table 49 below. We note that several of the temporary drug HCPCS C-codes have been replaced with permanent drug HCPCS J-codes, effective January 1, 2021. Their replacement codes are also listed in Table 49. The final payment rates for these codes can be found in Addendum BB to this final rule with comment period (which is available via the internet on the CMS website). In addition, the status indicator meanings can be found in Addendum DD1 to this final rule with comment period (which is available via the internet on the CMS website).

TABLE 49.—NEW LEVEL II HCPCS CODES FOR ANCILLARY SERVICES EFFECTIVE ON APRIL 1, 2020

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 PI
C9053*	J0791	Injection, crizanlizumab-tmca, 5 mg	K2
C9056**	J0223	Injection, givosiran, 0.5 mg	K2
C9057#	J1201	Injection, cetirizine hydrochloride, 0.5 mg	K2
C9058##	Q5120	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg	K2

*HCPCS code C9053, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J0791 (Injection, crizanlizumab-tmca, 5 mg) effective July 1, 2020.

**HCPCS code C9056, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J0223 (Injection, givosiran, 0.5 mg) effective July 1, 2020.

#HCPCS code C9057, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code J1201 (Injection, cetirizine hydrochloride, 0.5 mg) effective July 1, 2020.

##HCPCS code C9058, which was effective April 1, 2020, was deleted June 30, 2020 and replaced with HCPCS code Q5120 (Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg) effective July 1, 2020.

3. July 2020 HCPCS Codes for Which We Solicited Public Comments in the Proposed Rule

In the July 2020 ASC quarterly update (Transmittal 10188, Change Request 11842, dated June 19, 2020), we added several separately payable Category III CPT and Level II HCPCS codes to the list of covered surgical procedures and ancillary services. Table 33 of the CY 2020 OPPS/ASC proposed rule displayed the new HCPCS codes that were effective July 1, 2020.

In addition, through the July 2020 quarterly update CR, we also implemented ASC payments for two new Category III CPT codes as ASC covered ancillary services, effective July 1, 2020. These codes were listed in Table 34 of the CY 2020 OPPS/ASC proposed rule, along with the proposed comment indicator and payment indicator.

We invited public comments on these proposed payment indicators for the new Category III CPT code and Level II HCPCS codes newly recognized as ASC covered surgical procedures or covered ancillary services in July 2020 through the quarterly update CRs, as listed in Tables 32, 33, and 34 of the proposed rule.

We did not receive any public comments on the proposed ASC payment indicator assignments for the new Category III CPT codes or Level II HCPCS codes implemented in July 2020. Therefore, we are finalizing the proposed ASC payment indicator assignments for these codes, as indicated in Table 50 and 51 below. We note that several of the HCPCS C-codes have been replaced with HCPCS J-codes, effective January 1, 2021. Their replacement codes are listed in Table 50. The final payment rates for these codes can be found in Addendum AA and BB to this final rule with comment period (which is available via the internet on the CMS website). In addition, the status indicator meanings can be found in Addendum DD1 to this final rule with comment period (which is available via the internet on the CMS website).

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TABLE 50.—NEW LEVEL II HCPCS CODES FOR COVERED SURGICAL PROCEDURES AND ANCILLARY SERVICES EFFECTIVE ON JULY 1, 2020

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 PI
C1748	C1748	Endoscope, single-use (that is, disposable), upper GI, imaging/illumination device (insertable)	J7
C1849	C1849	Skin substitute, synthetic, resorbable, per square centimeter	N1
C9059	J1738	Injection, meloxicam, 1 mg	K2
C9061	J3241	Injection, teprotumumab-trbw, 10 mg	K2
C9063	J3032	Injection, eptinezumab-jjmr, 1 mg	K2
C9122	C9122	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	K2
C9759	C9759	Transcatheter intraoperative blood vessel microinfusion(s) (for example, intraluminal, vascular wall and/or perivascular) therapy, any vessel, including radiological supervision and interpretation, when performed	N1
C9762	C9762	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with strain imaging	Z2
C9763	C9763	Cardiac magnetic resonance imaging for morphology and function, quantification of segmental dysfunction; with stress imaging	Z2

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 PI
C9764	C9764	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed	G2
C9765	C9765	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed	J8
C9766	C9766	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed	G2
C9767	C9767	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel (s), when performed	J8
G2170*	G2170*	Percutaneous arteriovenous fistula creation (AVF), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (for example, transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed	G2
G2171**	G2171**	Percutaneous arteriovenous fistula creation (AVF), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (for example, vascular coil embolization with radiologic supervision and interpretation, wen performed) and fistulogram(s), angiography, enography, and/or ultrasound, with radiologic supervision and interpretation, when performed	J8
J0223	J0223	Injection, givosiran, 0.5 mg	K2
J0691	J0691	Injection, lefamulin, 1 mg	K2
J0742	J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	K2
J0791	J0791	Injection, crizanlizumab-tmca, 5 mg	K2
J0896	J0896	Injection, luspatercept-aamt, 0.25 mg	K2
J1201	J1201	Injection, cetirizine hydrochloride, 0.5 mg	K2
J1429	J1429	Injection, golodirsen, 10 mg	K2
J1558	J1558	Injection, immune globulin (Xembify), 100 mg	K2

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 PI
J7169	J7169	Injection, coagulation factor Xa (recombinant), inactivated-zhzo (Andexxa), 10 mg	K2
J7204	J7204	Injection, factor VIII, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per iu	K2
J7333	J7333	Hyaluronan or derivative, visco-3, for intraarticular injection, per dose	N1
J9177	J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	K2
J9198	J9198	Gemcitabine hydrochloride, (Infugem), 100 mg	K2
J9246	J9246	Injection, melphalan (evomela), 1 mg	K2
J9358	J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	K2
Q4227#	Q4227#	Amniocore, per square centimeter	N1
Q4228#	Q4228#	BioNextPATCH, per square centimeter	N1
Q4229#	Q4229#	Cogenex amniotic membrane, per square centimeter	N1
Q4230#	Q4230#	Cogenex flowable amnion, per 0.5 cc	N1
Q4231#	Q4231#	Corplex P, per cc.	N1
Q4232#	Q4232#	Corplex, per square centimeter	N1
Q4233#	Q4233#	Surfactor or Nudyn, per 0.5 cc	N1
Q4234#	Q4234#	Xcellerate, per square centimeter	N1
Q4235#	Q4235#	Amniorepair or altiply, per square centimeter	N1
Q4236#	Q4236#	CarePATCH, per square centimeter	N1
Q4237#	Q4237#	Cryo-cord, per square centimeter	N1
Q4238#	Q4238#	Derm-maxx, per square centimeter	N1
Q4239#	Q4239#	Amnio-maxx or Amnio-maxx lite, per square centimeter	N1
Q4240#	Q4240#	Corecyte, for topical use only, per 0.5 cc	N1
Q4241#	Q4241#	Polycyte, for topical use only, per 0.5 cc	N1
Q4242#	Q4242#	Amniocyte plus, per 0.5 cc	N1
Q4244#	Q4244#	Procenta, per 200 mg	N1
Q4245#	Q4245#	Amniotext, per cc	N1
Q4246#	Q4246#	Coretext or Protext, per cc	N1
Q4247#	Q4247#	Amniotext patch, per square centimeter	N1
Q4248#	Q4248#	Dermacyte Amniotic Membrane Allograft, per square centimeter	N1
Q5119	Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	K2
Q5120	Q5120	Injection, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5 mg	K2
0594T	0594T	Osteotomy, humerus, with insertion of an externally controlled intramedullary lengthening device, including intraoperative imaging, initial and subsequent alignment assessments, computations of adjustment schedules, and management of the intramedullary lengthening device	J8

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 PI
0596T	0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement	R2
0597T	0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement	R2
0600T	0600T	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous	J8
0601T	0601T	Ablation, irreversible electroporation; 1 or more tumors, including fluoroscopic and ultrasound guidance, when performed, open	J8
0614T	0614T	Removal and replacement of substernal implantable defibrillator pulse generator	J8
0616T	0616T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens	J8
0617T	0617T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with removal of crystalline lens and insertion of intraocular lens	J8
0618T	0618T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens placement or intraocular lens exchange	J8
0619T	0619T	Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed	J8

*HCPCS code C9754, which was effective January 1, 2019, was deleted June 30, 2020 and replaced with HCPCS code G2170 effective July 1, 2020.

**HCPCS code C9755, which was effective January 1, 2019, was deleted June 30, 2020 and replaced with HCPCS code G2171 effective July 1, 2020.

#HCPCS codes Q4227 through Q4248: The availability of an HCPCS code for a particular human cell, tissue, or cellular or tissue-based product (HCT/P) does not mean that that product is appropriately regulated solely under section 361 of the PHS Act and the FDA regulations in 21 CFR part 1271. Manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.

TABLE 51.—NEW CATEGORY III CPT CODE FOR COVERED ANCILLARY SERVICE EFFECTIVE ON JULY 1, 2020

CY 2020 HCPCS Code	CY 2021 HCPCS Code	CY 2021 Long Descriptor	CY 2021 PI
0598T	0598T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (for example, lower extremity)	Z2
0599T	0599T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; each additional anatomic site (for example, upper extremity) (List separately in addition to code for primary procedure)	N1

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4. October 2020 HCPCS Codes for Which We Are Soliciting Public Comments in This Final Rule With Comment Period

In the past, we released new and revised HCPCS codes that are effective October 1 through the October OPPS quarterly update CRs and incorporated these new codes in the final rule with comment period.

In the CY 2021 OPPS/ASC proposed rule (85 FR 48947), for CY 2021, consistent with our established policy, we proposed that the Level II HCPCS codes that will be effective October 1, 2020 would be flagged with comment indicator ''NI'' in Addendum BB to the CY 2021 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim ASC payment indicator for CY 2021. We did not receive any public comments on our proposal. As we stated in the CY 2021 OPPS/ASC proposed rule, we are inviting public comments in this CY 2021 OPPS/ASC final rule with comment period on the interim ASC payment indicator for these codes that we intend to finalize in the CY 2022 OPPS/ASC final rule with comment period.

5. January 2021 HCPCS Codes

a. Level II HCPCS Codes for Which We Are Soliciting Public Comments in This Final Rule With Comment Period

Consistent with past practice, we are soliciting comments on the new Level II HCPCS codes that are effective January 1, 2021 in the CY 2021 OPPS/ASC final rule with comment period, thereby updating the ASC payment system for the calendar year. These codes are released to the public via the CMS HCPCS website, and also through the January OPPS quarterly update CRs. We note that unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the G-codes listed in Addendum O to the CY 2021 OPPS/ASC proposed rule, most Level II HCPCS codes are not released until November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Therefore, we stated in the CY 2021 OPPS/ASC proposed rule with comment period that the Level II HCPCS codes that will be effective January 1, 2021 would be released to the public through this CY 2021 OPPS/ASC final rule with comment period, January 2021 ASC Update CR, and the CMS HCPCS website (85 FR 48948).

In addition, for CY 2021, we proposed to continue our established policy of assigning comment indicator ''NI'' in Addendum AA and Addendum BB to the CY 2021 OPPS/ASC final rule with comment period to the new Level II HCPCS codes that will be effective January 1, 2021 to indicate that we are assigning them an interim payment indicator, which is subject to public comment. We are inviting public comments in this CY 2021 OPPS/ASC final rule with comment period on the payment indicator assignments, which would then be finalized in the CY 2022 OPPS/ASC final rule with comment period.

b. CPT Codes for Which We Solicited Public Comments in the Proposed Rule

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. Specifically, for the new/revised CPT codes that we receive in a timely manner from the AMA's CPT Editorial Panel, we finalized our proposal to include the codes that would be effective January 1 in the OPPS/ASC proposed rules, along with proposed APC and status indicator assignments for them, and to finalize the APC and status indicator assignments in the OPPS/ASC final rules beginning with the CY 2016 OPPS/ASC final rule. For those new/revised CPT codes that were received too late for inclusion in the OPPS/ASC proposed rule, we finalized our proposal to establish and use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle. We note that even if we find that we need to create HCPCS G-codes in place of certain CPT codes for the PFS proposed rule, we do not anticipate that these HCPCS G-codes will always be necessary for OPPS purposes. We will make every effort to include proposed APC and status indicator assignments for all new and revised CPT codes that the AMA makes publicly available in time for us to include them in the proposed rule, and to avoid the resort to HCPCS G-codes and the resulting delay in utilization of the most current CPT codes. Also, we finalized our proposal to make interim APC and status indicator assignments for CPT codes that are not available in time for the proposed rule and that describe wholly new services (such as new technologies or new surgical procedures), solicit public comments, and finalize the specific APC and status indicator assignments for those codes in the following year's final rule.

For the CY 2021 OPPS update, we received the CPT codes that will be effective January 1, 2021 from AMA in time to be included in the proposed rule. The new, revised, and deleted CPT codes were listed in Addendum AA and Addendum BB to the CY 2021 OPPS/ASC proposed rule. The new and revised CPT codes were assigned to comment indicator ''NP'' in Addendum AA and Addendum BB of the CY 2021 OPPS/ASC proposed rule to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year, along with a proposed ASC payment indicator assignment, and that comments would be accepted on the proposed ASC payment indicator.

Further, we note that the CPT code descriptors that appeared in Addendum AA and BB to the CY 2021 OPPS/ASC proposed rule were short descriptors and did not fully describe the complete procedure, service, or item described by the CPT code. Therefore, we included the 5-digit placeholder codes and the long descriptors for the new and revised CY 2021 CPT codes in Addendum O to the proposed rule so that the public could adequately comment on the proposed ASC payment indicator assignments. The 5-digit placeholder codes were listed in Addendum O, specifically under the column labeled ''CY 2021 OPPS/ASC Proposed Rule 5-Digit AMA Placeholder Code''. The final CPT code numbers are included in this CY 2021 OPPS/ASC final rule with comment period, and can be found in Addendum AA, Addendum BB, and Addendum O.

For new and revised CPT codes effective January 1, 2021 that were received in time to be included in the CY 2021 OPPS/ASC proposed rule, we proposed the appropriate payment indicator assignments, and solicited public comments on the payment assignments. We stated we would accept comments and finalize the payment indicators in this CY 2021 OPPS/ASC final rule with comment period. We received comments on the ASC payment indicators for certain new CPT codes that will be effective January 1, 2021. These comments, and our responses, can be found in section XIII.C. (Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services) of this final rule with comment period.

Also, we note that we inadvertently omitted four new HCPCS codes, specifically, CPT codes 0627T, 0628T, 0629T, and 0630T, effective January 1, 2021 from Addendum AA of the CY 2021 OPPS/ASC proposed rule. The procedures described by the four new HCPCS codes are displayed in Addendum AA of this CY 2021 OPPS/ASC final rule with comment period with comment indicator ''NI'' to indicate that we are assigning them an interim payment indicator, which is subject to public comment. We are inviting public comments on the ASC payment indicators for CPT codes 0627T, 0628T, 0629T, and 0630T, which will be finalized in the CY 2022 OPPS/ASC final rule with comment period.

Finally, shown in Table 35 of the CY 2021 OPPS/ASC proposed rule (85 FR 48949) and reprinted in Table 52 below, we summarize our process for updating codes through our ASC quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the ASC payment system.

TABLE 52.—COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED HCPCS CODES

ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2020	HCPCS (CPT and Level II codes)	April 1, 2020	CY 2021 OPPS/ASC proposed rule	CY 2021 OPPS/ASC final rule with comment period
July 2020	HCPCS (CPT and Level II codes)	July 1, 2020	CY 2021 OPPS/ASC proposed rule	CY 2021 OPPS/ASC final rule with comment period
October 2020	HCPCS (CPT and Level II codes)	October 1, 2020	CY 2021 OPPS/ASC final rule with comment period	CY 2022 OPPS/ASC final rule with comment period
January 2021	CPT Codes	January 1, 2021	CY 2021 OPPS/ASC proposed rule	CY 2021 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2021	CY 2021 OPPS/ASC final rule with comment period	CY 2022 OPPS/ASC final rule with comment period

C. Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services

1. Covered Surgical Procedures

a. Covered Surgical Procedures Designated as Office-Based

(1) Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as ''office-based'' those procedures that are added to the ASC Covered Procedures List (CPL) in CY 2008 or later years that we determine are furnished predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that rule, we also finalized our policy to exempt all procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC CPL beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that rule by payment indicator ''P2'' (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight); ''P3'' (Office-based surgical procedures added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs); or ''R2'' (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated the procedure would be paid according to the standard ASC payment methodology based on its OPPS relative payment weight or at the MPFS nonfacility PE RVU-based amount.

Consistent with our final policy to annually review and update the ASC CPL to include all covered surgical procedures eligible for payment in ASCs, each year we identify covered surgical procedures as either temporarily office-based (these are new procedure codes with little or no utilization data that we have determined are clinically similar to other procedures that are permanently office-based), permanently office-based, or non office-based, after taking into account updated volume and utilization data.

(2) Changes for CY 2021 to Covered Surgical Procedures Designated as Office-Based

In developing the CY 2021 OPPS/ASC proposed rule (85 FR 48949 through 48953), we followed our policy to annually review and update the covered surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment (described in detail in section XIII.C.1.d), including their potential designation as office-based. We reviewed the most recent claims volume and utilization data (CY 2019 claims) and the clinical characteristics for all covered surgical procedures that are currently assigned a payment indicator in CY 2020 of ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight), as well as for those procedures assigned one of the temporary office-based payment

indicators, specifically ''P2'', ''P3'', or ''R2'' in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61376 through 61380).

Our review of the CY 2019 volume and utilization data of covered surgical procedures currently assigned a payment indicator of ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) resulted in our identification of six covered surgical procedures that we believe met the criteria for designation as permanently office-based. The data indicated that these procedures are performed more than 50 percent of the time in physicians' offices, and we believe that the services were of a level of complexity consistent with other procedures performed routinely in physicians' offices. The CPT codes that we proposed to permanently designate as office-based for CY 2021 are listed as Table 53.

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TABLE 53: PROPOSED ASC COVERED SURGICAL PROCEDURES TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2021

CY 2021 CPT Code	CY 2021 Long Descriptor	CY 2020 ASC Payment Indicator	Proposed CY 2021 ASC Payment Indicator*
11760	Repair of nail bed	G2	P3*
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)	J8	P3*
23077	Radical resection of tumor (eg, sarcoma), soft tissue of shoulder area; less than 5 cm	G2	P2*
44408	Colonoscopy through stoma; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed	G2	P2*
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy	G2	P2*
67500	Retrobulbar injection; medication (separate procedure, does not include supply of medication)	G2	P3*

* Payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the PFS proposed rates. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS proposed rule.

We also reviewed CY 2019 volume and utilization data and other information for 18 procedures designated as temporarily office-based and temporarily assigned one of the office-based payment indicators, specifically ''P2,'' ''P3'' or ''R2,'' as shown in Table 56 and Table 57 in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61380 through 61383). These procedures were surgical procedures that were designated as temporarily office-based in the CY 2019 OPPS/ASC final rule with comment period or were new CPT codes for CY 2020 that were designated as temporarily office-based. Of these 18 procedures, for each procedure, there were fewer than 50 claims in our data and no claims data for 11 of the 18 procedures described by CPT codes 64454, 64624, 65785, 67229, 0402T, 0512T, 0551T, 0566T, 0588T, 93985 and 93986. Therefore, we proposed to continue to designate these procedures, shown in Table 54, as temporarily office-based for CY 2021. The procedures for which the proposed office-based designation for CY 2021 is temporary are indicated by an asterisk in Addendum AA to the CY 2021 OPPS/ASC proposed rule with comment period (which is available via the internet on the CMS website).

TABLE 54: PROPOSED CY 2021 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED IN THE CY 2020 OPPS/ASC PROPOSED RULE

CY 2021 CPT/HCPCS Code	CY 2021 Long Descriptor	CY 2020 ASC Payment Indicator	Proposed CY 2021 ASC Payment Indicator*
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	P3	P3*
64624	Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed	P3	P3*
65785	Implantation of intrastromal corneal ring segments	P2	P2*
67229	Treatment of extensive or progressive retinopathy, 1 or more sessions, preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (eg, retinopathy of prematurity), photocoagulation or cryotherapy	R2	R2*
0402T	Collagen cross-linking of cornea, including removal of the corneal epithelium and intraoperative pachymetry, when performed (report medication separately)	R2	R2*

CY 2021 CPT/HCPCS Code	CY 2021 Long Descriptor	CY 2020 ASC Payment Indicator	Proposed CY 2021 ASC Payment Indicator*
0512T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2	R2*
0551T	Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume	R2	R2*
0566T	Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; injection of cellular implant into knee joint including ultrasound guidance, unilateral	R2	R2*
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve	R2	R2*
93985	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study	P2	P2*
93986	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study	P2	P2*

* Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the PFS final rates. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS final rule.

For the remaining seven procedures of the 18 procedures designated as temporarily office-based as shown in Table 56 and Table 57 in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61380 through 61383), we proposed to permanently assign an office-based designation for five of the procedures, represented by CPT codes 10007, 10011, 11102, 11104, and 11106. After reviewing CY 2019 volume and utilization data for these five procedures, the claims data were sufficient to indicate that these covered surgical procedures are performed predominantly in physicians' offices (greater than 50 percent of the time) and, therefore, we proposed to permanently assign one of the office-based payment indicators, specifically ''P2,'' ''P3'' or ''R2,''—to these codes for CY 2021 as shown in Table 55. For the two remaining procedures that had temporary office-based designations for CY 2020, described by CPT codes 10005 (Fine needle aspiration biopsy, including ultrasound guidance; first lesion) and 10009 (Fine needle aspiration biopsy, including ct guidance; first lesion), utilization data are sufficient to indicate that these covered surgical procedures are not performed predominantly in physician's offices (performed in physician's offices less than 50 percent of the time) and, therefore, we proposed to assign a non office-based payment indicator—''G2''—to these codes for CY 2021 as shown in Table 55.

TABLE 55: PROPOSED CY 2021 PAYMENT INDICATORS FOR ASC COVERED SURGICAL PROCEDURES NO LONGER DESIGNATED AS TEMPORARILY OFFICE-BASED

CY 2021 CPT/HCPCS Code	CY 2021 Long Descriptor	CY 2020 ASC Payment Indicator	Proposed CY 2021 ASC Payment Indicator*
10005	Fine needle aspiration biopsy, including ultrasound guidance; first lesion	P3	G2
10007	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion	P3	P3*
10009	Fine needle aspiration biopsy, including ct guidance; first lesion	P2	G2
10011	Fine needle aspiration biopsy, including mr guidance; first lesion	R2	R2*
11102	Tangential biopsy of skin (eg, shave, scoop, saucerize, curette); single lesion	P3	P3*
11104	Punch biopsy of skin (including simple closure, when performed); single lesion	P2	P3*
11106	Incisional biopsy of skin (eg, wedge) (including simple closure, when performed); single lesion	P3	P3*

* Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the PFS final rates. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS final rule.

As discussed in the August 2, 2007 revised ASC payment system final rule (72 FR 42533 through 42535), we finalized our policy to designate certain new surgical procedures temporarily as office-based until adequate claims data are available to assess their predominant sites of service, whereupon if we confirm their office-based nature, the procedures would be permanently assigned to the list of office-based procedures. In the absence of claims data, we stated we would use other available information, including our clinical advisors' judgment, predecessor CPT and Level II HCPCS codes, information submitted by representatives of specialty societies and professional associations, and information submitted by commenters during the public comment period.

For CY 2021 we proposed to designate two new CY 2021 CPT codes for ASC covered surgical procedures as temporarily office-based. After reviewing the clinical characteristics, utilization, and volume of related procedure codes, we determined that the procedures in Table 56 would be predominantly performed in physicians' offices. We believe the procedures described by CPT codes 0596T (Temporary female intraurethral valve-pump (that is, voiding prosthesis); initial insertion, including urethral measurement) and 0597T (Temporary female intraurethral valve-pump (that is, voiding prosthesis); replacement) are similar to CPT code 55285 (Cystourethroscopy for treatment of the female urethral syndrome with any or all of the following: urethral meatotomy, urethral dilation, internal urethrotomy, lysis of urethrovaginal septal fibrosis, lateral incisions of the bladder neck, and fulguration of polyp(s) of urethra, bladder neck, and/or trigone) which is currently on the list of covered surgical procedures and assigned a proposed payment indicator ''A2''—Surgical procedure on ASC list in CY 2007; payment based on OPPS relative payment weight.—for CY 2021. While CPT code 52285 is not subject to office-based determinations as it is assigned an ''A2'' payment indicator, we note that this procedure is predominantly performed in a physician office setting (52 percent based on CY 2019 claims). As such, we proposed to add CPT codes 0596T and 0597T in Table 56 to the list of temporarily office-based covered surgical procedures.

TABLE 56: PROPOSED CY 2021 PAYMENT INDICATORS FOR NEW CY 2021 CPT CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED

CY 2021 OPPS/ASC proposed rule 5-digit CMS placeholder code	CY 2021 Long Descriptor	Proposed CY 2021 ASC Payment Indicator**
0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement	R2**
0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement	R2**

** Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the PFS final rates. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS final rule.

Comment: Some commenters supported our proposed temporary office-based designations as well as the removal of temporary office-based designations for CPT codes 10005 (Fine needle aspiration biopsy, including ultrasound guidance; first lesion) and 10009 (Fine needle aspiration biopsy, including ct guidance; first lesion). Many commenters did not support our proposed temporary office-based designation for CPT code 64624 (Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed). Commenters argued that the office setting does not represent the predominant site of care where this procedure is furnished, noting that this procedure is more likely to be performed in a hospital outpatient department or ASC setting. Commenters note that CY 2020 claims and utilization data support this position.

Response: We thank commenters for the support of our proposed temporary office-based designations. For the first two quarters of CY 2020, we reviewed over 5,000 claims submitted for CPT code 64624. We observed that this procedure was performed 23.9 percent of the time in an office setting for the first two quarters of CY 2020, significantly less than the 50 percent threshold for a permanent office-based designation. Therefore, we agree with commenters that removing the temporary office-based designation for CPT code 64624 is appropriate. For CY 2021, we are finalizing a payment indicator of ''G2''—(Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight)—for CPT code 64624.

After consideration of the public comments we received, we are finalizing our proposal, without modifications, to remove the temporary office-based designation for CPT codes 10005 and 10009. Additionally, we are finalizing our proposal, with modifications, to designate the procedures shown in Table 57 as temporarily office-based for CY 2021. Further, after consideration of the public comments we received, we are finalizing our proposal, without modifications, to designate the procedures shown in Table 58 as permanently office-based beginning CY 2021.

TABLE 57: ASC COVERED SURGICAL PROCEDURES TO BE DESIGNATED AS TEMPORARILY OFFICE-BASED FOR CY 2021

CY 2021 CPT/HCPCS Code	CY 2021 Long Descriptor	CY 2021 ASC Payment Indicator**
0402T	Collagen cross-linking of cornea, including removal of the corneal epithelium and intraoperative pachymetry, when performed (report medication separately)	R2**
0512T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	R2**
0551T	Transperineal periurethral balloon continence device; adjustment of balloon(s) fluid volume	R2**
0566T	Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; injection of cellular implant into knee joint including ultrasound guidance, unilateral	R2**
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve	R2**
0596T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); initial insertion, including urethral measurement	R2**
0597T	Temporary female intraurethral valve-pump (ie, voiding prosthesis); replacement	R2**

CY 2021 CPT/HCPCS Code	CY 2021 Long Descriptor	CY 2021 ASC Payment Indicator**
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	P3**
65785	Implantation of intrastromal corneal ring segments	P2**
67229	Treatment of extensive or progressive retinopathy, 1 or more sessions, preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (eg, retinopathy of prematurity), photocoagulation or cryotherapy	R2**
93985	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study	P2**
93986	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study	P2**

** Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the PFS final rates. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS final rule.

TABLE 58: ASC COVERED SURGICAL PROCEDURES TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2021

CY 2021 CPT/HCPCS Code	CY 2021 Long Descriptor	CY 2021 ASC Payment Indicator**
10007	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion	P3**
10011	Fine needle aspiration biopsy, including mr guidance; first lesion	R2**
11102	Tangential biopsy of skin (eg, shave, scoop, saucerize, curette); single lesion	P3**
11104	Punch biopsy of skin (including simple closure, when performed); single lesion	P3**
11106	Incisional biopsy of skin (eg, wedge) (including simple closure, when performed); single lesion	P3**
11760	Repair of nail bed	P3**
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)	P3**
23077	Radical resection of tumor (eg, sarcoma), soft tissue of shoulder area; less than 5 cm	R2**
44408	Colonoscopy through stoma; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed	R2**
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy	P2**
67500	Retrobulbar injection; medication (separate procedure, does not include supply of medication)	P3**

** Payment indicators are based on a comparison of the final rates according to the ASC standard ratesetting methodology and the PFS final rates. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS final rule.

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(3) Comment Solicitation on Office-Based Exemption for Dialysis Vascular Access Procedures

As we stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59036), the office-based utilization for CPT codes 36902 and 36905 (dialysis vascular access procedures) was greater than 50 percent. However, we did not designate CPT codes 36902 and 36905 as office-based procedures for CY 2019. These codes became effective January 1, 2017 and CY 2017 was the first year we had claims volume and utilization data for CPT codes 36902 and 36905. We shared commenters' concerns that the available data were not adequate to make a determination that these procedures should be office-based, and believed it was premature to assign office-based payment status to those procedures for CY 2019. For CY 2019, CPT codes 36902 and 36905 were assigned payment indicators of ''G2''—Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative weight.

As we stated in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61378), volume and utilization data for CPT code 36902 for CY 2018 showed the procedure was performed more than 50 percent of the time in physicians' offices. However, the office-based utilization for CPT code 36902 had fallen from 62 percent based on 2017 data to 52 percent based on 2018 data. In addition, there was a sizeable increase in claims for this service in ASCs—from approximately 14,000 in 2017 to 38,000 in 2018. In light of these changes in utilization and due to the high utilization of this procedure in all settings (over 125,000 claims in 2018), we believed it may have been premature to assign office-based payment status to CPT code 36902 for CY 2020. Therefore, for CY 2020, we finalized our proposal to not designate CPT code 36902 as an office-based procedure, but to continue to assign CPT code 36902 a payment indicator of ''G2''—non office-based surgical procedure paid based on OPPS relative weights. Additionally, CY 2018 volume and utilization data for CPT code 36905 showed the procedure was not performed more than 50 percent of the time in physicians' offices and we finalized our proposal to retain its payment indicator of ''G2''—non office-based surgical procedure based on OPPS relative weights for CY 2020.

For the CY 2021 OPPS/ASC proposed rule, we reviewed CY 2019 volume and utilization data for CPT code 36902 and determined that this procedure was performed less than 50 percent of the time in physicians' offices. We note that the office-based utilization for CPT code 36902 has fallen from 52 percent in 2018 to 41 percent in 2019. Similarly,

CY 2019 volume and utilization data for CPT code 36905 continues to show that this procedure was performed less than 50 percent of the time in physician's offices. Therefore, we did not propose to designate CPT codes 36902 and 36905 as office-based procedures for CY 2021.

In past rulemaking, commenters have requested we permanently exempt dialysis vascular access procedures from office-based designations similar to our exemption for radiology services that involve certain nuclear medicine procedures and radiology services that involve contrast agents (42 CFR 416.171(d)(1) and (2)) (83 FR 59036). Commenters contended that an office-based designation for dialysis vascular access procedures (in particular CPT codes 36902 and 36905) would result in a lower ASC payment rate if frequently used additional services, which are often packaged under the ASC payment system but separately payable under the Physician Fee Schedule, are factored into the analysis. Therefore, an office-based designation and payment at Physician Fee Schedule amounts under the ASC payment system may provide an inappropriate and lower global payment, after factoring in additional surgical procedures and/or ancillary items and services, when compared to the Physician Fee Schedule. Further, commenters have noted that ASCs are generally able to provide a wider array of dialysis vascular access procedures than are typically available in the physician office setting and at a lower Medicare payment rate than the hospital outpatient department setting. Providing an office-based ASC payment rate using PFS non facility PE RVUs for dialysis vascular access procedures may reduce the number of ASCs willing to perform such services and, subsequently, reduce beneficiary access for dialysis vascular access procedures in an ASC setting. Such an outcome may inadvertently encourage migration of dialysis vascular access procedures-related services to the more expensive hospital outpatient department setting.

While current volume and utilization data shows that dialysis vascular access procedures are not predominantly performed in a physician's office setting, future data for office-based designations may illustrate a different result. ASC rates established at PFS non facility PE RVU values may reduce the number of ASCs performing these procedures and inadvertently encourage greater utilization in the hospital outpatient department setting. While we did not propose an exemption from payment at physician fee schedule non-facility PE RVU amounts as characterized by payment indicator ''P3'' for CY 2021, we contemplated implementing such an exemption in the future if necessary and sought comment on whether we might be justified in establishing a permanent exemption from Physician Fee Schedule non facility PE RVU amounts for dialysis vascular access procedures under § 416.171(d) in future rulemaking.

Comment: Some commenters supported a permanent exemption from Physician Fee Schedule non facility PE RVU amounts for dialysis vascular access procedures under § 416.171(d) in future rulemaking. However, other commenters, while supportive, did not believe an exemption was necessary as office utilization for such procedures was unlikely to rise above the 50 percent threshold.

Response: We appreciate the commenters' feedback regarding a potential exemption from Physician Fee Schedule non facility PE RVU amounts for dialysis vascular access procedures under § 416.171(d). We agree with commenters that such an exemption is not necessary at this time; however, we may consider such a proposal for future rulemaking.

b. ASC Covered Surgical Procedures To Be Designated as Device-Intensive

(1) Background

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59041), for a summary of our existing policies regarding ASC covered surgical procedures that are designated as device-intensive.

(2) Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2021

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 590401 through 59043), for CY 2019, we modified our criteria for device-intensive procedures to better capture costs for procedures with significant device costs. We adopted a policy to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. In addition, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent. Specifically, for CY 2019 and subsequent years, we adopted a policy that device-intensive procedures would be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost. Corresponding to this change in the cost criterion we adopted a policy that the default device offset for new codes that describe procedures that involve the implantation of medical devices will be 31 percent beginning in CY 2019. For new codes describing procedures that are payable when furnished in an ASC and involve the implantation of a medical device, we adopted a policy that the default device offset would be applied in the same manner as the policy we adopted in section IV.B.2. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948). We amended § 416.171(b)(2) of the regulations to reflect these new device criteria.

In addition, as also adopted in section IV.B.2. of CY 2019 OPPS/ASC final rule with comment period, to further align the device-intensive policy with the criteria used for device pass-through status, we specified, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received Food and Drug Administration (FDA) marketing authorization, has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA in accordance with 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not any of the following:

++ Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or

++ A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker).

Based on our modified device-intensive criteria, for CY 2021, we proposed to update the ASC CPL to indicate procedures that are eligible for payment according to our device-intensive procedure payment methodology, based on the proposed

individual HCPCS code device-offset percentages using the CY 2018 OPPS claims and cost report data available for the CY 2020 OPP/ASC proposed rule.

The ASC covered surgical procedures that we proposed to designate as device-intensive, and therefore subject to the device-intensive procedure payment methodology for CY 2021, are assigned payment indicator ''J8'' and are included in ASC Addendum AA to the CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website). The CPT code, the CPT code short descriptor, and the proposed CY 2021 ASC payment indicator, and an indication of whether the full credit/partial credit (FB/FC) device adjustment policy would apply because the procedure is designated as device-intensive are also included in Addendum AA to the proposed rule (which is available via the internet on the CMS website).

Under current policy, the payment rate under the ASC payment system for device-intensive procedures furnished with an implantable or inserted medical device are calculated by applying the device offset percentage based on the standard OPPS APC ratesetting methodology to the OPPS national unadjusted payment based on the standard ratesetting methodology to determine the device cost included in the OPPS payment rate for a device-intensive ASC covered surgical procedure, which we then set as equal to the device portion of the national unadjusted ASC payment rate for the procedure. We calculate the service portion of the ASC payment for device intensive procedures by applying the uniform ASC conversion factor to the service (non-device) portion of the OPPS relative payment weight for the device-intensive procedure. Finally, we sum the ASC device portion and ASC service portion to establish the full payment for the device-intensive procedure under the ASC payment system (82 FR 59409).

As discussed in section IV.A. of this final rule with comment period, we are approving the BAROSTIM NEO™ system for transitional pass-through device payment status. The applicant has stated that the BAROSTIM NEO™ would be reported with CPT code 0266T (Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)). There have been no device costs reported for CPT code 0266T in CY 2019 claims or in previous calendar years. Therefore, we are assigning a device offset percentage to 0266T in CY 2021 based on the clinically-similar procedure 0268T (Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)). Based on our review of CY 2019 claims data, CPT code 0268T has a device offset percentage of 96.04 percent. Therefore, for CY 2021, we are assigning device-intensive status to CPT code 0266T with a device offset percentage of 96.04 percent.

Comment: Some commenters requested that device-intensive designations for procedures under the ASC payment system be based solely on device-intensive designations under the OPPS.

Response: We are not accepting the commenters' recommendation. As we have stated in past rulemaking (79 FR 66924), under 42 CFR 416.167 and 416.171, most ASC payment rates are based on the OPPS relative payment weights, and our ASC policy with respect to device-intensive procedures is designed to be consistent with the OPPS. As such, a ''device-intensive'' designation identifies those procedures with significant device costs and applies to services that are performed both in the hospital outpatient department and the ASC setting. We believe that the device-intensive methodology for ASCs should align with the device-intensive policies for OPPS, and, therefore, procedures should not be device intensive in the ASC setting if they are not device intensive in the hospital outpatient setting. Accordingly, to be assigned device-intensive status in the ASC setting, the procedure must be identified as device-intensive in the hospital outpatient setting and have a device offset percentage that exceeds the 30 percent threshold as calculated using our standard ratesetting methodology as stated in 42 CFR 416.171(b)(2).

Comment: Several commenters requested that we restore the device-intensive status for CPT code 0200T (Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles, includes imaging guidance and bone biopsy, when performed), noting that we proposed device-intensive status for this procedure under the OPPS.

Response: Based on updated claims data for this final rule with comment period, CPT code 0200T has a device offset percentage of 20.39 percent based on the standard ratesetting methodology. Therefore, CPT code 0200T is ineligible for device-intensive status under the ASC payment system and we are finalizing a payment indicator of ''G2'' CPT code 0200T for CY 2021.

Comment: One commenter recommended that we assign device-intensive status to CPT code 66174 (Transluminal dilation of aqueous outflow canal; without retention of device or stent).

Response: Based on updated claims data for this final rule with comment period, CPT code 66174 has a device offset percentage of 24.70 percent. Therefore, CPT code 66174 is ineligible for device-intensive status under the ASC payment system. We are finalizing a payment indicator of ''A2''—Surgical procedure on ASC list in CY 2007; payment based on OPPS relative payment weight—for CPT code 66174 for CY 2021.

Comment: Some commenters supported the Advisory Panel on Hospital Outpatient Payment (HOP Panel) recommendation that CMS consider lowering the ASC device-intensive threshold from 30 percent to 25 percent to better capture device costs in the ASC setting.

Response: Our established policy under the ASC payment system, as discussed at greater length in section XIII.G. of this final rule, is to scale prospective ASC relative payment weights by comparing total payment using current year ASC scaled relative payment weights with the total payment using the prospective ASC relative payment weights, holding ASC utilization, the ASC conversion factor, and the mix of services constant from the claims year. Lowering the device-intensive threshold would have the effect of assigning a greater amount of device costs, and increasing estimated ASC expenditures for the prospective year. The increase in prospective year expenditures can be attributable to portions of ASC non-device costs, which are otherwise calculated using an ASC conversion factor that is lower than the OPPS conversion factor, being replaced with device costs which are calculated using the higher OPPS conversion factor so that device costs are held constant between the OPPS and ASC payment system. The increase in estimated prospective year expenditures would put additional downward pressure on the ASC weight scalar and otherwise reduce ASC payment rates for most surgical procedures. Accordingly, we do not believe it would be appropriate to lower the ASC device-intensive threshold at this time.

Comment: One commenter requested that we reevaluate our device cost calculations with respect to the device

offset percentage difference between CPT codes 64910 (Nerve repair; with synthetic conduit or vein allograft (*e.g.,* nerve tube), each nerve) and 64912 (Nerve repair; with nerve allograft, each nerve, first strand (cable)). The commenter noted that the device offset percentage for CPT code 64912 has historically been greater than the device offset percentage for CPT code 64910.

Response: We appreciate the commenters' recommendation. We note that CPT codes 64910 and 64912 each had less than 50 claims for this CY 2021 OPPS/ASC final rule with comment period. For relatively lower volume procedures such as these, the limited sample sizes may cause greater fluctuation in device cost statistics for these procedures on a year-to-year basis. The amount of packaged costs submitted on a claim, the hospital charges reported on the claim, as well as the cost-to-charge ratios for the hospitals that submitted these claims, can have a substantial impact on our device cost calculations for relatively lower volume procedures. However, we believe continuing to use our device-intensive methodology results in the most accurate and reliable device cost statistics for capturing changes in device costs over time and for purposes of determining device-intensive status and device offset percentages.

After consideration of the public comments we received, we are designating the ASC covered surgical procedures displayed in Addendum AA with payment indicator ''J8'' as device-intensive and subject to the device-intensive procedure payment methodology for CY 2021.

c. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC payment policy for costly devices implanted or inserted in ASCs at no cost/full credit or partial credit is set forth in § 416.179 of our regulations, and is consistent with the OPPS policy that was in effect until CY 2014. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66845 through 66848) for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices.) ASC payment is reduced by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device.

Effective CY 2014, under the OPPS, we finalized our proposal to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a device, capped at the device offset amount. Although we finalized our proposal to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPS, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75076 through 75080), we finalized our proposal to maintain our ASC policy for reducing payments to ASCs for specified device-intensive procedures when the ASC furnishes a device without cost or with full or partial credit. Unlike the OPPS, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the actual credit received when furnishing a specified device at full or partial credit. Therefore, under the ASC payment system, we finalized our proposal for CY 2014 to continue to reduce ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device without cost or with full or partial credit, respectively.

Under current ASC policy, all ASC device-intensive covered surgical procedures are subject to the no cost/full credit and partial credit device adjustment policy. Specifically, when a device-intensive procedure is performed to implant or insert a device that is furnished at no cost or with full credit from the manufacturer, the ASC would append the HCPCS ''FB'' modifier on the line in the claim with the procedure to implant or insert the device. The contractor would reduce payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost or with full credit to the ASC. We continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure furnished by the ASC.

Effective in CY 2019 (83 FR 59043 through 59044), for partial credit, we adopted a policy to reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the new device. The ASC will append the HCPCS ''FC'' modifier to the HCPCS code for the device-intensive surgical procedure when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a new device, ASCs have the option of either: (1) Submitting the claim for the device-intensive procedure to their Medicare contractor after the procedure's performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount. As finalized in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), to ensure our policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost or receive full credit or partial credit for the device, we apply our ''FB''/''FC'' modifier policy to all device-intensive procedures.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) we stated we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. In the CY 2020 OPPS/ASC final rule with comment period, we finalized continuing our existing policies for CY 2020. We note that we inadvertently omitted language that this policy would apply not just in CY 2019 but also in subsequent calendar years. We intended to apply this policy in CY 2019 and subsequent calendar years. Therefore, we proposed to apply our policy for partial credits specified in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) in CY 2021 and subsequent calendar years. Specifically, for CY 2021 and subsequent calendar years, we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the

device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device, ASCs have the option of either: (1) Submitting the claim for the device intensive procedure to their Medicare contractor after the procedure's performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount. We did not propose any other changes to our policies related to no/cost full credit or partial credit devices.

In the CY 2021 OPPS/ASC proposed rule, we did not propose any changes to these policies and we did not receive any comments on our policies related to no/cost full credit or partial credit devices. Therefore, we are finalizing continuing our existing policies for CY 2021 and subsequent years.

d. Additions to the List of ASC Covered Surgical Procedures

Section 1833(i)(1) of the Act requires us, in part, to specify, in consultation with appropriate medical organizations, surgical procedures that are appropriately performed on an inpatient basis in a hospital but that can be safely performed in an ASC, a CAH, or an HOPD and to review and update the list of ASC procedures at least every 2 years. We evaluate the ASC covered procedures list (ASC CPL) each year to determine whether procedures should be added to or removed from the list, and changes to the list are often made in response to specific concerns raised by stakeholders.

Under our current regulations at 42 CFR 416.2 and 416.166, covered surgical procedures furnished on or after January 1, 2008 are surgical procedures that meet the general standards specified in 42 CFR 416.166(b) and are not excluded under the general exclusion criteria specified in 42 CFR 416.166(c). Specifically, under 42 CFR 416.166(b), the general standards provide that covered surgical procedures are surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the internet on the CMS website that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. Section 42 CFR 416.166(c) sets out the general exclusion criteria used under the ASC payment system to evaluate the safety of procedures for performance in an ASC. The general exclusion criteria provide that covered surgical procedures do not include those surgical procedures that: (1) Generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life threatening in nature; (5) commonly require systemic thrombolytic therapy; (6) are designated as requiring inpatient care under 42 CFR 419.22(n); (7) can only be reported using a CPT unlisted surgical procedure code; or (8) are otherwise excluded under 42 CFR 411.15.

For purposes of identifying procedures eligible to be added to the covered surgical procedure list, we define surgical procedures as those procedures described by Category I CPT codes in the surgical range from 10000 through 69999 as well as those Category I and III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range (83 FR 59044 through 59045), that we have determined do not pose a significant safety risk, would not be expected to require an overnight stay when performed in an ASC, and are separately paid under the OPPS. We proposed to continue to apply the revised definition of ''surgery'' we adopted in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59029 through 59030), which includes certain ''surgery-like'' procedures that are assigned codes outside the CPT surgical range, for CY 2021 and subsequent years.

As discussed above, section 1833(i)(1) of the Act requires the Secretary to specify, in consultation with appropriate medical organizations, surgical procedures that are appropriately performed on an inpatient basis in a hospital but that can be safely performed on an ambulatory basis in an ASC, a CAH, or an HOPD and to review and update the list of ASC procedures at least every 2 years. The report accompanying the legislation establishing section 1833(i)(1) of the Act explained that Congress intended procedures routinely performed on an ambulatory basis in a physician's office that do not generally require the more elaborate facilities of an ASC not to be included in the list of ASC covered procedures (H.R. Rep. No. 96–1167, at 390–91, reprinted in 1980 U.S.C.C.A.N. 5526, 5753–54).

In consideration of the statutory requirements and legislative history, in the implementing regulations of the current ASC system (effective in 2008), which we adopted in the August 2, 2007 final ASC rule (72 FR 42487), we excluded procedures that would otherwise pose a significant safety risk to the typical Medicare beneficiary if performed in the ASC setting. However, we agreed with stakeholders who have noted that ASCs are increasingly able to safely provide a greater range of services as medical practice continues to evolve and advance. We also believe that physicians play an important role and should be able to exercise their clinical judgment in making site-of-service determinations. Accordingly, CMS has continued to reexamine the process of how we determine which procedures are payable under Medicare when furnished in the ASC setting, keeping in mind the statutory requirement in section 1833(i)(1)(A) of the Act that the Secretary must specify those surgical procedures that are appropriately performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in an ASC, CAH or HOPD as part of reviewing and updating the list of procedures.

In the CY 2020 OPPS/ASC final rule with comment period, we added total knee arthroplasty and several coronary intervention procedures to the ASC CPL (84 FR 61386 through 61397). Although the coronary intervention procedures involved blood vessels that could be considered major, based on our policy to consider the involvement of major blood vessels in the context of the clinical characteristics of the individual procedures and to maintain logical and clinical consistency in excluding procedures from the ASC CPL (72 FR 42481), as well as our review of the clinical characteristics of the procedures and their similarity to other procedures that were included on the ASC CPL, we believed these procedures could be safely performed in the ASC setting for appropriate beneficiaries. In the CY 2019 OPPS/ASC final rule with comment period, we also noted that in light of our conditions of coverage for ASCs, including 42 CFR 416.42, which require surgical procedures to be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the

ASC, we believe that the CfCs provide further assurance that services furnished in the ASC setting are held to a high standard of safety. While we acknowledged in the CY 2019 OPPS/ASC final rule with comment period that it could be more appropriate for certain beneficiaries to receive the coronary intervention procedures we were adding to the ASC CPL in a hospital-level setting, which typically has a higher level of emergency staff and equipment available, including onsite cardiac surgery backup, when compared to an ASC setting, we also noted that many beneficiaries could be ideal candidates to receive these services in an ASC setting and that beneficiaries and their physicians should be able to choose an appropriate site of service for surgeries based on the clinical characteristics of the patient and other factors (83 FR 59046). We continue to believe that relatively healthy and less complex patients would benefit from the shorter length of stay and reduced cost-sharing that would be expected in an ASC setting.

In the August 2, 2007 final rule with comment period establishing the revised ASC payment system, we discussed criteria for excluding procedures from the ASC CPL (72 FR 42478 through 42484). In that same final rule, we adopted the current general standards and general exclusion criteria described above. One of the general exclusion criteria we established for the revised ASC payment system, at § 416.166(c)(6), excludes any procedure on the OPPS Inpatient Only (IPO) list, which is a list of procedures for which we do not make payment under the OPPS and that are typically performed in the hospital inpatient setting because of the nature of the procedure, the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged, and the underlying physical condition of the patient (65 FR 18456). We also stated that we believed that any procedures for which we did not allow payment in the hospital outpatient setting due to safety concerns would not be safe to perform in an ASC (72 FR 42478). We stated that we were committed to revising the ASC CPL so that it excludes only those surgical procedures that pose significant safety risks to beneficiaries or that are expected to require an overnight stay (72 FR 42479).

Also in the August 2, 2007 final rule with comment period, we discussed the exclusion of procedures involving major blood vessels, but we noted that it was important to maintain flexibility in our review of procedures for safe performance in the ASC setting, consistent with our past practice regarding this criterion (72 FR 42481). We discussed that there were some procedures already on the ASC list being safely performed in ASCs that involve blood vessels that would generally be defined as major. We did not agree with commenters that it would be logical or clinically consistent for us to adopt a specific definition of major blood vessels to evaluate procedures for exclusion from ASC payment (72 FR 42481). We noted the involvement of major blood vessels is best considered in the context of the clinical characteristics of individual procedures.

We noted that we proposed to exclude surgical procedures that were expected to involve major blood vessels, major or prolonged invasion of body cavities, extensive blood loss, or that are emergent or life-threatening in nature from ASC payment, based on evaluation by our medical advisors (72 FR 42478 through 42479). We also noted that most of the procedures that our medical advisors identified as involving any of the characteristics listed in 42 CFR 416.65(b)(3) also require overnight or inpatient stays, reinforcing our belief that they should be excluded from ASC payment (72 FR 42478 through 42479). We also disagreed, at that time, that all procedures performed in HOPDs were appropriate for performance in ASCs. This was due in part to the fact that we believed that HOPDs were able to provide much higher acuity care, and because hospitals were subject to more stringent infection prevention, documentation, and patient assessment requirements than ASCs. As discussed in the August 2, 2007 final rule with comment period, ASCs were not required to meet patient safety standards consistent with those in place for hospitals (that is, hospital conditions of participation), and ASCs were not required, and are not currently required, to have the trained staff and equipment needed to provide the breadth and intensity of care that hospitals are required to maintain (72 FR 42479).

Many of these concerns have been addressed with the passage of time. We believe that our approach needs to evolve away from the criteria we established in 2008, in order to reflect the significant advances in medical practice and ASC capabilities over the last 12 years. In particular, we believe that significant advancements in medical practice, surgical techniques, medical technology, and other factors have allowed certain ASCs to safely perform procedures that were once too complex, including those involving major blood vessels and other general exclusion criteria. We acknowledge that ASCs and hospitals have different health and safety requirements. Despite this fact, ASCs often undergo accreditation as a condition of state licensure and share some similar licensure and compliance requirements with hospitals as well as meet Medicare conditions for coverage (see 42 CFR 416.40 through 416.54).

As mentioned above, in recent years, we have added procedures to the ASC CPL that were largely considered hospital inpatient procedures in the past, such as total knee arthroplasty (TKA) and certain coronary intervention procedures. As the practice of medicine has evolved, hospital lengths of stay have become shorter for many surgical procedures. Many services that used to be predominantly performed in the hospital inpatient setting are now routinely performed in the hospital outpatient setting on an ambulatory basis. Further, many procedures that are currently only payable as hospital outpatient services under Medicare fee-for-service are safely performed in the ASC setting for other payors. While we recognize that non-Medicare patients tend to be younger and have fewer comorbidities than the Medicare population, we note that careful patient selection can identify Medicare beneficiaries who are suitable candidates for these services in the ASC setting. Further, Medicare Advantage plans are not obligated to adopt the ASC CPL as it exists in Medicare fee-for-service and, based on Medicare Advantage encounter data, many MA enrollees have had services performed in the ASC setting that are not currently payable under Medicare fee-for-service.

In addition, the COVID–19 pandemic has highlighted the need for more healthcare access points throughout the country. Many ASCs temporarily closed or significantly scaled back their operations based on state and federal recommendations to delay elective procedures during the public health emergency associated with COVID–19 while some ASCs opted to temporarily enroll as hospitals. Looking ahead to after the pandemic, it will be more important than ever to ensure that the health care system has as many access points and patient choices for all Medicare beneficiaries as possible. Because the pandemic has forced many ASCs to close, thereby decreasing Medicare beneficiary access to care in that setting, we believe allowing greater flexibility for physicians and patients to choose ASCs as the site of care, particularly during the pandemic, would help to alleviate both access to care concerns for elective procedures as well as access to emergency care

concerns for hospital outpatient departments.

(1) Changes to the List of ASC Covered Surgical Procedures for CY 2021

Historically, we have reviewed the clinical characteristics of procedures and consulted with stakeholders and our clinical advisors to determine if those procedures would meet our existing regulatory criteria under 42 CFR 416.2 and 416.166. Our regulation at 416.166(b) specifies the general standard criteria for covered surgical procedures, and requires that covered surgical procedures be surgical procedures: (1) That are separately paid under OPPS, (2) that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and (3) for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. Additionally, 42 CFR 416.166(b) requires that a procedure not meet our exclusion criteria set forth in 42 CFR 416.166(c).

For CY 2021, we proposed to continue to apply our current policies and criteria set forth in 42 CFR 416.2 and 416.166 for updating the ASC CPL. In addition, we proposed two alternative options for modifying our approach to adding surgical procedures to the ASC CPL—(1) a nomination process for adding new procedures to the ASC CPL, and (2) a broader approach under which we would revise our regulatory criteria at 42 CFR 416.166 to evaluate potential additions to the ASC CPL. Under our first alternative proposal, a proposed nomination process along with modifications to certain regulatory criteria, we would accept and consider nominations submitted by March 1st, 2021 in our rulemaking for CY 2022. Under our second alternative proposal, we proposed to revise our regulatory criteria by removing certain general exclusions at 42 CFR 416.166(c) and under the revised criteria, we proposed to add certain surgical procedures to the ASC CPL beginning in CY 2021. We expected either of these options would have the effect of expanding the ASC CPL, while maintaining the balance between safety and access for Medicare beneficiaries.

A. Standard ASC CPL Review Process for CY 2021

For CY 2021, consistent with our current policy for reviewing the ASC CPL, we conducted a review of HCPCS codes that currently are paid under the OPPS, but not included on the ASC CPL, and that meet the definition of surgery to determine if changes in technology and/or medical practice affected the clinical appropriateness of these procedures for the ASC setting. Based on this review, and as explained in more detail below, we proposed to update the list of ASC covered surgical procedures by adding eleven procedures to the list for CY 2021 as shown in Table 40 of the CY 2021 OPPS/ASC proposed rule. Procedures that we proposed to add to the ASC CPL for CY 2021 include total hip arthroplasty (THA), vaginal colpopexy, transcervical uterine fibroid ablation, and intravascular lithotripsy procedures, among others. After reviewing the clinical characteristics of these eleven procedures and consulting with our clinical advisors, we determined that these procedures are separately paid under the OPPS, would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. We have assessed each of the proposed procedures against the regulatory safety criteria in the regulation at 42 CFR 416.166(c) and believe that none of the procedures meet the general exclusion criteria.

Of the eleven procedures we proposed to add, we believed that the THA procedure merited additional discussion in the CY 2021 OPPS/ASC proposed rule, given prior discussion of the procedure in past rulemaking, to explain our belief that the procedure meets existing safety criteria for purposes of adding this procedure to the ASC CPL. In the CY 2018 OPPS/ASC proposed rule, we solicited public comments on whether the THA procedure, CPT code 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft), met the criteria to be added to the ASC CPL. In the CY 2018 OPPS/ASC final rule with comment period, we noted that some commenters argued many ASCs are equipped to perform this procedure and orthopedic surgeons in ASCs are increasingly performing this procedure safely and effectively on non-Medicare patients and appropriate Medicare patients (82 FR 59412). Commenters also stated that adding THA to the ASC CPL would allow for greater choices in care settings for Medicare patients, would provide a more patient-centered approach to joint arthroplasty procedures, and would potentially be safer in some cases when performed in an outpatient setting to prevent certain hospital-acquired infections (82 FR 59412).

However, other commenters recommended that ASCs obtain enhanced certification from a national accrediting organization that certifies an ASC meets higher quality standards and can safely perform joint arthroplasty procedures (82 FR 59412). Some commenters opposed adding THA to the ASC CPL, as they believed the vast majority of ASCs are not equipped to safely perform these procedures on patients and the vast majority of Medicare patients are not suitable candidates to receive ''overnight'' joint arthroplasty procedures in an ASC setting (82 FR 59412). For CY 2018, we did not finalize adding THA to the ASC CPL, but noted that we would take commenters' suggestions and recommendations into consideration for future rulemaking.

In the CY 2021 OPPS/ASC proposed rule, we sought to continue to promote site neutrality, where possible, between the hospital outpatient department and ASC settings, and expand the ASC CPL to include as many procedures that can be performed in the HOPD as reasonably possible to advance that goal. Further, we believed that there are at least a subset of Medicare beneficiaries who may be suitable candidates to receive THA procedures in an ASC setting based on the beneficiaries' clinical characteristics. We believe physicians should continue to play an important role in exercising their clinical judgment when making site-of-service determinations, including for THA. We believe THA would meet our existing regulatory requirements established under 42 CFR 416.2 and 416.166(b) and (c) for covered surgical procedures in the ASC setting. In light of this information and the public comments submitted in support of adding THA to the ASC CPL in response to our CY 2018 public comment solicitation, we proposed to add THA to the ASC CPL in CY 2021, as shown in Table 40 of the CY 2021 OPPS/ASC proposed rule.

We proposed to add a total of eleven procedures, displayed in Table 40 of the CY 2021 OPPS/ASC proposed rule, with their HCPCS code long descriptors, to the list of ASC covered surgical procedures for CY 2021. We sought public comment on our proposal, including any medical evidence or literature to support the commenters' views on whether or not we should add any of these procedures to the ASC CPL for CY 2021. In addition, we also sought comment on the two alternative proposals described below. Note that under both alternative proposals, we still proposed to add the eleven

procedures proposed under this section for CY 2021.

Comment: Multiple commenters supported adding the eleven procedures we proposed to add to the ASC CPL under the established process for assessing procedures for inclusion on the ASC CPL. They noted that orthopedic surgeons in ASCs are increasingly performing these eleven procedures safely and effectively on non-Medicare-fee-for-service patients and appropriate Medicare patients. Two of these procedures, total hip arthroplasty (THA) and autologous chondrocyte knee implantation, received significant support from commenters. Commenters noted that due to advancements in clinical practice, less invasive techniques, patient selection, improved perioperative anesthesia, alternative postoperative pain management and expedited rehabilitation protocols, these procedures can be safely and effectively performed for Medicare beneficiaries in the ASC setting. These commenters observed that patients are typically not expected to require active medical monitoring and care at midnight following these procedures.

Several commenters opposed the addition of THA to the CPL due to the risk of jeopardizing patient safety as well as expanded beneficiary coinsurance obligations. These commenters also recommended CMS ensure beneficiaries are informed in advance that, unlike under the OPPS, ASC cost-sharing is not capped at the inpatient deductible and could exceed cost sharing in the hospital outpatient setting for the same procedure. One commenter stated that CMS should delay adding THA to the ASC CPL until there is more robust outcomes data available.

Response: We thank commenters for providing public comments on the appropriateness of adding THA and other procedures to the ASC CPL and recognize their concerns for ensuring patient health and quality care. As we have noted in the CY 2019 OPPS/ASC final rule (83 FR 59046) and the CY 2020 OPPS/ASC final rule (84 FR 61354), we continue to believe that the appropriate site of service for any surgical procedure, including THA, should be based on the physician's assessment of the patient and tailored to the individual patient's needs. We believe there are a number of less medically complex Medicare beneficiaries that could appropriately receive THA in an ASC setting. For these beneficiaries, physicians should continue to play an important role in exercising their clinical judgment when making site-of-service determinations.

We are aware that beneficiaries may incur greater cost-sharing for THA procedures in an ASC setting under our proposal, but note that this is not an occurrence that is unique to THA. As we stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59389), section 4011 of the 21st Century Cures Act (Pub. L. 114–255) amended section 1834 of the Act by adding a new subsection (t), which requires the Secretary to make available to the public via a searchable website, with respect to an appropriate number of items and services, the estimated payment amount for the item or service under the OPPS and ASC payment system and the estimated beneficiary liability applicable to the item or service. We implemented this provision by providing our Outpatient Procedure Price Lookup tool available via the internet at *https://www.medicare.gov/procedure-price-lookup*. This web page allows beneficiaries to compare their potential cost-sharing liability for procedures performed in the hospital outpatient setting versus the ASC setting. We believe this tool helps inform beneficiaries of potential cost-sharing amounts for receiving a service in the ASC setting compared to the outpatient setting, and note that this tool would include a comparison of cost-sharing liability for THA in the outpatient hospital and ASC settings in the future. Given these reasons, we do not believe a delay in the implementation of our proposed additions to the ASC CPL is warranted based on concerns relating to beneficiary safety or the potential for greater cost sharing expenses for beneficiaries.

We assessed each of the eleven procedures we proposed to add to the ASC CPL using the existing regulatory safety criteria and determined that these procedures meet each of the criteria. Based on our review of the clinical characteristics of the procedures and their similarity to other procedures that are currently included on the ASC CPL, we believe the eleven procedures (CPT codes 0266T, 0268T, 0404T, 21365, 27130, 27412, 57282, 57283, 57425, C9764, and C9766) can be safely performed in the ASC setting and note that the physician should determine whether a particular beneficiary would be a good candidate to undergo a procedure in the ASC setting rather than the hospital setting based on the clinical assessment of the patient. We agree with commenters who stated that advancements in clinical practice, less invasive techniques, patient selection, improved perioperative anesthesia, alternative postoperative pain management and expedited rehabilitation protocols have allowed these procedures to safely be performed in an ASC setting.

Therefore, in this final rule with comment period, we are finalizing our proposal without modification to add these eleven procedures to the ASC CPL. These procedures, listed in Table 59 of this CY 2021 OPPS/ASC final rule, are:

- CPT code 0266T (Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)),
- CPT code 0268T (Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed),
- CPT code 0404T (Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency),
- CPT code 21365 (Open treatment of complicated (eg, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with internal fixation and multiple surgical approaches,
- CPT code 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft
- CPT code 27412 (Autologous chondrocyte implantation, knee)
- CPT code 57282 (Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus))
- CPT code 57283 (Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy)
- CPT code 57425 (Laparoscopy, surgical, colpopexy (suspension of vaginal apex))
- CPT code C9764 (Revascularization, endovascular, open or percutaneous, lower extremity artery (ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed
- CPT code C9766 (Revascularization, endovascular, open or percutaneous, lower extremity artery (ies), except tibial/peroneal; with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed.

(1) Proposed Changes to General Exclusion Criterion for Procedures Requiring Inpatient Care To Conform to Proposed Changes to the Underlying Requirements Under the OPPS

As described in section IX.B. of the CY 2021 OPPS/ASC proposed rule, CMS proposed to eliminate the OPPS IPO list and amend 42 CFR 419.22(n) to state that effective beginning on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition, with the full list eliminated in its entirety by January 1, 2024. We believed that retaining § 416.166(c)(6) would ensure that procedures that are largely performed on an inpatient basis and cannot be safely performed on an ambulatory basis will not be added to the CPL prematurely. As a result, we proposed to revise the regulatory language and modify this standard to exclude procedures designated as requiring inpatient care under § 419.22(n) as of December 31, 2020.

Comment: Commenters had concerns about modifying the general exclusion criteria at § 416.166(c)(6) to exclude procedures designated as requiring inpatient care.

Several commenters supported retaining the exclusion of procedures designated as requiring inpatient care, due to patient safety and quality of care concerns. These commenters urged caution in how CMS modifies criteria and adds procedures to the CPL, with one noting that they do not believe there is currently enough information to determine if these procedures would be clinically appropriate to perform in an outpatient or ASC setting.

Other commenters opposed this modification and believed this exclusionary criterion should be removed. These commenters urged CMS not to finalize this proposal, as they believe it is counter to CMS' intention to expand physician and patient choice.

Response: We thank commenters for their suggestions. As we discuss in more detail later in this section, we believe that retaining regulatory text similar to § 416.166(c)(6) in CY 2021 will ensure that procedures that cannot be safely performed on an ambulatory basis will not be added to the CPL. As a result, we are modifying this standard for CY 2021 and future years to exclude procedures designated as requiring inpatient care under § 419.22(n) as of December 31, 2020. We are revising the regulatory language at § 416.166(c)(6) to reflect this change at § 416.166(b)(2)(i)(A).

(2) Alternative Proposals Under Consideration for CY 2021

In the CY 2021 OPPS/ASC proposed rule (85 FR 48958), we stated that, for CY 2021, we are continuing to build on our efforts to maximize patient and physician choice and access to care by exploring broader approaches to adding procedures to the ASC CPL in order to further increase the availability of ASCs as an alternative site of care for Medicare beneficiaries, often at a lower cost than other options. In light of the current national Public Health Emergency related to COVID–19 and its anticipated lasting effects on the health care system, we noted that we also believe a broader approach for adding procedures to the ASC CPL would allow for a more efficient use of healthcare resources and infrastructure. An expansion of the ASC CPL would maximize the ability of ASCs to divert patients that can be safely treated in an ASC setting away from the hospital setting, which would preserve the capacity of hospitals to treat more acute patients. We explained that expanding the procedures placed on the ASC CPL would also build on the policy changes we have made in recent years to further site neutrality between the HOPD and ASC settings. In light of these objectives, we proposed two alternatives to our existing policy of adding procedures to the ASC CPL, each of which we believed would further support these goals.

a. Alternative Proposal To Create a Nomination Process

Under the first approach, we proposed a nomination process for adding new procedures to the ASC CPL. We explained that this process would involve soliciting recommendations from external stakeholders, like medical specialty societies and other members of the public, for procedures that may be suitable candidates to add to the ASC CPL. As discussed in greater detail below, under this approach, we proposed to provide parameters as guidelines that we would strongly encourage stakeholders to consider in nominating procedures for the ASC CPL. We noted that we anticipated stakeholders, such as specialty societies that specialize in and have a deep understanding of the complexities involved in providing certain procedures, would be able to provide valuable suggestions as to which additional procedures may reasonably and safely be provided in an ASC.

While members of the public may already suggest procedures to be added to the CPL through meetings with CMS or through public comments to the proposed rule, we stated in the proposed rule that we believe it may be beneficial to adopt a streamlined process under which the public, particularly specialty societies that are very familiar with procedures in their specialty, can nominate procedures based on the latest evidence available as well as input from their memberships. We noted that we believe this revised process could increase transparency in how we are assessing procedures to add to the ASC list and also help ensure that we are assessing the list in a more streamlined fashion.

We proposed that the nomination process would be conducted through annual notice and comment rulemaking and the final determinations regarding nominated procedures would be decided in the final rule. Specifically, for the OPPS/ASC rulemaking for a calendar year, we would request stakeholder nominations by March 1 of the previous calendar year, with all nominations received by that date considered in the next applicable rulemaking cycle, likely the rulemaking for the following calendar year. Any nominations received after that date, including those received through comments as part of the rulemaking cycle, would generally be addressed in rulemaking the following year. CMS would evaluate procedures nominated by stakeholders based on the applicable statutory and regulatory requirements for ASC covered surgical procedures and the additional parameters specified in detail below. We proposed to establish the nomination process in the CY 2021 final rule to begin in CY 2021, for surgical procedures that could be added to the ASC CPL beginning in CY 2022. We proposed a process under which nominated procedures would be included in the proposed rule for that calendar year, along with a summary of the policy and factual justification for adding or not adding each procedure, which would allow members of the public to assess and provide comment on nominated procedures during the public comment period. We indicated that, after reviewing comments provided during the public comment period, CMS would finalize adding the procedures that meet the requisite criteria to the ASC CPL in the final rule. In the event that CMS disagreed with any procedures nominated, we would provide a specific rationale in the final rule. We stated that, in certain cases, CMS may need to defer a final determination regarding a nominated procedure to future rulemaking in order to provide sufficient time to evaluate and make the

most appropriate decision about the nominated procedure.

Under this alternative proposal, we proposed to update the ASC CPL by considering whether nominated procedures meet the requirements for covered surgical procedures under 42 CFR 416.166(b), which sets out the general standards for covered surgical procedures, requiring that surgical procedures be separately paid under the OPPS, not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. We also proposed to eliminate the general exclusion criteria in 42 CFR 416.166(c)(1) through (5) such that nominated procedures would not have to meet those criteria. Further, we proposed to modify § 416.166(c)(6) to align the regulatory text with the proposed elimination of the IPO list. Finally, we proposed that nominated procedures would need to meet the general exclusions at 42 CFR 416.166(c)(7) and (8).

With respect to the existing general exclusion at 42 CFR 416.166(c)(6), which excludes procedures designated as requiring inpatient care under 42 CFR 419.22(n) from classification as covered surgical procedures, we noted that this alternative proposal would modify this standard since the IPO list is being proposed to be eliminated beginning in CY 2021, as described in section IX.B of the CY 2021 OPPS/ASC proposed rule. Therefore, we proposed to modify this criterion to exclude procedures designated as requiring inpatient care under § 419.22(n) as of December 31, 2020. In other words, we would not accept any nominations for procedures to add to the ASC CPL if the procedure is on the CY 2020 IPO list. We proposed to retain the criteria at § 416.166(c)(6) through (8) and eliminate the five exclusions currently at § 416.166(c)(1) through (5) because we believed that the general standards at § 416.166(b) provide sufficient guardrails to ensure, along with appropriate patient selection and the complex medical judgment of the physician, that procedures can be performed safely on an ambulatory basis, including certain procedures that may involve these five exclusions. We explained that we believed this alternative proposal could balance the goals of increasing physician and patient choice and expanding site neutral options with patient safety considerations.

Additionally, we also proposed parameters for stakeholders to consider and specifically address in nominating procedures to add to the ASC CPL. These parameters would be general guidelines, not requirements, and we sought public comment on these suggested parameters including language changes, recommendations for additional parameters, potential unintended implications of the parameters we proposed, and whether we should finalize these parameters if this alternative proposal is finalized in the CY 2021 final rule.

We stated that we believe a nomination process will take time to develop and stakeholders will need time to consider and evaluate potential nominations. We proposed to implement this process for CY 2021 in order to accept nominations for procedures to be added to the ASC CPL beginning in CY 2022.

b. Alternative Proposal To Revise Criteria and Add Codes to the ASC–CPL

In the CY 2021 OPPS/ASC proposed rule (85 FR 4896), we also considered another alternative approach that would allow for more immediate changes to the ASC CPL for CY 2021 and beyond. Specifically, under this alternative proposal, we proposed to keep the existing general standards under 42 CFR 416.166(b) that currently require covered surgical procedures to be surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the internet on the CMS website, separately paid under the OPPS, not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. However, under this alternative proposal, we proposed to eliminate five of the current general exclusion criteria at 42 CFR 416.166(c)(1) through (5). We considered whether these five exclusionary criteria may no longer be necessary to determine what procedures can be safely added to the ASC CPL because many ASCs are currently able to safely provide services with these characteristics based on prior stakeholder feedback and public comments we have received.

We explored whether it is appropriate to remove the general exclusion criteria, which we explained would allow physicians practicing in the ASC setting, who have the greatest familiarity and insight into the needs of individual beneficiaries, to use their complex medical judgment to determine whether they can safely perform a procedure in the ASC, given the entirety of the circumstances, including the clinical profile of the patient, the surgical back-up available at the ASC, and the ability to safely and timely respond to unexpected complications. Under this alternative proposal, we stated that we would keep the remaining three general exclusion criteria at 42 CFR 416.166(c)(6) through (8), as the original reasons we adopted them in CY 2008 continue to exist, subject to the proposed modifications to § 416.166(c)(6). These criteria would continue to prohibit the addition of certain procedures to the ASC CPL, namely those that are: designated as requiring inpatient care under 42 CFR 419.22(n) as of December 31, 2020; can only be reported using a CPT unlisted surgical procedure code; or otherwise excluded under 42 CFR 411.15. We proposed to retain these criteria and eliminate the previous five criteria because we believe that the general standards alone are sufficient guardrails to ensure, along with appropriate patient selection and complex medical judgment of the physician, that the procedure can be performed safely on an ambulatory basis, including procedures that involve these five characteristics.

We noted that, with respect to the existing general exclusion at 42 CFR 416.166(c)(6), which excludes procedures designated as requiring inpatient care under 42 CFR 419.22(n) from classification as covered surgical procedures, the alternative proposal would modify this standard since the IPO list was proposed to be eliminated beginning in CY 2021, as described in section IX.B of the CY 2021 OPPS/ASC proposed rule. Therefore, we proposed to modify this criterion to exclude procedures designated as requiring inpatient care under 419.22(n) as of December 31, 2020. In other words, not all procedures on the current (that is, CY 2020) IPO list would necessarily meet the remaining revised criteria to be added to the ASC CPL. However, because any procedure not on the IPO can be performed safely on an ambulatory basis in the hospital outpatient setting, we believe that the remaining criteria in 42 CFR 416.166, most notably the exclusion of services that are on the current IPO list, could sufficiently limit the expansion of the ASC CPL to those services that can be safely performed on an ambulatory basis. As previously mentioned, we proposed to retain the criteria in § 416.166(c)(6) through (8) and

eliminate the five criteria currently at § 416.166(c)(1) through (5) because we believe that the general standards at § 416.166(b) provide sufficient guardrails to ensure, along with appropriate patient selection and the complex medical judgment of the physician, that procedures can be performed safely on an ambulatory basis, including certain procedures that may involve these five characteristics. We explained that we believed this alternative proposal could balance the goals of increasing physician and patient choice and expanding site neutral options with patient safety considerations.

We identified approximately 270 potential surgery or surgery-like codes that we believed would meet the proposed revised criteria for being added to the ASC CPL under 42 CFR 416.166. That is, we reviewed these procedures and found that they would meet the proposed revised regulatory requirements that would be in effect if we were to adopt this alternative proposal. Specifically, the identified procedures under this alternative proposal were surgical procedures that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure, that have not been designated as requiring inpatient care under § 419.22(n) as of December 31, 2020, that can be reported without using a CPT unlisted surgical procedure code, and are not otherwise excluded under 42 CFR 411.15.

Additionally, we noted that, while several of the identified procedures may typically require active medical monitoring and care at midnight following the procedure, we expect that an appropriately selected patient population in the ASC setting would be healthier and less complex and would likely not require active monitoring or medical care at midnight following the procedure. We believed that these procedures are safe to perform in an ASC setting because all procedures identified are already payable in the HOPD setting and, therefore, are already safely performed on an ambulatory basis, consistent with the statutory requirement under section 1833(i)(1) of the Act. We proposed to retain the general standard criteria, as we believe these criteria are sufficient to ensure that procedures meet the statutory requirements and can be safely performed in ASCs. We sought public comment on whether any of these procedures would typically require care after midnight, and, therefore, should not be added to the ASC CPL.

We stated that we believed this alternative proposal could have beneficial effects for Medicare beneficiaries and healthcare professionals. For beneficiaries, expansion of the ASC CPL would increase access to procedures in ambulatory surgery settings, often at a lower cost. ASCs and healthcare professionals would also benefit from this proposal as this expansion would better utilize the potential of existing healthcare resources and expand the capacity of the healthcare system. Further, under this alternative, physicians would have greater flexibility to divert patients who can be safely treated in the ASC setting away from hospitals and preserve hospital capacity for more acute patients.

We acknowledged that this approach was a departure from the existing criteria that we established effective beginning in 2008. However, we believed that this approach would expand and build upon our 2008 policy intent. In the August 2, 2007 final rule with comment period, we discussed criteria for procedures excluded from the ASC CPL under the revised ASC payment system (72 FR 42478 through 42484). However, although there are differences, much of the underlying rationale we used to develop the August 2, 2007 final rule revised criteria remains true under the broader CY 2021 proposal. For example, in the August 2, 2007 final rule with comment period, we indicated that we believed that any procedure for which we did not allow payment in the hospital outpatient setting due to safety concerns would not be safe to perform in an ASC (72 FR 42478). Much like we are considering now, we excluded from the ASC list any procedure on the IPO list, and committed to excluding surgical procedures that pose significant safety risks to beneficiaries or that are expected to require an overnight stay (72 FR 42478 through 42479). Although there are some differences when comparing our CY 2008 criteria and the proposed CY 2021 criteria, such as removing several of the original general exclusion criteria, permitting the addition of procedures to the ASC CPL that would have been prohibited by those criteria, and the different accreditation requirements and conditions of participation requirements between HOPDS and ASCs, these concerns have largely been addressed by the progress in medical practice and ASC capabilities in the twelve years since the criteria were developed as previously noted. We noted that, in particular, given advances in the practice of medicine and the evolving nature of ASCs, we believe ASCs are now better equipped to safely perform procedures that were once too complex or risky to be performed safely on Medicare beneficiaries in the ASC setting. As previously mentioned, although ASCs and hospitals have different health and safety requirements, many ASCs often undergo accreditation as a condition of state licensure and share some similar licensure and compliance requirements with hospitals. We recognized that each of these requirements provides additional safeguards for the health and safety of Medicare beneficiaries receiving surgical procedures in an ASC.

(3) Comment Solicitation on Potential Revisions to the ASC Conditions for Coverage if Alternative 2 Is Adopted

In the proposed rule (85 FR 48962), we stated that we were considering allowing more invasive and lengthy surgical procedures to be performed in ASCs. We were seeking public input regarding what revisions to the ASC CfCs would be needed, if any, to ensure patient safety in response to the additional range of complex services that would be added to the ASC–CPL and noted that we might adopt such revisions as final in the CY 2021 final rule.

We also solicited comments on specific examples contained within the current ASC CfCs. We noted that we were especially interested in public comments about some specific CfCs and whether they should be more prescriptive and require additional elements. Those items included expanded risk evaluations, additional nursing personnel, requiring staff be trained in Advanced Cardiac Life Support, and the requirement that ASCs identify certain patient conditions or more complex procedures that require a medical history and physical examination prior to surgery.

(3) Summary of Proposals

For CY 2021, we proposed to add eleven procedures using the standard ASC CPL review process under our current regulations. In addition, we included two alternative proposals that we noted that we might finalize for CY 2021. One alternative was to establish a nomination process for CY 2021, which would allow us to propose to add nominated procedures beginning in CY 2022. Under this proposal, external stakeholders, such as professional

specialty societies, would nominate procedures that can be safely performed in the ASC setting based on the requirements in the ASC regulations, revised as described in the CY 2021 OPPS/ASC proposed rule (that is, retaining the general standard criteria and eliminating five of the general exclusion criteria), along with suggested parameters and all other regulatory standards. CMS would review and finalize procedures through annual rulemaking.

Alternatively, we proposed to revise the ASC CPL criteria under 42 CFR 416.166, retaining the general standard criteria and eliminating five of the general exclusion criteria. Using these revised criteria, we proposed to add approximately 270 potential surgery or surgery-like codes to the CPL that are not on the CY 2020 IPO list. We proposed to finalize only one of these alternative proposals, and we welcomed public comment as to which policy should be adopted in the final rule.

After consideration of the issues discussed earlier in this section, we noted that we believed that these proposed policies struck an appropriate balance between flexibility for physicians to exercise their complex medical judgment in factoring in patient safety considerations and flexibility for patients to choose from more settings of care in which to receive surgical procedures.

Comment: Many commenters were concerned that the alternative proposal to revise the general exclusion criteria at 42 CFR 416.166(c) and add 267 potential surgery or surgery-like procedures that are not on the current IPO list to the ASC–CPL list would not give adequate consideration to patient safety or stakeholder input. One commenter urged CMS not to finalize this alternative proposal, which the commenter believed would eliminate several safety ''guardrails.'' Another commenter stated that CMS should not remove the proposed exclusion criteria for the ASC CPL at 42 CFR 416.166(c) in light of what the commenter believed were oversight, quality, and safety concerns. Specifically, the commenter felt that procedures excluded by these safeguards were major and potentially life-threatening procedures that were appropriately excluded from ASCs, ASCs are not generally equipped to handle extensive blood loss or emergent and life-threatening procedures, the time waiting for emergency transport to a hospital would potentially place beneficiary life in jeopardy, and that these risks may occur even if a physician believes that the individual beneficiary's clinical condition would allow these procedures to be performed in an ASC.

Several commenters supported the alternative proposal to revise the general exclusion criteria at 42 CFR 416.166(c) and add 267 potential surgery or surgery-like procedures not on the current IPO list to the ASC CPL. They believed that medical research and technological advances have allowed for similar outcomes and a comparable quality of care for patients in both the outpatient hospital and ASC settings. One commenter supported this alternative proposal because they believed expanding the ASC CPL would increase the availability of ASCs as alternative care sites and preserve inpatient hospital capacity for higher acuity patients. The commenter agreed with CMS that significant advancements in medical practice, surgical techniques, and technology have allowed certain ASCs to perform procedures that were once too complex to be safely performed in an ASC.

Some commenters urged CMS not to treat ASCs as the equivalent of hospital outpatient departments because, as the commenter explained, they are not regulated as hospitals and do not have the necessary resources on site to provide the higher level of care necessary to perform many of the surgical procedures we would add to the ASC CPL if our proposal is finalized.

One commenter supported removing the five exclusionary criteria at 42 CFR 416.166(c)(1) through (5), stating that physicians are best equipped to make decisions about site of service for their patients.

Response: Under § 416.166, covered surgical procedures are those surgical procedures that meet the general standards specified in § 416.166(b) and are not excluded under the general exclusion criteria specified in § 416.166(c). Both of our alternatives included a proposal to eliminate the exclusion criteria at § 416.166(c)(1) through (5), which currently require that covered surgical procedures do not include procedures that: (1) Generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life threatening in nature; or (5) commonly require systemic thrombolytic therapy. While these are important considerations in determining whether a surgical procedure may be safely performed in an ASC, we considered that it may no longer be necessary for CMS to apply these five exclusionary criteria because, as we have heard from many stakeholders, ASCs are currently and increasingly able to safely provide services with these characteristics.

We have previously recognized the importance of increasing flexibility in our review of procedures for safe performance in the ASC setting, and we have been able to add surgical procedures to the ASC CPL that were once considered hospital inpatient procedures, including, for example, total knee arthroplasty and certain coronary intervention procedures involving major blood vessels. We believe it important that we adapt the ASC CPL in light of the significant advances in medical practice, surgical techniques, and ASC capabilities that have enabled some ASCs to safely perform procedures that were once too complex for the ASC setting, including those involving major blood vessels and other general exclusion criteria. Indeed, as we noted earlier, many procedures that are currently only payable as hospital outpatient services under Medicare are safely performed in the ASC setting for other payors. We acknowledge that non-Medicare patients tend to be younger and have fewer comorbidities than the Medicare population, but careful patient selection can identify Medicare beneficiaries who are suitable candidates to receive these services in the ASC setting. We have long recognized the importance of ensuring that the health care system has as many access points and patient choices for all Medicare beneficiaries as possible, and we believe it is important that we continue to support greater flexibility for physicians and patients to choose ASCs as the site of care in supporting those important goals.

We agree with commenters who support our proposal to revise the general exclusion criteria at § 416.166(c), to eliminate § 416.166(c)(1) through (5), because medical advances and careful patient selection have allowed procedures that were once too complex for the ASC setting to now be safely performed in ASCs. Importantly, physicians have always played a critically significant role in determining the appropriate site of care for their patients, and we believe it is appropriate that patient choice and physician judgement determine whether a surgical procedure may be safely performed in the ASC setting for each individual patient. Therefore, we are finalizing our proposal for CMS to no longer apply the exclusion criteria at § 416.166(c)(1) through (5) beginning on January 1, 2021. However, while CMS will no longer apply those five criteria in determining whether a procedure is a covered surgical procedure, we believe they are important safety factors that

physicians consider in making site-of-service determinations for their specific beneficiaries. Accordingly, general exclusions one through five will continue to be displayed under a new paragraph (d) titled ''Physician considerations beginning January 1, 2021,'' at § 416.166(d) for physicians to consider in selecting the most appropriate site of service for their patients.

Consistent with our recognition of the primary importance of the role physicians play in exercising their clinical judgment for each specific patient to assess whether a covered surgical procedure can be safely performed in the ASC setting, for all the same reasons we identify above, we are also recognizing that physicians are better-positioned than CMS to determine that a surgical procedure is not expected to pose a significant safety risk for a specific beneficiary and is one for which standard medical practice for the specific beneficiary dictates the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. While these two considerations, currently reflected in § 416.166(b), are ones that CMS has made to date in determining whether a surgical procedure is a covered surgical procedure, we are also shifting the responsibility for these two considerations from CMS to physicians, as now reflected in § 416.166(d)(1) and (2).

CMS will continue to designate procedures as covered surgical procedures. That is, we will continue to determine that surgical procedures can be covered surgical procedures if, under current § 416.166(b), they are separately paid under the OPPS, and, under current § 416.166(c)(6) through (8), are not designated as requiring inpatient care under 42 CFR 419.22(n), are not only able to be reported using a CPT unlisted surgical procedure code, or are not otherwise excluded under 42 CFR 411.15. We are revising § 416.166(b) to reflect these requirements for procedures to be designated by CMS as covered surgical procedures. With regard to the criterion at current § 416.166(c)(6), that is, covered surgical procedures are those not designated as requiring inpatient care under 42 CFR 419.22(n), as described in section IX.B. of the CY 2021 OPPS/ASC proposed rule, CMS is eliminating the OPPS IPO list and amending 42 CFR 419.22(n) to state that effective beginning on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a three-year transition, with the IPO list eliminated in its entirety by January 1, 2024. Therefore, we are specifying in revised § 416.166(b) that covered surgical procedures may not include those surgical procedures that are designated as requiring inpatient care under 42 CFR 419.22(n) as of December 31, 2020. If CMS determines that a surgical procedure meets the four requirements at revised § 416.166(b), CMS will designate the procedure a covered surgical procedure and place it on the ASC CPL. Physicians then have the opportunity to assess whether their specific patients can or cannot safely receive such covered surgical procedure in the ASC setting based on the considerations now reflected in § 416.166(d).

We disagree with the commenters who believe that expansion of the ASC CPL would negatively affect beneficiary safety or quality of care. We believe the policy we are finalizing to allow patients and physicians to determine the most appropriate site of care for an individual patient will continue to ensure patient safety. As we discuss above, physicians and patients are best-positioned to make patient-specific site-of-service determinations for their individual patients. Physicians have the greatest familiarity with and understanding of the needs of their individual patients and will use their complex medical judgment to determine whether a procedure can be safely performed in the ASC, given their patients' clinical profiles, available surgical back-up at the ASC, and the ability to safely and timely respond to unexpected complications, among other important considerations.

We believe there are numerous other safety considerations that will affect a physician's decision to perform a particular service in the ASC setting, separate from the inclusion of the procedure on the ASC CPL and the physician's medical judgment. These include the Medicare Conditions for Coverage (CfCs), Medicare's ASC quality rating program (ASCQR), public and private accreditations and certifications, malpractice insurance premiums, and the pressures of market competition, all of which could be negatively impacted if an ASC does not appropriately take patient safety concerns into account when deciding to perform a particular procedure in the ASC setting. We are confident that all of these factors will help to ensure facilities and providers carefully assess each patient and determine the most appropriate site of service for procedures on the ASC CPL.

In accordance with our final policy that CMS will apply the four criteria at new § 416.166(b)(2), we are adding the 267 surgery and surgery-like codes to the ASC CPL we proposed to add under the second alternative because they meet the requirements at new § 416.166(b)(2). This policy is in keeping with our policy changes made in recent years to further site neutrality between the HOPD and ASC settings. With this addition of procedures to the ASC CPL, CMS is making available a broader range of surgical procedures that Medicare will pay for when performed in the ASC setting, which will further increase the availability of ASCs as an alternative site of care for Medicare beneficiaries, while also ensuring patient safety through CMS's and physicians' respective roles in determining that procedures can be safely performed in an ASC.

Physicians are not required to maintain new documentation of their determination that procedures meet the revised CPL regulatory criteria, beyond what they are already required by Medicare. At this time, we believe that additional documentation and compliance activities associated with the revision of the CPL criteria are not necessary, as we noted earlier there remain many factors that encourage ASCs and physicians to appropriately consider patient safety in making site-of-service determinations for individual beneficiaries.

Comment: The majority of commenters supported the alternative proposal to establish a process for the public to nominate procedures for addition to the ASC CPL. These commenters generally supported this proposal because they believed it would better address beneficiary safety concerns than the alternative proposal to remove the general exclusion criteria at § 416.166(c)(1) through (5). Several commenters noted that this alternative proposal would formalize the review process that occurs currently, provide transparency, and increase opportunity for engagement with providers and external stakeholders. One commenter believed that establishing a formal nomination process would streamline the process for specialty societies to suggest procedures that can be safely performed in ASCs. Several commenters believed a nomination process would avoid the potential patient safety risks associated with adding 267 procedures to the ASC CPL before stakeholders are able to review the procedures and analyze whether they are appropriate to furnish in an ASC. One commenter believed that CMS should formalize a stakeholder nomination process for future years with greater transparency and standardization. Another commenter recommended that CMS

give greater consideration to nominations from professional specialty societies, which include physicians who have clinical expertise regarding procedures that can be performed in an ASC.

A number of commenters, largely hospitals and hospital associations, opposed both alternatives and raised safety concerns about expanding the ASC CPL. These commenters stated that both proposals would ''substantially weaken the agency's process'' and explained that Medicare beneficiary safety and quality of care could be negatively affected if Medicare pays for these higher risk surgical procedures when performed in an ASC. A few commenters believed we should finalize both alternative proposals, which they viewed as complementary and not mutually exclusive. Another commenter felt that finalizing both proposals would remove a barrier to physicians exercising their clinical judgment as to the appropriate setting of care for a particular patient.

Response: In the CY 2021 OPPS/ASC proposed rule (85 FR 48959), we proposed a nomination process that would involve CMS updating the ASC CPL if we determined that a nominated procedure met the requirements for covered surgical procedures under the regulations at 42 CFR 416.166, as we proposed to amend them. We proposed that the nomination process would be conducted through annual notice and comment rulemaking such that stakeholders would nominate surgical procedures they believed should be added to the ASC CPL by March 1, and CMS would propose and potentially finalize those nominated procedures for addition to the ASC CPL in the next applicable rulemaking cycle. We explained in the proposed rule that we believed a nomination process would provide external stakeholders, including specialty societies and physicians, a formalized process for notifying CMS of procedures that should be added to the ASC CPL. As with our other alternative proposal, we also proposed that we would revise the general exclusion criteria at § 416.166(c) by eliminating § 416.166(c)(1) through (5).

With regard to the proposal to eliminate the general exclusions at § 416.166(c), which as we noted was a common feature of both alternative proposals, we discussed previously in this section that we are finalizing this proposal beginning January 1, 2021. We believe physicians may consider each of those five safety factors at current § 416.166(c)(1) through (5) in making site-of-service determinations for their specific beneficiaries. In addition, we explained that physicians will now consider whether a surgical procedure is not expected to pose a significant safety risk for specific beneficiaries and is one for which standard medical practice dictates the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure—criteria at § 416.166(b) that have until now been part of CMS's process for adding procedures to the ASC CPL. While CMS will still designate surgical procedures as covered surgical procedures and add them to the ASC CPL, we will apply only the following four criteria. The procedure is: (1) Separately paid under the OPPS; (2) not designated as requiring inpatient care under § 419.22(n) as of December 31, 2020; (3) not only able to be reported using a CPT unlisted surgical procedure code; or (4) not otherwise excluded under § 411.15.

In light of the policies we are finalizing, we believe it is still appropriate for us to adopt a process whereby stakeholders notify CMS of procedures to be added to the ASC CPL, but a slightly different and simpler process than the nomination process alternative we proposed. We agree with commenters that a formalized process whereby the public notifies CMS of procedures to be added to the ASC CPL would provide more transparency and increase opportunities for CMS to engage with providers and external stakeholders in adding procedures to the ASC CPL. However, because CMS will now be applying only the four criteria listed in new § 416.166(b)(2) to determine whether a surgical procedure is a covered surgical procedure, and given that CMS's role will be more limited than it was when it applied the more subjective safety criteria, CMS will be able to more expeditiously determine whether a surgical procedure meets the regulatory requirements for inclusion on the ASC CPL, and therefore, we do not believe a full nomination process is necessary.

CMS will add surgical procedures to the ASC CPL as we become aware of new surgical procedures that meet the four requirements at new § 416.166(b)(2), but we expect the industry may become aware of other procedures that CMS may not know about, and has therefore not considered for inclusion on the ASC CPL. In that case, a member of the public may notify CMS of a surgical procedure any time they believe a surgical procedure meets the requirements at new § 416.166(b)(2). CMS will confirm whether the procedure does in fact meet those requirements and will add it to the ASC CPL if it does. In accordance with the new regulations we are finalizing at new § 416.166(d), physicians will then assess whether their specific patients can or cannot safely receive such covered surgical procedure in the ASC setting based on the patient-specific considerations reflected in new § 416.166(d). The process we are finalizing is not a nominations process so much as a notification process, which we are adding at new § 416.166(e), titled ''Additions to the list of ASC covered surgical procedures beginning January 1, 2021,'' to provide that we will add surgical procedures to the ASC CPL as follows: (1) CMS identifies a surgical procedure that meets the requirements at paragraph (b)(2) of this section. (2) CMS is notified of a surgical procedure that could meet the requirements at paragraph (b)(2) of this section and CMS confirms that such surgical procedure meets those requirements.

Comment: In the CY 2021 OPPS/ASC proposed rule (85 FR 48959 through 48960), we suggested parameters for stakeholders to use when evaluating procedures for nomination. Two commenters agreed that the parameters were appropriate and would be essential considerations during the proposed nomination process but recommended modifications, such as removing the fourth parameter on nearby facilities or adding an additional parameter evaluating whether data are available to inform the appropriate clinical support and monitoring for patients in an ASC setting. Another commenter noted that the parameters were a useful baseline for adding procedures and could be refined with exceptions or counterexamples in future years.

Response: We thank the commenters for their feedback. We proposed that stakeholders would consider the parameters we described in the proposed rule and address them in a nomination process. As we have indicated, we are not adopting the nomination process described in the proposed rule. Rather, we are adopting a simpler approach whereby entities may notify CMS of procedures they believe meet the four requirements at new § 416.166(b)(2). If CMS confirms a procedure does meet those four requirements, CMS will add it to the ASC CPL. At that point, it will be up to physicians to determine whether a procedure on the ASC CPL is safe for their specific patients to receive in an ASC. We are not adopting the parameters we discussed in the proposed rule because we are not adopting the more formal nomination process we described in that rule. However, in keeping with our final

policies, which emphasize the importance of physicians' safety determinations for their specific patients in deciding whether to perform a covered surgical procedure in an ASC, physicians should find the parameters useful in deciding whether to perform a covered surgical procedure on a particular ASC patient.

Comment: We received a few comments that specifically addressed the requested information regarding the expansion of the existing ASC CfCs. Commenters that supported adopting the alternative proposal to revise the criteria and add additional procedures to the ASC CPL did not believe it would be necessary to change the ASC CfCs if the alternative proposal is finalized. Commenters that did not support the proposed changes to the ASC CPL process and criteria suggested that CMS expand the ASC CfCs if either of the alternative proposals is finalized. One commenter also suggested that CMS reinstate the CFCs that were removed in the 2019 Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction final rule (84 FR 51732, 51737 through 52739). Other commenters recommended we work with clinical experts and other stakeholders to make appropriate changes to the CfCs.

Response: We thank the commenters for their helpful responses to the RFI. In keeping with our efforts to reduce provider burden and our stated objectives of prioritizing patient choice and physician judgement in determining the most appropriate site of service for a beneficiary, we are declining to modify the ASC CfCs at this time. We believe there are numerous considerations which effectively incentivize careful patient selection in ASCs, including accreditation requirements, insurer and provider privileges, state licensure requirements, and competitive market forces, to name only a few. Additionally, we will continue all measures described in our current CfCs and in Appendix L of the State Operations Manual. We may revisit modifying the ASC CfCs in the future should the need arise.

After consideration of the public comments we received, we are finalizing our proposal to add eleven procedures using the standard ASC CPL review process under our current regulations. In addition, we are revising the definition of covered surgical procedures at § 416.166(a) to conform to the changes we are making to the requirements for covered surgical procedures at § 416.166(b)(1) and (2) and (c), whereby CMS will determine whether the four specified criteria are met as the basis for adding surgical procedures to the ASC CPL. CMS will add 267 procedures to the ASC CPL, based upon these changes to the regulatory criteria. We also recognize that physicians may consider certain safety factors when determining the most appropriate site of care for a specific patient. We are adding a new § 416.166(d) to reflect these considerations. Finally, we are adding new § 416.166(e), which describes how CMS will add a surgical procedure to the ASC CPL, either on its own initiative or based on a notification from the public that a procedure not currently on the ASC CPL meets the criteria for addition to the ASC CPL.

New CPT and HCPCS codes for covered procedures and their final payment indicators for CY 2021 can be found in section XIII.B of this CY 2021 OPPS/ASC Final Rule. All ASC covered procedures and their final payment indicators for CY 2021 are also included in Addendum BB to this CY 2021 OPPS/ASC final rule (which is available via the internet on the CMS website).

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TABLE 59: FINAL ADDITIONS TO THE LIST OF ASC COVERED SURGICAL PROCEDURES FOR CY 2021 UNDER STANDARD REVIEW PROCESS

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	J8
0268T	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	J8
0404T	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency	G2
21365	Open treatment of complicated (e.g., comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with internal fixation and multiple surgical approaches	G2
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft	J8
27412	Autologous chondrocyte implantation, knee	G2
57282	Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus)	G2
57283	Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy)	G2
57425	Laparoscopy, surgical, colpopexy (suspension of vaginal apex)	G2
C9764	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed	G2
C9766	Revascularization, endovascular, open or percutaneous, any vessel (s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed	G2

TABLE 60: FINAL ADDITIONS TO THE ASC CPL UNDER SECOND ALTERNATIVE PROPOSAL CONSIDERED FOR CY 2021

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
19307	Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle	G2
20100	Exploration of penetrating wound (separate procedure); neck	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
20101	Exploration of penetrating wound (separate procedure); chest	G2
20102	Exploration of penetrating wound (separate procedure); abdomen/flank/back	G2
20660	Application of cranial tongs, caliper, or stereotactic frame, including removal (separate procedure)	G2
21049	Excision of benign tumor or cyst of maxilla; requiring extra-oral osteotomy and partial maxillectomy (eg, locally aggressive or destructive lesion[s])	G2
21172	Reconstruction superior-lateral orbital rim and lower forehead, advancement or alteration, with or without grafts (includes obtaining autografts)	G2
21175	Reconstruction, bifrontal, superior-lateral orbital rims and lower forehead, advancement or alteration (eg, plagiocephaly, trigonocephaly, brachycephaly), with or without grafts (includes obtaining autografts)	G2
21193	Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; without bone graft	G2
21195	Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation	J8
21256	Reconstruction of orbit with osteotomies (extracranial) and with bone grafts (includes obtaining autografts) (eg, micro-ophthalmia)	G2
21261	Periorbital osteotomies for orbital hypertelorism, with bone grafts; combined intra- and extracranial approach	G2
21263	Periorbital osteotomies for orbital hypertelorism, with bone grafts; with forehead advancement	G2
21346	Open treatment of nasomaxillary complex fracture (lefort ii type); with wiring and/or local fixation	G2
21365	Open treatment of complicated (eg, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with internal fixation and multiple surgical approaches	G2
21385	Open treatment of orbital floor blowout fracture; transantral approach (caldwell-luc type operation)	G2
21386	Open treatment of orbital floor blowout fracture; periorbital approach	G2
21387	Open treatment of orbital floor blowout fracture; combined approach	G2
21395	Open treatment of orbital floor blowout fracture; periorbital approach with bone graft (includes obtaining graft)	G2
21408	Open treatment of fracture of orbit, except blowout; with bone grafting (includes obtaining graft)	G2
21470	Open treatment of complicated mandibular fracture by multiple surgical approaches including internal fixation, interdental fixation, and/or wiring of dentures or splints	J8
21601	Excision of chest wall tumor including rib(s)	G2
21742	Reconstructive repair of pectus excavatum or carinatum; minimally invasive approach (nuss procedure), without thoracoscopy	G2
21743	Reconstructive repair of pectus excavatum or carinatum; minimally invasive approach (nuss procedure), with thoracoscopy	G2
22100	Partial excision of posterior vertebral component (eg, spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; cervical	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
22101	Partial excision of posterior vertebral component (eg, spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; thoracic	G2
23470	Arthroplasty, glenohumeral joint; hemiarthroplasty	J8
23473	Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component	J8
24150	Radical resection of tumor, shaft or distal humerus	G2
24935	Stump elongation, upper extremity	G2
25170	Radical resection of tumor, radius or ulna	G2
25909	Amputation, forearm, through radius and ulna; re-amputation	G2
27006	Tenotomy, abductors and/or extensor(s) of hip, open (separate procedure)	G2
27027	Decompression fasciotomy(ies), pelvic (buttock) compartment(s) (eg, gluteus medius-minimus, gluteus maximus, iliopsoas, and/or tensor fascia lata muscle), unilateral	G2
27057	Decompression fasciotomy(ies), pelvic (buttock) compartment(s) (eg, gluteus medius-minimus, gluteus maximus, iliopsoas, and/or tensor fascia lata muscle) with debridement of nonviable muscle, unilateral	G2
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft	J8
27179	Open treatment of slipped femoral epiphysis; osteoplasty of femoral neck (heyman type procedure)	G2
27235	Percutaneous skeletal fixation of femoral fracture, proximal end, neck	G2
27412	Autologous chondrocyte implantation, knee	G2
27477	Arrest, epiphyseal, any method (eg, epiphysiodesis); tibia and fibula, proximal	J8
27485	Arrest, hemiepiphyseal, distal femur or proximal tibia or fibula (eg, genu varus or valgus)	G2
27722	Repair of nonunion or malunion, tibia; with sliding graft	J8
28360	Reconstruction, cleft foot	G2
28805	Amputation, foot; transmetatarsal	G2
29868	Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral	G2
31241	Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery	G2
31292	Nasal/sinus endoscopy, surgical, with orbital decompression; medial or inferior wall	G2
31293	Nasal/sinus endoscopy, surgical, with orbital decompression; medial and inferior wall	G2
31294	Nasal/sinus endoscopy, surgical, with optic nerve decompression	G2
31584	Laryngoplasty; with open reduction and fixation of (eg, plating) fracture, includes tracheostomy, if performed	G2
31587	Laryngoplasty, cricoid split, without graft placement	G2
31600	Tracheostomy, planned (separate procedure);	G2
31601	Tracheostomy, planned (separate procedure); younger than 2 years	G2
31610	Tracheostomy, fenestration procedure with skin flaps	G2
31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe	J8
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes	J8
31785	Excision of tracheal tumor or carcinoma; cervical	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
32551	Tube thoracostomy, includes connection to drainage system (eg, water seal), when performed, open (separate procedure)	G2
32560	Instillation, via chest tube/catheter, agent for pleurodesis (eg, talc for recurrent or persistent pneumothorax)	G2
32561	Instillation(s), via chest tube/catheter, agent for fibrinolysis (eg, fibrinolytic agent for break up of multiloculated effusion); initial day	G2
32562	Instillation(s), via chest tube/catheter, agent for fibrinolysis (eg, fibrinolytic agent for break up of multiloculated effusion); subsequent day	G2
32601	Thoracoscopy, diagnostic (separate procedure); lungs, pericardial sac, mediastinal or pleural space, without biopsy	G2
32604	Thoracoscopy, diagnostic (separate procedure); pericardial sac, with biopsy	G2
32606	Thoracoscopy, diagnostic (separate procedure); mediastinal space, with biopsy	G2
32607	Thoracoscopy; with diagnostic biopsy(ies) of lung infiltrate(s) (eg, wedge, incisional), unilateral	G2
32608	Thoracoscopy; with diagnostic biopsy(ies) of lung nodule(s) or mass(es) (eg, wedge, incisional), unilateral	G2
32609	Thoracoscopy; with biopsy(ies) of pleura	G2
33244	Removal of single or dual chamber implantable defibrillator electrode(s); by transvenous extraction	G2
33272	Removal of subcutaneous implantable defibrillator electrode	G2
34101	Embolectomy or thrombectomy, with or without catheter; axillary, brachial, innominate, subclavian artery, by arm incision	G2
34111	Embolectomy or thrombectomy, with or without catheter; radial or ulnar artery, by arm incision	G2
34201	Embolectomy or thrombectomy, with or without catheter; femoropopliteal, aortoiliac artery, by leg incision	G2
34203	Embolectomy or thrombectomy, with or without catheter; popliteal-tibio-peroneal artery, by leg incision	G2
34421	Thrombectomy, direct or with catheter; vena cava, iliac, femoropopliteal vein, by leg incision	G2
34471	Thrombectomy, direct or with catheter; subclavian vein, by neck incision	G2
34501	Valvuloplasty, femoral vein	G2
34510	Venous valve transposition, any vein donor	G2
34520	Cross-over vein graft to venous system	G2
34530	Saphenopopliteal vein anastomosis	G2
35011	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm and associated occlusive disease, axillary-brachial artery, by arm incision	G2
35045	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm, pseudoaneurysm, and associated occlusive disease, radial or ulnar artery	G2
35180	Repair, congenital arteriovenous fistula; head and neck	G2
35184	Repair, congenital arteriovenous fistula; extremities	G2
35190	Repair, acquired or traumatic arteriovenous fistula; extremities	G2
35201	Repair blood vessel, direct; neck	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
35206	Repair blood vessel, direct; upper extremity	G2
35226	Repair blood vessel, direct; lower extremity	G2
35231	Repair blood vessel with vein graft; neck	G2
35236	Repair blood vessel with vein graft; upper extremity	G2
35256	Repair blood vessel with vein graft; lower extremity	G2
35261	Repair blood vessel with graft other than vein; neck	G2
35266	Repair blood vessel with graft other than vein; upper extremity	G2
35286	Repair blood vessel with graft other than vein; lower extremity	G2
35321	Thromboendarterectomy, including patch graft, if performed; axillary-brachial	G2
35860	Exploration for postoperative hemorrhage, thrombosis or infection; extremity	G2
35879	Revision, lower extremity arterial bypass, without thrombectomy, open; with vein patch angioplasty	G2
35881	Revision, lower extremity arterial bypass, without thrombectomy, open; with segmental vein interposition	G2
35883	Revision, femoral anastomosis of synthetic arterial bypass graft in groin, open; with nonautogenous patch graft (eg, dacron, eptfe, bovine pericardium)	G2
35884	Revision, femoral anastomosis of synthetic arterial bypass graft in groin, open; with autogenous vein patch graft	G2
35903	Excision of infected graft; extremity	G2
36460	Transfusion, intrauterine, fetal	G2
36838	Distal revascularization and interval ligation (dril), upper extremity hemodialysis access (steal syndrome)	G2
37183	Revision of transvenous intrahepatic portosystemic shunt(s) (tips) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract recannulization/dilatation, stent placement and all associated imaging guidance and documentation)	J8
37191	Insertion of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	J8
37192	Repositioning of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	J8
37193	Retrieval (removal) of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	G2
37195	Thrombolysis, cerebral, by intravenous infusion	G2
37213	Transcatheter therapy, arterial or venous infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, continued treatment on subsequent day during course of thrombolytic therapy, including follow-up catheter contrast injection, position change, or exchange, when performed;	G2
37214	Transcatheter therapy, arterial or venous infusion for thrombolysis other than coronary, any method, including radiological supervision and	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
	interpretation, continued treatment on subsequent day during course of thrombolytic therapy, including follow-up catheter contrast injection, position change, or exchange, when performed; cessation of thrombolysis including removal of catheter and vessel closure by any method	
37244	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation	J8
37565	Ligation, internal jugular vein	G2
37600	Ligation; external carotid artery	G2
37605	Ligation; internal or common carotid artery	G2
37606	Ligation; internal or common carotid artery, with gradual occlusion, as with selverstone or crutchfield clamp	G2
37615	Ligation, major artery (eg, post-traumatic, rupture); neck	G2
37619	Ligation of inferior vena cava	G2
38120	Laparoscopy, surgical, splenectomy	G2
38207	Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage	G2
38208	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing, per donor	G2
38209	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, with washing, per donor	G2
38210	Transplant preparation of hematopoietic progenitor cells; specific cell depletion within harvest, t-cell depletion	G2
38211	Transplant preparation of hematopoietic progenitor cells; tumor cell depletion	G2
38212	Transplant preparation of hematopoietic progenitor cells; red blood cell removal	G2
38213	Transplant preparation of hematopoietic progenitor cells; platelet depletion	G2
38214	Transplant preparation of hematopoietic progenitor cells; plasma (volume) depletion	G2
38215	Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma, mononuclear, or buffy coat layer	G2
38240	Hematopoietic progenitor cell (hpc); allogeneic transplantation per donor	G2
38531	Biopsy or excision of lymph node(s); open, inguinofemoral node(s)	G2
38720	Cervical lymphadenectomy (complete)	G2
39401	Mediastinoscopy; includes biopsy(ies) of mediastinal mass (eg, lymphoma), when performed	G2
39402	Mediastinoscopy; with lymph node biopsy(ies) (eg, lung cancer staging)	G2
42842	Radical resection of tonsil, tonsillar pillars, and/or retromolar trigone; without closure	G2
42844	Radical resection of tonsil, tonsillar pillars, and/or retromolar trigone; closure with local flap (eg, tongue, buccal)	G2
43020	Esophagotomy, cervical approach, with removal of foreign body	G2
43280	Laparoscopy, surgical, esophagogastric fundoplasty (eg, nissen, toupet procedures)	G2

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43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh	G2
43282	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; with implantation of mesh	G2
43420	Closure of esophagostomy or fistula; cervical approach	G2
43510	Gastrotomy; with esophageal dilation and insertion of permanent intraluminal tube (eg, celestin or mousseaux-barbin)	G2
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum	J8
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum	G2
43651	Laparoscopy, surgical; transection of vagus nerves, truncal	G2
43652	Laparoscopy, surgical; transection of vagus nerves, selective or highly selective	G2
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)	J8
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only	G2
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only	G2
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components	G2
43830	Gastrostomy, open; without construction of gastric tube (eg, stamm procedure) (separate procedure)	G2
43831	Gastrostomy, open; neonatal, for feeding	G2
44180	Laparoscopy, surgical, enterolysis (freeing of intestinal adhesion) (separate procedure)	G2
44186	Laparoscopy, surgical; jejunostomy (eg, for decompression or feeding)	G2
44950	Appendectomy;	G2
44955	Appendectomy; when done for indicated purpose at time of other major procedure (not as separate procedure) (list separately in addition to code for primary procedure)	N1
44970	Laparoscopy, surgical, appendectomy	G2
47370	Laparoscopy, surgical, ablation of 1 or more liver tumor(s); radiofrequency	G2
47371	Laparoscopy, surgical, ablation of 1 or more liver tumor(s); cryosurgical	G2
47490	Cholecystostomy, percutaneous, complete procedure, including imaging guidance, catheter placement, cholecystogram when performed, and radiological supervision and interpretation	G2
49185	Sclerotherapy of a fluid collection (eg, lymphocele, cyst, or seroma), percutaneous, including contrast injection(s), sclerosant injection(s), diagnostic study, imaging guidance (eg, ultrasound, fluoroscopy) and radiological supervision and interpretation when performed	G2
49323	Laparoscopy, surgical; with drainage of lymphocele to peritoneal cavity	G2
49405	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); visceral (eg, kidney, liver, spleen, lung/mediastinum), percutaneous	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
49491	Repair, initial inguinal hernia, preterm infant (younger than 37 weeks gestation at birth), performed from birth up to 50 weeks postconception age, with or without hydrocelectomy; reducible	G2
49492	Repair, initial inguinal hernia, preterm infant (younger than 37 weeks gestation at birth), performed from birth up to 50 weeks postconception age, with or without hydrocelectomy; incarcerated or strangulated	G2
50020	Drainage of perirenal or renal abscess, open	G2
50541	Laparoscopy, surgical; ablation of renal cysts	G2
50542	Laparoscopy, surgical; ablation of renal mass lesion(s), including intraoperative ultrasound guidance and monitoring, when performed	G2
50543	Laparoscopy, surgical; partial nephrectomy	G2
50544	Laparoscopy, surgical; pyeloplasty	G2
50945	Laparoscopy, surgical; ureterolithotomy	G2
51060	Transvesical ureterolithotomy	G2
51845	Abdomino-vaginal vesical neck suspension, with or without endoscopic control (eg, stamey, raz, modified pereyra)	G2
51860	Cystorrhaphy, suture of bladder wound, injury or rupture; simple	G2
51990	Laparoscopy, surgical; urethral suspension for stress incontinence	G2
53500	Urethrolysis, transvaginal, secondary, open, including cystourethroscopy (eg, postsurgical obstruction, scarring)	G2
54332	1-stage proximal penile or penoscrotal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap	G2
54336	1-stage perineal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap	G2
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue	J8
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue	J8
54535	Orchiectomy, radical, for tumor; with abdominal exploration	G2
54650	Orchiopexy, abdominal approach, for intra-abdominal testis (eg, fowler-stephens)	G2
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed	G2
55970	Intersex surgery; male to female	G2
55980	Intersex surgery; female to male	G2
57106	Vaginectomy, partial removal of vaginal wall;	G2
57107	Vaginectomy, partial removal of vaginal wall; with removal of paravaginal tissue (radical vaginectomy)	G2
57109	Vaginectomy, partial removal of vaginal wall; with removal of paravaginal tissue (radical vaginectomy) with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling (biopsy)	G2
57282	Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus)	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
57283	Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy)	G2
57284	Paravaginal defect repair (including repair of cystocele, if performed); open abdominal approach	G2
57285	Paravaginal defect repair (including repair of cystocele, if performed); vaginal approach	G2
57292	Construction of artificial vagina; with graft	G2
57330	Closure of vesicovaginal fistula; transvesical and vaginal approach	G2
57335	Vaginoplasty for intersex state	G2
57423	Paravaginal defect repair (including repair of cystocele, if performed), laparoscopic approach	G2
57425	Laparoscopy, surgical, colpopexy (suspension of vaginal apex)	G2
57555	Excision of cervical stump, vaginal approach; with anterior and/or posterior repair	G2
58263	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s), with repair of enterocele	G2
58270	Vaginal hysterectomy, for uterus 250 g or less; with repair of enterocele	G2
58290	Vaginal hysterectomy, for uterus greater than 250 g;	G2
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	G2
58292	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s), with repair of enterocele	G2
58294	Vaginal hysterectomy, for uterus greater than 250 g; with repair of enterocele	G2
58770	Salpingostomy (salpingoneostomy)	G2
58920	Wedge resection or bisection of ovary, unilateral or bilateral	G2
58925	Ovarian cystectomy, unilateral or bilateral	G2
59030	Fetal scalp blood sampling	G2
59409	Vaginal delivery only (with or without episiotomy and/or forceps);	G2
59612	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps);	G2
60252	Thyroidectomy, total or subtotal for malignancy; with limited neck dissection	G2
60260	Thyroidectomy, removal of all remaining thyroid tissue following previous removal of a portion of thyroid	G2
60271	Thyroidectomy, including substernal thyroid; cervical approach	G2
60502	Parathyroidectomy or exploration of parathyroid(s); re-exploration	G2
60512	Parathyroid autotransplantation (list separately in addition to code for primary procedure)	N1
60520	Thymectomy, partial or total; transcervical approach (separate procedure)	G2
61623	Endovascular temporary balloon arterial occlusion, head or neck (extracranial/intracranial) including selective catheterization of vessel to be occluded, positioning and inflation of occlusion balloon, concomitant neurological monitoring, and radiologic supervision and interpretation of all angiography required for balloon occlusion and to exclude vascular injury post occlusion	J8
61626	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation),	J8

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
	percutaneous, any method; non-central nervous system, head or neck (extracranial, brachiocephalic branch)	
61720	Creation of lesion by stereotactic method, including burr hole(s) and localizing and recording techniques, single or multiple stages; globus pallidus or thalamus	G2
62000	Elevation of depressed skull fracture; simple, extradural	G2
62351	Implantation, revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; with laminectomy	G2
63011	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), 1 or 2 vertebral segments; sacral	G2
63012	Laminectomy with removal of abnormal facets and/or pars inter-articularis with decompression of cauda equina and nerve roots for spondylolisthesis, lumbar (gill type procedure)	G2
63015	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), more than 2 vertebral segments; cervical	G2
63016	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), more than 2 vertebral segments; thoracic	G2
63017	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), more than 2 vertebral segments; lumbar	G2
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (list separately in addition to code for primary procedure)	N1
63040	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; cervical	G2
63043	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional cervical interspace (list separately in addition to code for primary procedure)	N1
63048	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; each additional segment, cervical, thoracic, or lumbar (list separately in addition to code for primary procedure)	N1
63057	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; each additional segment, thoracic or lumbar (list separately in addition to code for primary procedure)	N1
63064	Costovertebral approach with decompression of spinal cord or nerve root(s) (eg, herniated intervertebral disc), thoracic; single segment	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
63066	Costovertebral approach with decompression of spinal cord or nerve root(s) (eg, herniated intervertebral disc), thoracic; each additional segment (list separately in addition to code for primary procedure)	N1
63075	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, single interspace	G2
63076	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, each additional interspace (list separately in addition to code for primary procedure)	N1
63741	Creation of shunt, lumbar, subarachnoid-peritoneal, -pleural, or other; percutaneous, not requiring laminectomy	J8
64804	Sympathectomy, cervicothoracic	G2
64911	Nerve repair; with autogenous vein graft (includes harvest of vein graft), each nerve	G2
69725	Decompression facial nerve, intratemporal; including medial to geniculate ganglion	G2
69955	Total facial nerve decompression and/or repair (may include graft)	G2
69960	Decompression internal auditory canal	G2
69970	Removal of tumor, temporal bone	G2
C9602	Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	J8
C9603	Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	N1
C9604	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel	J8
C9605	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)	N1
C9607	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; single vessel	J8
C9608	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)	N1
C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-d rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (ebus) guided transtracheal and/or transbronchial sampling (eg,	G2

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
	aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)	
C9758	Blinded procedure for nyha class iii/iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (e.g., ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study	G2
0184T	Excision of rectal tumor, transanal endoscopic microsurgical approach (ie, tems), including muscularis propria (ie, full thickness)	G2
0221T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; lumbar	G2
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)	J8
0267T	Implantation or replacement of carotid sinus baroreflex activation device; lead only, unilateral (includes intra-operative interrogation, programming, and repositioning, when performed)	G2
0268T	Implantation or replacement of carotid sinus baroreflex activation device; pulse generator only (includes intra-operative interrogation, programming, and repositioning, when performed)	J8
0312T	Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (egj), with implantation of pulse generator, includes programming	G2
0404T	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency	G2
0453T	Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; mechano-electrical skin interface	G2
0454T	Insertion or replacement of a permanently implantable aortic counterpulsation ventricular assist system, endovascular approach, and programming of sensing and therapeutic parameters; subcutaneous electrode	G2
0457T	Removal of permanently implantable aortic counterpulsation ventricular assist system; mechano-electrical skin interface	G2
0458T	Removal of permanently implantable aortic counterpulsation ventricular assist system; subcutaneous electrode	G2
0460T	Repositioning of previously implanted aortic counterpulsation ventricular assist device; subcutaneous electrode	G2
0499T	Cystourethroscopy, with mechanical dilation and urethral therapeutic drug delivery for urethral stricture or stenosis, including fluoroscopy, when performed	G2
0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and	J8

CY 2021 CPT/ HCPCS Code	CY 2021 Long Descriptor	Final CY 2021 ASC Payment Indicator
	intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion	
0515T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; complete system (includes electrode and generator [transmitter and battery])	J8
0516T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; electrode only	G2
0517T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; pulse generator component(s) (battery and/or transmitter) only	J8
0518T	Removal of only pulse generator component(s) (battery and/or transmitter) of wireless cardiac stimulator for left ventricular pacing	G2
0519T	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter)	J8
0520T	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter), including placement of a new electrode	J8

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2. Covered Ancillary Services

This section was inadvertently omitted from the CY 2021 OPPS/ASC Proposed Rule. We are finalizing the continuation of our existing policies relating to covered ancillary services without change. In the CY 2019 OPPS/ASC final rule (83 FR 59062 through 59063), consistent with the established ASC payment system policy (72 FR 42497), we finalized the policy to update the ASC list of covered ancillary services to reflect the payment status for the services under the CY 2019 OPPS final rule. As discussed in prior rulemaking, maintaining consistency with the OPPS may result in changes to ASC payment indicators for some covered ancillary services because of changes that are being finalized under the OPPS for CY 2021. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2020, but will be packaged under the CY 2021 OPPS, to maintain consistency with the OPPS, we would also package the ancillary service under the ASC payment system for CY 2021. In the CY 2019 OPPS/ASC final rule, we finalized the policy to continue this reconciliation of packaged status for subsequent calendar years. Comment indicator ''CH'', which is discussed in section XIII.F. of the CY 2021 OPPS/ASC proposed rule, is used in Addendum BB to this CY 2021 OPPS/ASC final rule (which is available via the internet on the CMS website) to indicate covered ancillary services for which we are finalizing a change in the ASC payment indicator to reflect a finalized change in the OPPS treatment of the service for CY 2021.

Comment: One commenter requested that we add CPT code 91040 (Esophageal balloon distension study, diagnostic, with provocation when performed) to our list of covered ancillary services. Commenter stated that esophageal balloon distension studies are often performed in conjunction with esophagogastroduodenoscopy procedures. The commenter noted that not adding this procedure sets a standard that an ancillary service must be performed 100 percent of the time with the surgical procedure in order for it to be considered integral, which results in a smaller subset of ancillary procedures being eligible for payment in the ASC setting.

Response: Services included in our list of covered ancillary services must be integral to the performance of a covered surgical procedure. However, based on the description of the procedure, we do not believe this service is integral to the performance of the surgical procedures identified by the commenter, specifically CPT codes 43235 (Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)), 43236 (Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance), or 43239 (Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple), or other surgical procedures. Therefore, we are not adding CPT code 91040 to the list of ASC covered ancillary services for CY 2021.

New CPT and HCPCS codes for covered ancillary services and their final payment indicators for CY 2021 can be found in section XIII.B of this CY 2021 OPPS/ASC Final Rule. All ASC covered ancillary services and their

final payment indicators for CY 2021 are also included in Addendum BB to this CY 2021 OPPS/ASC final rule (which is available via the internet on the CMS website).

D. Update and Payment for ASC Covered Surgical Procedures and Covered Ancillary Services

1. ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy, we use the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year to calculate the national unadjusted payment rates for procedures with payment indicators ''G2'' and ''A2''. Payment indicator ''A2'' was developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and, therefore, were subject to transitional payment prior to CY 2011. Although the 4-year transitional period has ended and payment indicator ''A2'' is no longer required to identify surgical procedures subject to transitional payment, we retained payment indicator ''A2'' because it is used to identify procedures that are exempted from the application of the office-based designation.

The rate calculation established for device-intensive procedures (payment indicator ''J8'') is structured so only the service portion of the rate is subject to the ASC conversion factor. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61397 through 61400), we updated the CY 2019 ASC payment rates for ASC covered surgical procedures with payment indicators of ''A2'', ''G2'', and ''J8'' using CY 2018 data, consistent with the CY 2020 OPPS update. We also updated payment rates for device-intensive procedures to incorporate the CY 2020 OPPS device offset percentages calculated under the standard APC ratesetting methodology, as discussed earlier in this section.

Payment rates for office-based procedures (payment indicators ''P2'', ''P3'', and ''R2'') are the lower of the PFS nonfacility PE RVU-based amount or the amount calculated using the ASC standard rate setting methodology for the procedure. In the CY 2020 OPPS/ASC final rule with comment period, we updated the payment amounts for office-based procedures (payment indicators ''P2'', ''P3'', and ''R2'') using the most recent available MPFS and OPPS data. We compared the estimated CY 2020 rate for each of the office-based procedures, calculated according to the ASC standard rate setting methodology, to the PFS nonfacility PE RVU-based amount to determine which was lower and, therefore, would be the CY 2020 payment rate for the procedure under our final policy for the revised ASC payment system (§ 416.171(d)).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75081), we finalized our proposal to calculate the CY 2014 payment rates for ASC covered surgical procedures according to our established methodologies, with the exception of device removal procedures. For CY 2014, we finalized a policy to conditionally package payment for device removal procedures under the OPPS. Under the OPPS, a conditionally packaged procedure (status indicators ''Q1'' and ''Q2'') describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a covered surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indicator ''N1'') under the ASC payment system. Under the OPPS, device removal procedures are conditionally packaged and, therefore, would be packaged under the ASC payment system. There would be no Medicare payment made when a device removal procedure is performed in an ASC without another surgical procedure included on the claim; therefore, no Medicare payment would be made if a device was removed but not replaced. To ensure that the ASC payment system provides separate payment for surgical procedures that only involve device removal—conditionally packaged in the OPPS (status indicator ''Q2'')—we continued to provide separate payment since CY 2014 and assigned the current ASC payment indicators associated with these procedures.

b. Update to ASC Covered Surgical Procedure Payment Rates for CY 2021

We proposed to update ASC payment rates for CY 2021 and subsequent years using the established rate calculation methodologies under § 416.171 and using our definition of device-intensive procedures, as discussed in section XII.C.1.b. of this CY 2021 OPPS/ASC proposed rule. Because the proposed OPPS relative payment weights are generally based on geometric mean costs, the ASC system would generally use the geometric mean to determine proposed relative payment weights under the ASC standard methodology. We proposed to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators ''A2'' and ''G2''.

We proposed to calculate payment rates for office-based procedures (payment indicators ''P2'', ''P3'', and ''R2'') and device-intensive procedures (payment indicator ''J8'') according to our established policies and, for device-intensive procedures, using our modified definition of device-intensive procedures, as discussed in section XII.C.1.b. of the CY 2021 OPPS/ASC proposed rule. Therefore, we proposed to update the payment amount for the service portion of the device-intensive procedures using the standard ASC rate setting methodology and the payment amount for the device portion based on the proposed CY 2021 device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. Payment for office-based procedures would be at the lesser of the proposed CY 2021 MPFS nonfacility PE RVU-based amount or the proposed CY 2021 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2020, for CY 2021 we proposed to continue our policy for device removal procedures, such that device removal procedures that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2'') would be assigned the current ASC payment indicators associated with those procedures and would continue to be paid separately under the ASC payment system. A summary of the comments received and our responses to those comments are set forth below.

Comment: One commenter disagreed with the proposed CY 2021 ASC payment rates for the surgical procedures described by the following CPT/HCPCS codes, requesting that CMS increase payment in the ASC setting for the following codes:

- CPT 22869 (Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level)
- CPT 62287 (Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography

and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar)

- CPT 64575 (Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve))
- CPT 64454 (Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed)
- CPT 64624 (Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed)

Response: We update the data on which we establish payment rates each year through rulemaking and note that ASC rates are derived from OPPS payment rates, which are required to be reviewed and updated at least annually under section 1833(t)(9) of the Act. Based on our analysis of the latest hospital OPPS and ASC claims data used for this final rule with comment period, we are updating ASC payment rates for CY 2021 using the established rate calculation methodologies under § 416.171 of the regulations and our definition of device-intensive procedures, as discussed in section XII.C.1.b. of this CY 2021 OPPS/ASC final rule with comment period. We do not generally make additional payment adjustments to specific procedures. Therefore, we are finalizing the payment indicators for the HCPCS codes 22869, 62287, 64575, 64454, and 64624 as proposed.

Comment: Two commenters recommended that CMS eliminate the prohibition against ASC billing for services using an unlisted CPT surgical procedure code.

Response: Under § 416.166(c)(7), covered surgical procedures do not include procedures that can only be reported using a CPT unlisted surgical procedure code. As discussed in the August 2, 2007 final rule (72 FR 42485), it is not possible to know what specific procedure would be represented by an unlisted code, and therefore, it is not possible to evaluate procedures reported by unlisted CPT codes according to applicable regulatory criteria at § 416.166. Therefore, we are not accepting this recommendation.

After consideration of the public comments we received, we are finalizing our proposed policies without modification to calculate the CY 2021 payment rates for ASC covered surgical procedures according to our established rate calculation methodologies under § 416.171 and using the modified definition of device-intensive procedures as discussed in section XIII.C.1.b. of this CY 2021 OPPS/ASC final rule. For covered office-based surgical procedures, the payment rate is the lower of the final CY 2021 MPFS nonfacility PE RVU-based amount or the final CY 2021 ASC payment amount calculated according to the ASC standard ratesetting methodology. The final payment indicators and rates set forth in this final rule with comment period are based on a comparison using the PFS PE RVUs and the conversion factor effective January 1, 2021. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS final rule with comment period, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

c. Limit on ASC Payment Rates for Low-Volume Device-Intensive Procedures

As stated in section XIII.D.1.b. of this CY 2021 OPPS/ASC proposed rule, the ASC payment system generally uses OPPS geometric mean costs under the standard methodology to determine proposed relative payment weights under the standard ASC ratesetting methodology. However, for low-volume device-intensive procedures, the proposed relative payment weights are based on median costs, rather than geometric mean costs, as discussed in section IV.B.5. of this CY 2021 OPPS/ASC proposed rule.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61400), we finalized our policy to limit the ASC payment rate for low-volume device-intensive procedures to a payment rate equal to the OPPS payment rate for that procedure. Under our new policy, where the ASC payment rate based on the standard ASC ratesetting methodology for low volume device-intensive procedures would exceed the rate paid under the OPPS for the same procedure, we establish an ASC payment rate for such procedures equal to the OPPS payment rate for the same procedure. For CY 2020, this policy only affected HCPCS code 0308T, which had very low claims volume (7 claims from CY 2018 used for CY 2020 ratesetting in the OPPS). Additionally, we amended § 416.171(b) of the regulations to reflect the new limit on ASC payment rates for low-volume device-intensive procedures. CMS' existing regulation at § 416.171(b)(2) requires the payment for the device portion of a device-intensive procedure to be set at an amount derived from the payment rate for the equivalent item under the OPPS using our standard ratesetting methodology. We added paragraph (b)(4) to § 416.171 to require that, notwithstanding paragraph (b)(2), low volume device-intensive procedures where the otherwise applicable payment rate calculated based on the standard methodology for device-intensive procedures would exceed the payment rate for the equivalent procedure set under the OPPS, the payment rate for the procedure under the ASC payment system would be equal to the payment rate for the same procedure under the OPPS.

Based on our review of CY 2019 claims using our standard ratesetting methodology, there are no low volume device-intensive procedures that would exceed the rate paid under the OPPS for the same procedure. However, there was a single claim containing CPT code 0308T that was unable to be used for the CY 2021 OPPS/ASC proposed rule ratesetting process as it was packaged into a comprehensive APC. As a result, there was no available cost data from CY 2019 claims data to construct relative payment weights for CPT code 0308T. As discussed in section III.D.2., under the OPPS, we proposed to establish the payment weight for the CY 2021 OPPS for CPT code 0308T using the CY 2020 OPPS final rule median cost of $20,229.78 and relative payment weight as reflecting the most recent claims and cost data. Similarly, as there were no usable claims with CPT code 0308T from CY 2019, which we would normally use for the CY 2021 OPPS/ASC proposed rule under our standard ratesetting methodology to establish an appropriate payment rate in CY 2021 for CPT code 0308T using the most recent claims and cost data, we proposed to establish the payment rate under the ASC payment system for CY 2021 using the CY 2020 final rule OPPS median cost and relative payment weight as reflecting the most recent available claims and cost data.

However, CPT code 0308T was designated as a low volume device-intensive procedure in CY 2020. For CY 2020, under the low-volume procedure payment policies in effect through CY 2019, the available claims data would have resulted in a payment rate of approximately $111,019.30 for CPT code 0308T when performed in the ASC setting, which would have been several times greater than the OPPS payment rate. Therefore, for CY 2020 we finalized our policy to limit the ASC payment rate for low-volume device intensive procedures to a payment rate equal to the OPPS payment rate for the procedures. This policy had the effect of limiting the ASC payment rate for CPT code 0308T to the applicable payment rate under the OPPS (which was

$20,675.62 in CY 2020). Therefore, for the CY 2021 OPPS/ASC proposed rule, we proposed to apply a payment rate under the ASC payment system equal to the OPPS payment rate for CPT code 0308T, which is $20,994.57 in the CY 2021 OPPS/ASC proposed rule. Further, in the absence of claims data for the CY 2021 OPPS/ASC proposed rule, we also proposed in this CY 2021 OPPS/ASC proposed rule to continue the CY 2020 final rule device offset percentage of 90.18 percent for CPT code 0308T.

Comment: Commenters supported our proposal to apply a payment rate under the ASC payment system equal to the OPPS payment rate for CPT code 0308T and to continue the CY 2020 final rule device offset percentage of 90.18 percent for CPT code 0308T.

Response: We thank the commenters for their support. After consideration of the public comments we received, for CY 2021, we are finalizing our policy to limit the ASC payment rate for low-volume device intensive procedures to a payment rate equal to the OPPS payment rate for the procedures. Based on our review of CY 2019 claims using our standard ratesetting methodology for this final rule with comment period, there are no low volume device-intensive procedures that would exceed the rate paid under the OPPS for the same procedure. However, claims data show two claims containing CPT code 0308T that are unable to be used for this CY 2021 OPPS/ASC final rule with comment period ratesetting process. Under the low-volume device intensive procedure policy that we are adopting in this final rule with comment period, the ASC payment rate for CPT code 0308T is limited to the applicable payment rate under the OPPS (which is $20,766.56 in CY 2021). Further, in the absence of claims data for this final rule with comment period, we are finalizing our proposal to continue to use the CY 2020 final rule device offset percentage of 90.18 percent for CPT code 0308T in CY 2021.

2. Payment for Covered Ancillary Services

a. Background

Our payment policies under the ASC payment system for covered ancillary services generally vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators ''N'', ''Q1'', and ''Q2'') under the OPPS. In the CY 2013 OPPS/ASC rulemaking (77 FR 45169 and 77 FR 68457 through 68458), we further clarified our policy regarding the payment indicator assignment of procedures that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2''). Under the OPPS, a conditionally packaged procedure describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are generally packaged (payment indictor ''N1'') under the ASC payment system (except for device removal procedures, as discussed in section IV. of this CY 2021 OPPS/ASC proposed rule). Thus, our policy generally aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for those ancillary services also to be paid, ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies generally provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates and package payment for drugs and biologicals for which payment is packaged under the OPPS. However, as discussed in section XIII.D.3. of the CY 2021 OPPS/ASC proposed rule, for CY 2019, we finalized a policy to unpackage and pay separately at ASP + 6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting, even though payment for these drugs continues to be packaged under the OPPS. We generally pay for separately payable radiology services at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount (''Z3''), regardless of which is lower (§ 416.171(d)(1)).

Similarly, we also finalized our policy to set the payment indicator to ''Z2'' for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight using the ASC standard ratesetting methodology and, therefore, will include the cost for the contrast agent (§ 416.171(d)(2)).

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS.

Our ASC policies also provide separate payment for: (1) Certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue; and (2) certain implantable items that have pass-through payment status under the OPPS. These categories do not have prospectively established ASC payment rates according to ASC payment system policies (72 FR 42502 and 42508 through 42509; § 416.164(b)). Under the ASC payment system, we have designated corneal tissue acquisition and hepatitis B vaccines as contractor-priced. Corneal tissue acquisition is contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplantation. Hepatitis B vaccines are contractor-priced based on invoiced costs for the vaccine.

Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and are contractor-priced. Under the revised ASC payment system (72 FR 42502), payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (non-device) portion of the procedure's OPPS relative payment weight if the APC weight for the procedure includes other packaged device costs. We also refer to this methodology as applying a ''device offset'' to the ASC payment for the associated surgical procedure. This ensures that duplicate payment is not

provided for any portion of an implanted device with OPPS pass-through payment status.

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized that, beginning in CY 2015, certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS are covered ancillary services when they are integral to an ASC covered surgical procedure. We finalized that diagnostic tests within the medicine range of CPT codes include all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT. In the CY 2015 OPPS/ASC final rule with comment period, we also finalized our policy to pay for these tests at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (79 FR 66933 through 66934). We finalized that the diagnostic tests for which the payment is based on the ASC standard ratesetting methodology be assigned to payment indicator ''Z2'' and revised the definition of payment indicator ''Z2'' to include a reference to diagnostic services and those for which the payment is based on the PFS nonfacility PE RVU-based amount be assigned payment indicator ''Z3,'' and revised the definition of payment indicator ''Z3'' to include a reference to diagnostic services.

Comment: One commenter recommended that CMS solicit comments from stakeholders regarding development of a more transparent and consistent policy regarding valuation of pass-through devices implanted in the ASC setting. The commenter further notes that CMS has published its method for valuing pass-through devices implanted in the hospital outpatient setting clearly in the **Federal Register**, and that, in the ASC setting, payment for a qualifying procedure and the associated pass-through device should be separate. However, the commenter disagreed with CMS's approach to valuation of pass-through devices implanted in the ASC setting as contractor-priced.

Response: We thank the commenter for their recommendation. We will take the commenters' concerns into consideration in determining if additional instructions or future guidance for the MACs are warranted.

b. Payment for Covered Ancillary Services for CY 2021

We proposed to update the ASC payment rates and to make changes to ASC payment indicators, as necessary, to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2021 OPPS and ASC payment rates and subsequent year payment rates. We also proposed to continue to set the CY 2021 ASC payment rates and subsequent year payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for CY 2021 and subsequent year payment rates.

Covered ancillary services and their final payment indicators for CY 2021 are listed in Addendum BB of this CY 2021 OPPS/ASC final rule with comment period (which is available via the internet on the CMS website). For those covered ancillary services where the payment rate is the lower of the proposed rates under the ASC standard rate setting methodology and the PFS final rates, the final payment indicators and rates set forth in the proposed rule are based on a comparison using the proposed PFS rates effective January 1, 2021. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS final rule, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

3. CY 2021 ASC Packaging Policy for Non-Opioid Pain Management Treatments

Section 6082 of the ''Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act,'' also referred to as the ''SUPPORT for Patients and Communities Act'' (SUPPORT Act) (Pub. L. 115–271) was enacted on October 24, 2018. Section 6082(a) of the SUPPORT Act requires in part that the Secretary: ''(i) shall, as soon as practicable, conduct a review (part of which may include a request for information) of payments for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives; (ii) may, as the Secretary determines appropriate, conduct subsequent reviews of such payments; and (iii) shall consider the extent to which revisions under this subsection to such payments (such as the creation of additional groups of covered OPD services to classify separately those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce payment incentives to use opioids instead of non-opioid alternatives for pain management.'' Section 6082(b) of the SUPPORT Act requires that the Secretary conduct a similar type of review in ambulatory surgical centers.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59066 through 59072), we finalized the policy to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2019. We also finalized conforming changes to § 416.164(a)(4) to exclude non-opioid pain management drugs that function as a supply when used in a surgical procedure from our policy to package payment for drugs and biologicals for which separate payment is not allowed under the OPPS into the ASC payment for the covered surgical procedure. We added a new § 416.164(b)(6) to include non-opioid pain management drugs that function as a supply when used in a surgical procedure as covered ancillary services that are integral to a covered surgical procedure. Finally, we finalized a change to § 416.171(b)(1) to exclude non-opioid pain management drugs that function as a supply when used in a surgical procedure from our policy to pay for ASC covered ancillary services an amount derived from the payment rate for the equivalent item or service set under the OPPS.

For the CY 2020 OPPS/ASC proposed rule (84 FR 39424 through 39427), we reviewed payments under the ASC for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. We used available data to analyze the payment and utilization patterns associated with specific non-opioid alternatives to determine whether our packaging policies reduced the use of non-opioid alternatives. For the CY 2020 OPPS/ASC proposed rule (84 FR 39426), we proposed to continue our policy to pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC

setting for CY 2020. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61177), after reviewing data from stakeholders and Medicare claims data, we did not find compelling evidence to suggest that revisions to our OPPS payment policies for non-opioid pain management alternatives were necessary for CY 2020. We finalized our proposal to continue to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2020. Under this policy, the only FDA-approved drug that met these criteria was Exparel.

We conducted an evaluation to determine whether there are payment incentives for using opioids instead of non-opioid alternatives in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61176 to 61180). The results of our review and evaluation of our claims data did not provide evidence to indicate that the OPPS packaging policy had the unintended consequence of discouraging the use of non-opioid treatments for postsurgical pain management in the hospital outpatient department. Our updated review of claims data for the CY 2020 proposed rule showed a continued decline in the utilization of Exparel® in the ASC setting, which supported our proposal to continue paying separately for Exparel® in the ASC setting.

4. Evaluation and CY 2021 Payment for Non-Opioid Alternatives

Over the last 2 years, we have conducted detailed evaluations of our payment policies regarding the use of opioids and non-opioid alternatives. We have reviewed multiple years of Medicare claims data, all public comments received on this topic, and studies and data from external stakeholders. Each of these reviews have led to the consistent conclusion that CMS's packaging policies are not discouraging the use of non-opioid alternatives or impeding access to these products, with the exception of Exparel, which was the only non-opioid pain management drug that functions as a surgical supply when furnished in the ASC setting.

Section 6082(a) of the SUPPORT Act also provides that after an initial review, the Secretary can conduct subsequent reviews of covered payments as the Secretary deems appropriate. In light of the fact that CMS has conducted a thorough review of payments for opioids and evidence-based non-opioid alternatives for pain management to ensure that there are not financial incentives to use opioids instead of non-opioid alternatives, we did not believe that conducting a similar review for CY2021 would be a fruitful effort. After careful consideration, we concluded we had fulfilled the statutory requirement to review payments for opioids and evidence-based non-opioid alternatives for pain management to ensure that there are not financial incentives to use opioids instead of non-opioid alternatives, as described in the CY 2020 OPPS/ASC rulemaking. We are committed to evaluating our current policies to adjust payment methodologies, if necessary, in order to ensure appropriate access for beneficiaries amid the current opioid epidemic. However, we did not believe conducting a similar CY 2021 review would yield significantly different outcomes or new evidence that would prompt us to change our payment policies under the OPPS or ASC payment system.

Current claims data suggest that CMS' current policies are not providing a disincentive for the utilization of non-opioid alternatives, including Exparel, in the hospital outpatient department or ASC. A preliminary claims analysis showed that the total units of Exparel employed in the ASC setting has increased over the last year. From CY 2015 to CY 2018, we saw an annual decline in the total units of Exparel furnished in the ASC setting, with 244,756 total units provided in CY 2015 dropping to 60,125 total units provided in CY 2018. In CY 2019, ASCs furnished a total of 1,379,286 units of Exparel. Due to this positive trend that reflects the increased use of non-opioid treatment for pain, we did not believe that further changes are necessary under the ASC payment system for non-opioid pain management drugs that function as a surgical supply in the ASC setting. Therefore, for CY 2021, we proposed to continue our policy to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2021.

The comments we received and our responses to those comments are set forth below.

Comment: Multiple commenters, including individual stakeholders, hospital and physician groups, national medical associations, device manufacturers, and groups representing the pharmaceutical industry, supported the proposal to continue to unpackage and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting, such as Exparel, for CY 2021. These commenters believed that packaged payment for non-opioid alternatives presents a barrier to access to non-opioid pain management drugs and that separate payment for non-opioid pain management drugs would be an appropriate response to the opioid drug abuse epidemic. Several commenters suggested that CMS expand this policy, including commenters who asked that CMS develop a policy that pays separately for drugs that are administered at the time of ophthalmic surgery and have an FDA-approved indication to treat or prevent postoperative pain.

Response: We appreciate these comments. After reviewing the information provided by the commenters, we continue to believe that separate payment is appropriate for non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2021. Therefore, as discussed in greater detail below, we are finalizing our proposal to continue to unpackage and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting without modification.

Comment: Several commenters requested that the drug Omidria, CPT J1097, (*phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*), be excluded from the ASC payment system packaging policy once its pass-through status expires on September 30, 2020, because they believe it is a non-opioid pain management drug that functions as a surgical supply when furnished in the ASC setting. Omidria is indicated for maintaining pupil size by preventing intraoperative miosis and reducing postoperative ocular pain in cataract or intraocular surgeries. The commenters stated that extensive clinical evidence has been published in medical literature demonstrating that Omidria reduces dependence on opioids for patients undergoing cataract surgery and postoperative prescription opioids. The commenters noted that OMIDRIA is FDA-approved for intraocular use in cataract procedures, a pain management drug, a non-opioid, and functions, and was previously packaged, as a surgical supply during cataract surgery according to CMS' definition of a surgical supply. Commenters asserted that the use of Omidria decreases

patients' need for fentanyl during surgeries and provided an unpublished manuscript that has been submitted, but not approved, for publication in a peer-reviewed journal, which suggested that Omidria reduces opioid use after surgery based on pill counts.

Response: We thank commenters for their feedback on Omidria. Omidria received pass-through status for a 3-year period from 2015 to 2017. After expiration of its pass-through status, it was packaged under both the OPPS and the ASC payment system. Subsequently, Omidria's pass-through status under the OPPS was reinstated in October 1, 2018 through September 30, 2020 as required by section 1833(t)(6)(G) of the Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018 (Pub. L. 115–141), which means that Omidria continued to be paid separately under the ASC payment system through September 30, 2020. We note that our previous review of the clinical evidence submitted by commenters during CY 2020 rulemaking concluded that the studies the commenter submitted were not sufficiently compelling to revise our payment policy for Omidria. Moreover, the results of a CMS analysis of cataract procedures performed on Medicare beneficiaries in the OPPS between January 2015 and July 2019 comparing procedures performed with Omidria to procedures performed without Omidria did not demonstrate a significant decrease in fentanyl utilization during the cataract surgeries in the OPPS when Omidria was used. Our findings also did not suggest any decrease in opioid utilization post-surgery for procedures involving Omidria.

However, we continue to believe the separate payment is appropriate for non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2021. After careful consideration of the commenters' assertion that Omidria meets this definition, we believe that Omidria qualifies as a non-opioid pain management drug that functions as a surgical supply when furnished in the ASC setting and will therefore exclude Omidria from packaging under the ASC payment system beginning October 1, 2020, and in CY 2021, in accordance with this policy.

Comment: Two commenters briefly mentioned the drug IV acetaminophen, CPT code J0131, which they believe may reduce opioid usage if CMS paid separately for the drug. These commenters believed CPT code J0131 is a highly effective medication that also decreases use of post-operative opioids.

Response: We thank commenters for their comments. We do not find it appropriate to pay separately for IV acetaminophen as suggested by these commenters due to our drug packaging threshold policies, which are discussed in section V.B.1.a to this final rule with comment period. In accordance with section 1833(t)(16)(B) of the Act, we finalized our proposal to set the drug packaging threshold for CY 2021 to $130. To the extent that the items and services mentioned by the commenters are effective alternatives to opioid prescriptions, we encourage providers to use them when medically necessary.

Comment: Commenters suggested modified payment for ''pain block'' CPT codes 64415, 64416, 64417, 64445, 64446, 64447, 64448, and 64450. Two commenters stated that providers use these pain blocks to mitigate the post-operative pain that is otherwise typically addressed with short-term opioid use. Additionally, a few commenters noted that CPT code J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0.1 mg*) used for treatment of ocular inflammation and pain following ophthalmic surgery is administered through CPT code 0356T (*Insertion of drug-eluting implant (including punctal dilation and implant removal when performed) into lacrimal canaliculus, each*). These commenters felt CPT code 0356T, which commenters state describes the administration of CPT code J1096, should also receive separate or additional payment due to the alleged clinical benefits of the drug, including treatment of pain.

Response: We thank the commenters for their suggestions. The ''pain block'' procedure codes and drug administration code discussed above do not qualify as non-opioid pain management drugs that function as surgical supplies, and therefore, do not qualify for separate payment when furnished in the ASC setting. At this time, we have not found compelling evidence to revise our policies to provide separate payment for the non-opioid pain management alternatives described above under the OPPS or ASC payment systems for CY 2021. To the extent that the items and services mentioned by the commenters are effective alternatives to opioid prescriptions, we encourage providers to use them when medically appropriate. For a greater discussion on CPT code 0356T, please see section III. D. (Administration of Lacrimal Ophthalmic Insert Into Lacrimal Canaliculus (APC 5692)) of this final rule with comment period.

Comment: Some commenters encouraged CMS to establish permanent separate payment for drugs that are currently on drug pass-through status in the OPPS and ASC settings, such as Dexycu (HCPCS code J1095). Regarding Dexycu specifically, one commenter stated that permanent separate payment for ophthalmic drugs is appropriate due to growing evidence that these drugs reduce reliance on opioids used in association with cataract surgeries. They noted that they were conducting a new, comprehensive study of a longitudinal claim dataset that will provide deeper insights into the association between cataract surgery and opioid utilization, as well as the role of Dexycu in reducing the prescribing of opioids.

Response: We refer readers to section V.A., ''OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals'' of this final rule with comment period regarding pass-through payments under the OPPS. Once a drug's pass-through status expires, we determine whether that drug is eligible for separate payment under our policy for non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting. We thank commenters for conducting studies regarding their specific products and look forward to reviewing the results.

Comment: Commenters requested separate payment for various non-drug pain management treatments that they believe are viable alternatives to opioids, such as ERAS® protocols or spinal cord stimulators (SCS), that they believe decrease the number of opioid prescriptions beneficiaries receive during and following an outpatient visit or procedure. For SCS, several commenters noted that this therapy may lead to a reduction in the use of opioids for chronic pain patients. They noted that neurostimulation is a key alternative to opioid prescription for the management and recommended that CMS increase access to SCS.

Response: We appreciate the responses from commenters on this topic. At this time, we have not found compelling evidence that our current payment policies discourage use of the various non-drug alternatives for non-opioid pain management commenters described, such that separate payment would be warranted under the OPPS or ASC payment systems for CY 2021. We do not find it appropriate to revise our policies at this time based on these comments; however, we plan to take these comments and suggestions into consideration for future rulemaking. We agree that providing incentives to avoid or reduce opioid prescriptions may be one of several strategies for addressing the opioid epidemic. To the extent that

the items and services mentioned by the commenters are effective alternatives to opioid drugs, we encourage providers to use them when medically appropriate. We look forward to working with stakeholders as we further consider suggested refinements to the OPPS and the ASC payment system to encourage use of non-opioid pain management treatments.

After consideration of the public comments that we received, we are finalizing the policy to continue to unpackage and pay separately at ASP + 6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2021 as proposed. We will continue to analyze the issue of access to other non-opioid alternatives for pain management in the OPPS and ASC settings. This policy is also discussed in section II.A.3.b. of this final rule with comment period.

E. New Technology Intraocular Lenses (NTIOLs)

New Technology Intraocular Lenses (NTIOLs) are intraocular lenses that replace a patient's natural lens that has been removed in cataract surgery and that also meet the requirements listed in § 416.195.

1. NTIOL Application Cycle

Our process for reviewing applications to establish new classes of NTIOLs is as follows:

• Applicants submit their NTIOL requests for review to CMS by the annual deadline. For a request to be considered complete, we require submission of the information that is found in the guidance document entitled ''Application Process and Information Requirements for Requests for a New Class of New Technology Intraocular Lenses (NTIOLs) or Inclusion of an IOL in an Existing NTIOL Class'' posted on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html*.

• We announce annually, in the proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Public Law 103–432 and our regulations at § 416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests in the proposed rule.

• In the final rule updating the ASC and OPPS payment rates for the following calendar year, we—

++ Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments.

++ When a new NTIOL class is created, identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome.

++ Set the date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

++ Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

2. Requests To Establish New NTIOL Classes for CY 2021

We did not receive any requests for review to establish a new NTIOL class for CY 2021.

3. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is $50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we did not propose to revise the payment adjustment amount for CY 2021.

The comments and our responses to the comments are set forth below.

Comment: One commenter requested that we re-evaluate our payment adjustment for new NTIOL class. Commenters noted that our $50 payment adjustment has not been adjusted since CY 1999 and that the stagnant payment adjustment has been a barrier to intraocular lens innovation. The commenter requested that the $50 be inflated to 2021 dollars and updated by inflation in subsequent years.

Response: We thank the commenter for their recommendation. We did not propose revising the payment adjustment amount for CY 2021. However, we will take the commenter's recommendations into consideration in future rulemaking.

4. Announcement of CY 2022 Deadline for Submitting Requests for CMS Review of Applications for a New Class of NTIOLS

In accordance with § 416.185(a) of our regulations, CMS announces that in order to be considered for payment effective beginning in CY 2022, requests for review of applications for a new class of new technology IOLs must be received by 5:00 p.m. EST, on March 1, 2021. Send requests via email to *outpatientpps@cms.hhs.gov* or by mail to ASC/NTIOL, Division of Outpatient Care, Mailstop C4–05–17, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850. To be considered, requests for NTIOL reviews must include the information requested on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs*.

F. ASC Payment and Comment Indicators

1. Background

In addition to the payment indicators that we introduced in the August 2, 2007 final rule, we created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy-relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC CPL prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services, including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, or NTIOLs.

We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators included in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the status of a specific HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted. The comment indicator ''NI'' is used in the OPPS/ASC final rule to indicate new

codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator ''NI'' also is assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, and the interim payment indicator assigned is subject to comment, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622).

The comment indicator ''NP'' is used in the OPPS/ASC proposed rule to indicate new codes for the next calendar year for which the proposed payment indicator assigned is subject to comment. The comment indicator ''NP'' also is assigned to existing codes with substantial revisions to their descriptors, such that we consider them to be describing new services, and the proposed payment indicator assigned is subject to comment, as discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70497).

The ''CH'' comment indicator is used in Addenda AA and BB to the proposed rule (which are available via the internet on the CMS website) to indicate that the payment indicator assignment has changed for an active HCPCS code in the current year and the next calendar year, for example if an active HCPCS code is newly recognized as payable in ASCs; or an active HCPCS code is discontinued at the end of the current calendar year. The ''CH'' comment indicators that are published in the final rule with comment period are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment.

2. ASC Payment and Comment Indicators for CY 2021

For CY 2021, we proposed new and revised Category I and III CPT codes as well as new and revised Level II HCPCS codes. Therefore, proposed Category I and III CPT codes that are new and revised for CY 2021 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2021 compared to the CY 2020 descriptors are included in ASC Addenda AA and BB to the CY 2021 OPPS/ASC proposed rule were labeled with proposed comment indicator ''NP'' to indicate that these CPT and Level II HCPCS codes were open for comment as part of the proposed rule. Proposed comment indicator ''NP'' meant a new code for the next calendar year or an existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year; and denoted that comments would be accepted on the proposed ASC payment indicator for the new code.

For the CY 2021 update, we proposed to add ASC payment indicator ''K5''—Items, Codes, and Services for which pricing information and claims data are not available. No payment made.—to ASC Addendum DD1 to the CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website). New drug HCPCS codes that do not have claims data or payment rate information are currently assigned to OPPS status indicator ''E2''—Not paid by Medicare when submitted on outpatient claims (any outpatient bill type). These codes are categorized and included in the ASC payment system as nonpayable codes and are currently assigned an ASC payment indicator ''Y5''—Non-surgical procedure/item not valid for Medicare purposes because of coverage, regulation and/or statute; no payment made—because that is the ASC payment indicator that currently best describes the status of these HCPCS codes. However, ''Y5'' assignments include both drug codes that would not be integral to the performance of a surgical procedure and are therefore not payable in the ASC payment system and codes that may become separately payable in the ASC payment system. Since there is not a separate payment indicator that describes the subset of drug codes that will become payable when claims data or payment information is available, the existing ASC payment indicators cannot currently communicate the distinction between these two classes of drugs. Therefore, for CY 2021 and subsequent calendar years, we proposed to add ASC payment indicator ''K5''—Items, Codes, and Services for which pricing information and claims data are not available. No payment made.—to ASC Addendum DD1 to the CY 2021 OPPS/ASC proposed rule (which is available via the internet on the CMS website) to indicate those services and procedures that CMS anticipates will become payable when claims data or payment information becomes available.

In the CY 2021 OPPS/ASC proposed rule, we stated we would respond to public comments on ASC payment and comment indicators and finalize their ASC assignment in the CY 2021 OPPS/ASC final rule with comment period. We refer readers to Addenda DD1 and DD2 of the CY 2021 OPPS/ASC proposed rule (which are available via the internet on the CMS website) for the complete list of ASC payment and comment indicators proposed for the CY 2021 update.

We did not receive any public comments on the proposed ASC payment and comment indicators. Therefore, we are finalizing their use as proposed without modification. Addenda DD1 and DD2 to this CY 2021 OPPS/ASC final rule (which are available via the internet on the CMS website) contain the complete list of ASC payment and comment indicators for CY 2021.

G. Calculation of the ASC Payment Rates and the ASC Conversion Factor

1. Background

In the August 2, 2007 final rule (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and the OPPS relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 being equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007, as required under section 1833(i)(2)(E) of the Act (72 FR 42522). We adopted a policy to make the system budget neutral in subsequent calendar years (72 FR 42532 through 42533; § 416.171(e)).

We note that we consider the term ''expenditures'' in the context of the budget neutrality requirement under section 1833(i)(2)(D)(ii) of the Act to mean expenditures from the Medicare Part B Trust Fund. We do not consider expenditures to include beneficiary coinsurance and copayments. This distinction was important for the CY 2008 ASC budget neutrality model that considered payments across the OPPS, ASC, and MPFS payment systems. However, because coinsurance is almost always 20 percent for ASC services, this interpretation of expenditures has minimal impact for subsequent budget

neutrality adjustments calculated within the revised ASC payment system.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-step illustration of the final budget neutrality adjustment calculation based on the methodology finalized in the August 2, 2007 final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of $41.401. For covered office-based surgical procedures, covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XII.D.2. of this CY 2021 OPPS/ASC proposed rule), and certain diagnostic tests within the medicine range that are covered ancillary services, the established policy is to set the payment rate at the lower of the MPFS unadjusted nonfacility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive procedures).

As discussed in the August 2, 2007 final rule (72 FR 42517 through 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified IPPS hospital wage indexes to the labor-related share, which is 50 percent of the ASC payment amount based on a GAO report of ASC costs using 2004 survey data. Beginning in CY 2008, CMS accounted for geographic wage variation in labor costs when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment under the IPPS, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003.

The reclassification provision in section 1886(d)(10) of the Act is specific to hospitals. We believe that using the most recently available pre-floor and pre-reclassified IPPS hospital wage indexes results in the most appropriate adjustment to the labor portion of ASC costs. We continue to believe that the unadjusted hospital wage indexes, which are updated yearly and are used by many other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs. Therefore, the wage index for an ASC is the pre-floor and pre-reclassified hospital wage index under the IPPS of the CBSA that maps to the CBSA where the ASC is located.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252) and 2010 Census Bureau data. (A copy of this bulletin may be obtained at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2013/b13-01.pdf*). In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963), we implemented the use of the CBSA delineations issued by OMB in OMB Bulletin 13–01 for the IPPS hospital wage index beginning in FY 2015.

OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. OMB Bulletin No. 15–01 made changes that are relevant to the IPPS and ASC wage index. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79750) for a discussion of these changes and our implementation of these revisions. (A copy of this bulletin may be obtained at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2015/15-01.pdf*).

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. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58864 through 58865) for a discussion of these changes and our implementation of these revisions. (A copy of this bulletin may be obtained at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf*).

For CY 2021, the proposed CY 2021 ASC wage indexes fully reflect the OMB labor market area delineations (including the revisions to the OMB labor market delineations discussed above, as set forth in OMB Bulletin Nos. 15–01 and 17–01).

We note that, in certain instances, there might be urban or rural areas for which there is no IPPS hospital that has wage index data that could be used to set the wage index for that area. For these areas, our policy has been to use the average of the wage indexes for CBSAs (or metropolitan divisions as applicable) that are contiguous to the area that has no wage index (where ''contiguous'' is defined as sharing a border). For example, for CY 2014, we applied a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville-Fort Stewart, GA) and CBSA 08 (Rural Delaware).

When all of the areas contiguous to the urban CBSA of interest are rural and there is no IPPS hospital that has wage index data that could be used to set the wage index for that area, we determine the ASC wage index by calculating the average of all wage indexes for urban areas in the state (75 FR 72058 through 72059). (In other situations, where there are no IPPS hospitals located in a relevant labor market area, we continue our current policy of calculating an urban or rural area's wage index by calculating the average of the wage indexes for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index.)

2. Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2021 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and PFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). The OPPS relative payment weights are scaled to maintain budget neutrality for the OPPS. We then scale the OPPS relative payment weights again to establish the ASC relative payment weights. To accomplish this we hold estimated total ASC payment levels constant between

calendar years for purposes of maintaining budget neutrality in the ASC payment system. That is, we apply the weight scalar to ensure that projected expenditures from the updated ASC payment weights in the ASC payment system equal to what would be the current expenditures based on the scaled ASC payment weights. In this way we ensure budget neutrality and that the only changes to total payments to ASCs result from increases or decreases in the ASC payment update factor.

Where the estimated ASC expenditures for an upcoming year are higher than the estimated ASC expenditures for the current year, the ASC weight scalar is reduced, in order to bring the estimated ASC expenditures in line with the expenditures for the baseline year. This frequently results in ASC relative payment weights for surgical procedures that are lower than the OPPS relative payment weights for the same procedures for the upcoming year. Therefore, over time, even if procedures performed in the HOPD and ASC receive the same update factor under the OPPS and ASC payment system, payment rates under the ASC payment system would increase at a lower rate than payment for the same procedures performed in the HOPD as a result of applying the ASC weight scalar to ensure budget neutrality.

Consistent with our established policy, we proposed to scale the CY 2021 relative payment weights for ASCs according to the following method. Holding ASC utilization, the ASC conversion factor, and the mix of services constant from CY 2019, we proposed to compare the total payment using the CY 2020 ASC relative payment weights with the total payment using the CY 2021 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2020 and CY 2021. We proposed to use the ratio of CY 2020 to CY 2021 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2021. The proposed CY 2021 ASC weight scalar was 0.8494. Consistent with historical practice, we would scale the ASC relative payment weights of covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes, which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights.

Scaling would not apply in the case of ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services. The ASC payment weights for those services without predetermined national payment amounts (that is, those services with national payment amounts that would be based on OPPS relative payment weights) would be scaled to eliminate any difference in the total payment between the current year and the update year.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. At the time of the CY 2021 OPPS/ASC proposed rule, we had 90 percent of CY 2019 ASC claims data available.

A summary of the comments we received and our responses to those comments are set forth below.

Comment: Many commenters believe that CMS needs to reduce the disparity in payments between ASCs and HOPDs. Commenters stated that ASC payment rates are less than 50 percent of the HOPD payment rates for some high volume procedures. Many of these same commenters support the discontinuation of the ASC weight scalar, which they believe is the cause of the payment gap between ASCs and HOPDs. Commenters suggested that the ASC weight scalar as currently applied may make it economically infeasible for ASC facilities to continue to perform Medicare cases, hurting beneficiaries by limiting their access to high-quality outpatient surgical care. One commenter highlighted this concern and suggested that while expansion of the ASC Covered Procedures List would allow more procedures to be performed in the ASC, these additional procedures will not be performed in the ASC if ASC payment rates are lowered to unsustainable levels over time. Multiple commenters suggested that eliminating the secondary rescaling of the ASC relative payment weights, and instead applying the OPPS relative payment weights to ASC services, would allow ASCs to continue to provide quality surgical care for Medicare patients. They provided that, while they understand the additional scaling factor that CMS applies to the ASC relative payment weights maintains budget neutrality within the ASC payment system, this scaling contributes to the large payment differentials for similar services between the ASC and HOPD systems.

Response: We thank commenters for flagging this important issue. As we stated in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59421) we share commenters' concerns about the effects of payment disparities between the OPPS and ASC payment systems. We note that applying the weight scalar in calculation of ASC payment rates, which is 0.8591 for this final rule with comment period, ensures that the ASC payment system remains budget neutral. We understand the commenters do not believe it is necessary to calculate a weight scalar under the ASC payment system. The commenters contend that application of the weight scalar to ASC payment rates has led to increasingly large differences in the amount of payment for similar services between the OPPS and the ASC payment system. We understand commenters' concerns, however, we are unable to calculate a single weight scalar for both the OPPS and the ASC payment system without rescaling OPPS payment weights in a non-budget neutral manner. We will take the points that the commenters raised into consideration as part of our efforts to improve choice and competition in the Medicare program. However, as noted in previous rulemaking (83 FR 59076), we do not believe that the ASC cost structure is identical to the hospital cost structure. Further, we do not collect cost data from ASCs, and therefore we lack the necessary data to assess the actual differences in costs between the hospital outpatient department and ASC settings.

To create an analytic file to support calculation of the weight scalar and budget neutrality adjustment for the wage index (discussed below), we summarized available CY 2019 ASC claims by ASC and by HCPCS code. We used the National Provider Identifier for the purpose of identifying unique ASCs within the CY 2019 claims data. We used the supplier zip code reported on the claim to associate State, county, and CBSA with each ASC. This file is available to the public as a supporting data file for the CY 2021 OPPS/ASC proposed rule and is posted on the CMS website at: *http://http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/ASCPaymentSystem.html.*

Comment: One commenter noted that our CY 2021 NPRM ASC Supplier Specific file incorrectly assigned certain ASCs in the previous CBSA of 16974 (Chicago-Naperville-Arlington Heights, IL) to the default CBSA 14 (Illinois)

rather than the new CBSA of 16984 (Chicago-Naperville-Evanston, IL) applicable to their location.

Response: We appreciate the commenter's observation and agree that ASCs in the previous CBSA of 16974 were erroneously assigned to default CBSA 14 rather than the new CBSA of 16984. We have corrected the CBSA assignment for these ASCs for this final rule with comment period.

b. Updating the ASC Conversion Factor

Under the OPPS, we typically apply a budget neutrality adjustment for provider level changes, most notably a change in the wage index values for the upcoming year, to the conversion factor. Consistent with our final ASC payment policy, for the CY 2017 ASC payment system and subsequent years, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79751 through 79753), we finalized our policy to calculate and apply a budget neutrality adjustment to the ASC conversion factor for supplier level changes in wage index values for the upcoming year, just as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor. For CY 2021, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2019 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2021 ASC wage indexes. Specifically, holding CY 2019 ASC utilization, service-mix, and the proposed CY 2021 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2020 ASC wage indexes and the total adjusted payment using the proposed CY 2021 ASC wage indexes. We used the 50-percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2020 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2021 ASC wage indexes and applied the resulting ratio of 0.9999 (the proposed CY 2021 ASC wage index budget neutrality adjustment) to the CY 2020 ASC conversion factor to calculate the proposed CY 2021 ASC conversion factor.

Section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated amounts established under the revised ASC payment system in a calendar year, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (CPI–U), U.S. city average, as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. The statute does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI–U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at § 416.171(a)(2)(ii)), to update the ASC conversion factor using the CPI–U for CY 2010 and subsequent calendar years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59080), we finalized our proposal to apply the MFP-adjusted hospital market basket update to ASC payment system rates for an interim period of 5 years (CY 2019 through CY 2023), during which we will assess whether there is a migration of the performance of procedures from the hospital setting to the ASC setting as a result of the use of a MFP-adjusted hospital market basket update, as well as whether there are any unintended consequences, such as less than expected migration of the performance of procedures from the hospital setting to the ASC setting. In addition, we finalized our proposal to revise our regulations under § 416.171(a)(2), which address the annual update to the ASC conversion factor. During this 5-year period, we intend to assess the feasibility of collaborating with stakeholders to collect ASC cost data in a minimally burdensome manner and could propose a plan to collect such information. We refer readers to that final rule for a detailed discussion of the rationale for these policies.

As stated in the CY 2021 OPPS/ASC proposed rule, the hospital market basket update for CY 2021 was projected to be 3.0 percent, as published in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32738), based on IHS Global Inc.'s (IGI's) 2019 fourth quarter forecast with historical data through the third quarter of 2019.

We finalized the methodology for calculating the MFP adjustment in the CY 2011 PFS final rule with comment period (75 FR 73394 through 73396) and revised it in the CY 2012 PFS final rule with comment period (76 FR 73300 through 73301) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70500 through 70501). As stated in the CY 2021 OPPS/ASC proposed rule (85 FR 32739), the proposed MFP adjustment for CY 2021 was projected to be 0.4 percentage point, as published in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32739) based on IGI's 2019 fourth quarter forecast.

For CY 2021, we proposed to utilize the hospital market basket update of 3.0 percent minus the MFP adjustment of 0.4 percentage point, resulting in an MFP-adjusted hospital market basket update factor of 2.6 percent for ASCs meeting the quality reporting requirements. Therefore, we proposed to apply a 2.6 percent MFP-adjusted hospital market basket update factor to the CY 2020 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2021 ASC payment amounts. The ASCQR Program affected payment rates beginning in CY 2014 and, under this program, there is a 2.0 percentage point reduction to the update factor for ASCs that fail to meet the ASCQR Program requirements. We refer readers to section XIV.E. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 59138 through 59139) and section XIV.E. of this CY 2021 OPPS/ASC proposed rule for a detailed discussion of our policies regarding payment reduction for ASCs that fail to meet ASCQR Program requirements. We proposed to utilize the hospital market basket update of 3.0 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then subtract the 0.4 percentage point MFP adjustment. Therefore, we proposed to apply a 0.6 percent MFP-adjusted hospital market basket update factor to the CY 2020 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also proposed that if more recent data are subsequently available (for example, a more recent estimate of the hospital market basket update or MFP adjustment), we would use such data, if appropriate, to determine the CY 2021 ASC update for the CY 2021 OPPS/ASC final rule with comment period.

For CY 2021, we proposed to adjust the CY 2020 ASC conversion factor ($47.747) by the proposed wage index budget neutrality factor of 0.9999 in addition to the MFP-adjusted hospital market basket update of 2.6 percent discussed above, which resulted in a proposed CY 2021 ASC conversion factor of $48.984 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we proposed to adjust the CY 2020 ASC conversion factor ($47.747) by the proposed wage index budget neutrality factor of 0.9999 in addition to the quality reporting/MFP-adjusted hospital market basket update of 0.6 percent discussed above, which resulted in a proposed CY 2021 ASC conversion factor of $48.029.

The comments we received on our proposals for updating the CY 2021 ASC

conversion factor and our responses are set forth below.

Comment: The majority of commenters supported continued use of the hospital market basket for updating ASC payments on an annual basis. Some commenters suggested that maintaining alignment in the update factor used in the OPPS and ASC payment system will encourage the migration of care to the lower cost ASC setting and ensure that ASCs remain a viable high quality and lower cost option for patients. Other commenters supported this approach as it would promote site-neutrality between the two settings of care through more comparable payment. Other commenters supported the continued use of the hospital market basket to update ASC payment rates, but believed that the migration of services to ASCs would be limited due to the ASC budget neutrality adjustments. Specifically, commenters stated that CMS' current approach to maintaining budget neutrality in the ASC payment system caused increasingly large differences in the amount of payment for similar services provided in the ASC and HOPD settings, and there was no evidence of corresponding changes in capital and operating costs between the ASC and HOPD settings to support this growing payment differential. Commenters suggested that widening the gap in payment amounts for similar services provided in the ASC and hospital outpatient department settings could make it economically infeasible for ASCs to perform certain procedures for Medicare beneficiaries, causing financial hardships for ASCs, discouraging them from furnishing those procedures, and thereby discouraging the migration of services from the HOPD to the ASC setting.

Response: We appreciate the commenters' support. We believe using the same update factor to calculate payments to ASC and hospital outpatient departments encourages the migration of services from the hospital setting to the ASC setting, and could potentially increase the presence of ASCs in health care markets or geographic areas where previously there were none or few. The migration of services from the higher cost hospital outpatient setting to the ASC setting is likely to result in savings to beneficiaries and the Medicare program. This policy will also further our goal of giving both physicians and beneficiaries a greater choice in selecting the care setting that best suits their needs.

Comment: Several commenters provided input on collecting cost data from ASCs. They suggested that if CMS chooses to collect cost data from ASCs, for instance to develop a market basket, the agency should consider establishing a market basket that can be applied to both the ASC and hospital outpatient setting. They believed this would ensure that payments using the same relative weights and update factor would remain aligned over time, noting that HOPDs and ASCs incur similar types of costs.

These commenters offered to work with CMS in developing a survey or other low burden data collection activity. They suggested an initial effort to identify and calculate expense categories as a percentage of total expenses to help determine the appropriate weights and price proxies for the ASC setting. These commenters also urged CMS to recognize the variability among ASCs and recognize that cost experience can differ depending on factors such as specialties served, facility size, and geographic location. Commenters also requested that CMS keep in mind the administrative burdens placed on ASC staff in meeting current regulatory requirements and that requiring any formal cost reports from ASCs may run counter to the agency's desire to establish policies that allow ASCs to deliver services to Medicare beneficiaries efficiently.

Response: We thank the commenters for their input and we will take these suggestions into consideration in future policy development. As discussed in the CY 2019 OPPS/ASC final rule with comment period, we will continue to assess the feasibility of collaborating with stakeholders to collect ASC cost data in a minimally burdensome manner and potentially propose a plan to collect such information during the 5-year period in which CMS has updated the ASC payment methodology to rely upon the hospital market basket as the update factor (83 FR 59077). We will continue to assess the feasibility of collaborating with stakeholders to collect ASC cost data in a minimally burdensome manner for future policy development.

After consideration of the public comments we received, consistent with our proposal that if more recent data are subsequently available (for example, a more recent estimate of the hospital market basket update and MFP), we would use such data, if appropriate, to determine the CY 2021 ASC update for the CY 2021 OPPS/ASC final rule with comment period, we are incorporating more recent data to determine the final CY 2021 ASC update.

For this CY 2021 OPPS/ASC final rule with comment period, the 10-year moving average growth of the MFP for FY 2021 is projected to be –0.1 percentage point, based on IGI's June 2020 macroeconomic forecast, as published in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58797). However, under section 1833(i)(2)(D)(v) of the Act, the Secretary is required to reduce (not increase) the annual update factor by changes in economy-wide productivity. Accordingly, we are applying a final MFP adjustment of 0.0 percentage point for CY 2021.

Therefore, for this CY 2021 OPPS/ASC final rule with comment period, the hospital market basket update for CY 2021 is 2.4 percent, as published in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58796–7), based on IGI's 2020 second quarter forecast with historical data through the first quarter of 2020. The MFP adjustment for this CY 2020 OPPS/ASC final rule with comment period is 0.0 percentage point, as published in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58797).

For CY 2021, we are finalizing the hospital market basket update of 2.4 percent minus the MFP adjustment of 0.0 percentage point, resulting in an MFP-adjusted hospital market basket update factor of 2.4 percent for ASCs meeting the quality reporting requirements. Therefore, we apply a 2.4 percent MFP-adjusted hospital market basket update factor to the CY 2020 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2021 ASC payment rates. We are finalizing the hospital market basket update of 2.4 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then subtract the 0.0 percentage point MFP adjustment. Therefore, we apply a 0.4 percent MFP-adjusted hospital market basket update factor to the CY 2020 ASC conversion factor for ASCs not meeting the quality reporting requirements.

For CY 2021, we are adjusting the CY 2020 ASC conversion factor ($47.747) by a wage index budget neutrality factor of 1.0012 in addition to the MFP-adjusted hospital market basket update of 2.4 percent, discussed above, which results in a final CY 2021 ASC conversion factor of $48.952 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we are adjusting the CY 2020 ASC conversion factor ($47.747) by the wage index budget neutrality factor of 1.0012 in addition to the quality reporting/MFP-adjusted hospital market basket update of 0.4 percent discussed above, which results in a final CY 2021 ASC conversion factor of $47.996.

3. Display of Final CY 2021 ASC Payment Rates

Addenda AA and BB to this CY 2021 OPPS/ASC final rule (which are available on the CMS website) display the final ASC payment rates for CY 2021 for covered surgical procedures and covered ancillary services, respectively. For those covered surgical procedures and covered ancillary services where the payment rate is the lower of the proposed rates under the ASC standard ratesetting methodology and the MPFS final rates, the final payment indicators and rates set forth in this CY 2021 OPPS/ASC final rule are based on a comparison using the PFS rates that would be effective January 1, 2021. For a discussion of the PFS rates, we refer readers to the CY 2021 PFS proposed rule that is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

The final payment rates included in addenda AA and BB to this CY 2021 OPPS/ASC final rule reflect the full ASC payment update and not the reduced payment update used to calculate payment rates for ASCs not meeting the quality reporting requirements under the ASCQR Program. These addenda contain several types of information related to the final CY 2021 payment rates. Specifically, in Addendum AA, a ''Y'' in the column titled ''To be Subject to Multiple Procedure Discounting'' indicates that the surgical procedure would be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50-percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session.

Display of the comment indicator ''CH'' in the column titled ''Comment Indicator'' indicates a change in payment policy for the item or service, including identifying discontinued HCPCS codes, designating items or services newly payable under the ASC payment system, and identifying items or services with changes in the ASC payment indicator for CY 2021. Display of the comment indicator ''NI'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that comments will be accepted on the interim payment indicator for the new code. Display of the comment indicator ''NP'' in the column titled ''Comment Indicator'' indicates that the code is new (or substantially revised) and that comments will be accepted on the ASC payment indicator for the new code.

For CY 2021, we proposed to add a new column to ASC Addendum BB titled ''Drug Pass-Through Expiration during Calendar Year'' where we would flag through the use of an asterisk each drug for which pass-through payment is expiring during the calendar year (that is, on a date other than December 31st).

The values displayed in the column titled ''Final CY 2021 Payment Weight'' are the final relative payment weights for each of the listed services for CY 2021. The final relative payment weights for all covered surgical procedures and covered ancillary services where the ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Therefore, scaling was not applied to the device portion of the device-intensive procedures, services that are paid at the MPFS nonfacility PE RVU-based amount, separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS, or services that are contractor-priced or paid at reasonable cost in ASCs. This includes separate payment for non-opioid pain management drugs.

To derive the final CY 2021 payment rate displayed in the ''Final CY 2021 Payment Rate'' column, each ASC payment weight in the ''Final CY 2021 Payment Weight'' column was multiplied by final CY 2021 conversion factor of $48.952. The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update factor as reduced by the productivity adjustment. The final CY 2021 ASC conversion factor uses the CY 2021 MFP-adjusted hospital market basket update factor of 2.4 percent (which is equal to the projected hospital market basket update of 2.4 percent minus a projected MFP adjustment of 0.0 percentage point).

In Addendum BB, there are no relative payment weights displayed in the ''Final CY 2021 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''Final CY 2021 Payment'' column displays the final CY 2021 national unadjusted ASC payment rates for all items and services. The final CY 2021 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are based on ASP data used for payment in physicians' offices in 2020.

Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are proposed to be excluded from payment in ASCs for CY 2021.

XIV. Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

A. Background

1. Overview

CMS seeks to promote higher quality and more efficient healthcare for Medicare beneficiaries. Consistent with these goals, CMS has implemented quality reporting programs for multiple care settings including the quality reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Reporting (OQR) Program, formerly known as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP). The Hospital OQR Program is generally aligned with the quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (IQR) Program.

2. Statutory History of the Hospital OQR Program

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72065) for a detailed discussion of the statutory history of the Hospital OQR Program.

3. Regulatory History of the Hospital OQR Program

We refer readers to the CY 2008 through 2019 OPPS/ASC final rules with comment period (72 FR 66860 through 66875; 73 FR 68758 through 68779; 74 FR 60629 through 60656; 75 FR 72064 through 72110; 76 FR 74451 through 74492; 77 FR 68467 through 68492; 78 FR 75090 through 75120; 79 FR 66940 through 66966; 80 FR 70502 through 70526; 81 FR 79753 through 79797; 82 FR 59424 through 59445; 83 FR 59080 through 59110; and 84 FR 61410 through 61420) for the regulatory history of the Hospital OQR Program. We have codified certain requirements under the Hospital OQR Program at § 419.46.

4. Codify Statutory Authority for Hospital OQR Program

The Hospital OQR Program regulations are codified at § 419.46. In the CY 2021 OPPS/ASC proposed rule (85 FR 48984), we proposed to update the regulations to include a reference to the statutory authority for the Hospital OQR Program. Section 1833(t)(17)(A) of the Social Security Act (the Act) states that subsection (d) hospitals (as defined

under section 1886(d)(1)(B) of the Act) that do not submit data required for measures selected with respect to such a year, in the form and manner required by the Secretary, will incur a 2.0 percentage point reduction to their annual Outpatient Department (OPD) fee schedule increase factor. We proposed to redesignate the existing paragraphs (a) through (h) as paragraphs (b) through (i) and codify the Hospital OQR Program's statutory authority at new § 419.46(a). Because of the proposed redesignations, the cross-references throughout § 419.46 were also proposed to be updated. Table 61 shows the correlation between the proposed cross-references.

TABLE 61: Correlation Between the Cross-References Proposed to be Removed and Added Throughout § 419.46

Proposed Newly Redesignated Paragraphs	Proposed Cross-references to be Removed	Proposed Cross-references to be Added
(d)(3)(ii) and (iii)	(c)(2)	(d)(2)
(g)(2)(viii)	(e)(1)	(f)(1)
(i)(1)	(h)(2) and (3)	(i)(2) and (3)
(i)(3)	(h)(2)	(i)(2)
(i)(3)(ii)	(h)(3)(i)(A)	(i)(3)(i)(A)

We requested public comment on this proposal.

We refer readers to section XIV.E. of the CY 2021 OPPS/ASC proposed rule for a detailed discussion of the payment reduction for hospitals that fail to meet Hospital OQR Program requirements for the CY 2023 payment determination (85 FR 48772).

The following is a summary of the comment we received and our response that comment.

Comment: A commenter supported our proposal to codify the statutory authority for the Hospital OQR Program.

Response: We thank the commenter for their support.

After consideration of the public comments received, we are finalizing our proposals as proposed.

B. Hospital OQR Program Quality Measures

1. Considerations in Selecting Hospital OQR Program Quality Measures

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74458 through 74460) for a detailed discussion of the priorities we consider for the Hospital OQR Program quality measure selection. We did not propose any changes to these policies.

2. Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations

We previously adopted a policy to retain measures from a previous year's Hospital OQR Program measure set for subsequent years' measure sets in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68471). For more information regarding this policy, we refer readers to that final rule with comment period. We codified this policy at § 419.46(h)(1) in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59082). We did not propose any changes to these policies.

3. Removal of Quality Measures From the Hospital OQR Program Measure Set

a. Immediate Removal

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60634 through 60635), we finalized a process for removal of Hospital OQR Program measures, based on evidence that the continued use of the measure as specified raises patient safety concerns.[104] We codified this policy at § 419.46(h)(2) in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59082). In the case of suspension or removal due to patient safety concerns, action would need to be taken quickly and may not coincide with rulemaking cycles (77 FR 68472). In this case, we would promptly remove the measure and notify hospitals of its removal, and confirm the removal of the measure in the next rulemaking cycle. We did not propose any changes to these policies.

b. Consideration Factors for Removing Measures

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60635), we finalized to use the regular rulemaking process to remove a measure for circumstances for which we do not believe that continued use of a measure raises specific patient safety concerns.[105] We codified this policy at § 419.46(h)(3) in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59082). In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59083 through 59085), we clarified, finalized, and codified at § 419.46(h)(3) an updated set of factors[106] and policies for determining whether to remove measures from the Hospital OQR Program. We refer readers to that final rule with comment period for a detailed discussion of our policies regarding measure removal factors. We did not propose any changes to these policies.

4. Summary of Hospital OQR Program Measure Set for the CY 2023 Payment Determination and Subsequent Years

We refer readers to the CY 2020 OPPS/ASC final rule with comment period (84 FR 61410 through 61420) for a summary of the previously adopted Hospital OQR Program measure set for the CY 2022 payment determination and subsequent years.

In the CY 2021 OPPS/ASC proposed rule (85 FR 48985), we did not propose any changes to the previously adopted measure set. Table 62 summarizes the previously finalized Hospital OQR Program measure set for the CY 2023

[104] We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68472 through 68473) for a discussion of our reasons for changing the term ''retirement'' to ''removal'' in the Hospital OQR Program.

[105] We initially referred to this process as ''retirement'' of a measure in the 2010 OPPS/ASC proposed rule, but later changed it to ''removal'' during final rulemaking.

[106] We note that we previously referred to these factors as ''criteria'' (for example, 77 FR 68472 through 68473); we now use the term ''factors'' in order to align the Hospital OQR Program terminology with the terminology we use in other CMS quality reporting and pay-for-performance (value-based purchasing) programs.

payment determination and subsequent years.

TABLE 62: Hospital OQR Program Measure Set for the CY 2023 Payment Determination and Subsequent Years

NQF #	Measure Name
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
0514	OP-8: MRI Lumbar Spine for Low Back Pain†
None	OP-10: Abdomen CT – Use of Contrast Material
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0499	OP-22: Left Without Being Seen†
0661	OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
0658	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
1536	OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	OP-37a: OAS CAHPS – About Facilities and Staff**
None	OP-37b: OAS CAHPS – Communication About Procedure**
None	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery**
None	OP-37d: OAS CAHPS – Overall Rating of Facility**
None	OP-37e: OAS CAHPS – Recommendation of Facility**

† We note that NQF endorsement for this measure was removed.
* Measure voluntarily collected as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).
** Measure reporting delayed beginning with CY 2018 reporting and for subsequent years as discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59432 through 59433).

The following is a summary of the comments we received and our response those comments.

Comment: A few commenters supported retaining the current Hospital OQR Program measure set.

Response: We thank commenters for their support.

5. Maintenance of Technical Specifications for Quality Measures

CMS maintains technical specifications for previously adopted Hospital OQR Program measures. These specifications are updated as we modify the Hospital OQR Program measure set. The manuals that contain specifications for the previously adopted measures can be found on the QualityNet website at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1196289981244*. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59104 through 59105), where we changed the frequency of the Hospital OQR Program Specifications Manual release beginning with CY 2019 and subsequent years, such that we will release a manual once every 12 months and release addenda as necessary. We did not propose any changes to these policies.

6. Public Display of Quality Measures

We refer readers to the CY 2009, CY 2014, and CY 2017 OPPS/ASC final rules with comment period (73 FR 68777 through 68779, 78 FR 75092, and 81 FR 79791, respectively) for our previously finalized policies regarding public display of quality measures.

a. Codification

In the 2009 OPPS/ASC final rule with comment period (73 FR 68778), we finalized that hospitals sharing the same CMS Certification Number (CCN) must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes. While we previously finalized this policy, it was not codified. In the CY 2021 OPPS/ASC proposed rule (85 FR 48987, we proposed to codify this policy by adding language at the

redesignated paragraph (d)(1). The newly redesignated paragraph (d)(1) would specify that ''Hospitals sharing the same CCN must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes.'' We solicited public comment on our proposal. The following is a summary of the comment we received and our response that comment.

Comment: One commenter expressed concern with the proposal to codify this previously finalized policy to combine Hospital OQR Program data for multiple hospitals under the same CCN. The commenter believes that CMS should publicly report data for individual facilities (that is, campuses and locations), not by CCN.

Response: We disagree with the commenter; we believe data should be reported by CCN, because it is difficult to identify cases by facilities since billing is done under CCNs. Under our current policy, we publish quality data by the corresponding hospital CCN and indicate instances where data from two or more hospitals are combined to form the publicly reported measures on the Hospital Compare website and the successor Care Compare website. In the CY 2014 OPPS/ASC proposed rule (78 FR 43645), we noted that in a situation in which a larger hospital has taken over ownership of a smaller hospital, the smaller hospital's CCN is replaced by the larger hospital's CCN (the principal CCN). For data display purposes, we only display data received under the principal CCN. If both hospitals submit data, those data are not distinguishable in the warehouse [107] and are calculated together as one hospital.

After consideration of the public comments received, we are finalizing our proposal as proposed.

b. Overall Hospital Quality Star Rating

In the CY 2021 OPPS/ASC proposed rule (85 FR 48987), we proposed a methodology to calculate the Overall Hospital Quality Star Rating (Overall Star Rating). The Overall Star Rating would utilize data collected on hospital inpatient and outpatient measures that are publicly reported on a CMS website, including data from the Hospital OQR Program. We refer readers to section XVI. ''Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years'' of the CY 2021 OPPS/ASC final rule with comment period for details.

C. Administrative Requirements

1. QualityNet Account and Security Administrator/Security Official

The previously finalized QualityNet security administrator requirements, including setting up a QualityNet account and the associated timelines, are described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109). We codified these procedural requirements at § 419.46(a) in that final rule with comment period.

In the CY 2021 OPPS/ASC proposed rule (85 FR 48772), we proposed to use the term ''security official'' instead of ''security administrator'' to denote the exercise of authority invested in the role. The term ''security official'' would refer to ''the individual(s)'' who have responsibilities for security and account management requirements for a hospital's QualityNet account. To be clear, this proposed update in terminology would not change the individual's responsibilities or add burden. We proposed to revise existing § 419.46(a)(2) and redesignate § 419.46(b)(2), by replacing the term ''security administrator'' with the term ''security official.'' The redesignated paragraph (b)(2) would read: ''Identify and register a QualityNet security official as part of the registration process under paragraph (b)(1) of this section.''

We invited public comment on our proposal. However, we did not receive any comments on this proposal. We are finalizing our proposal as proposed.

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75108 through 75109), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70519) and the CY 2019 OPPS/ASC final rule with comment period (83 FR 59103 through 59104) for requirements for participation and withdrawal from the Hospital OQR Program. We codified these procedural requirements regarding participation status at § 419.46(a) and (b).

In the CY 2021 OPPS/ASC proposed rule (85 FR 48772), we proposed to revise existing § 419.46(b), redesignated § 419.46(c), by removing the phrase ''submit a new participation form'' to align with previously finalized policy. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59103through 83 FR 59104), we removed submission of Notice of Participation (NoP) form as a program requirement. We also proposed to update internal cross-references as a result of the redesignations discussed under section XIV.A.4. of the CY 2021 OPPS/ASC proposed rule. The proposed redesignated § 419.46(c) would specify that a withdrawn hospital will not be able to later sign up to participate in that payment update, is subject to a reduced annual payment update as specified under § 419.46(i), and is required to renew participation as specified in § 419.46(b) in order to participate in any future year of the Hospital OQR Program. Our proposal also included updated cross-referenced provisions in the redesignated § 419.46(c).

We solicited public comment on our proposal. However, we did not receive any comments on this proposal. We are finalizing our proposal as proposed.

D. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

1. Hospital OQR Program Annual Submission Deadlines

We refer readers to the CYs 2014, 2016, and 2018 OPPS/ASC final rules with comment period (78 FR 75110 through 75111; 80 FR 70519 through 70520; and 82 FR 59439) where we finalized our policies for data submission deadlines. We codified these submission requirements at § 419.46(c). The submission deadlines for the CY 2023 payment determination and subsequent years are illustrated in Table 63.

[107] The data reviewed are maintained in the CMS Integrated Data Repository (IDR). The IDR is a high volume data warehouse integrating Medicare Parts A, B, C, and D, and DME claims, beneficiary and provider data sources, along with ancillary data such as contract information and risk scores. Additional information is available at *https://www.cms.gov/Research-Statistics-Data-andSystems/Computer-Data-and-Systems/IDR/index.html.*

TABLE 63: CY 2023 Payment Determination and Subsequent Years

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2021 (April 1 - June 30)	11/1/2021
Q3 2021(July 1 – September 30)	2/1/2022
Q4 2021 (October 1 - December 31)	5/1/2022
Q1 2022 (January 1 - March 31)	8/1/2022

In the CY 2021 OPPS/ASC proposed rule (85 FR 48772), we proposed a change to our submission deadlines to align with statute. We proposed that all deadlines falling on a nonwork day be moved forward consistent with section 216(j) of the Act, 42 U.S.C. 416(j), ''Periods of Limitation Ending on Nonwork Days,'' beginning with the effective date of this rule. Section 1872 of the Act, incorporates section 216(j) of the Act, to apply to Title XVIII, the Medicare program to which the Hospital OQR Program is administered. We proposed that all deadlines occurring on a Saturday, Sunday, legal holiday, or on any other day all or part of which is declared to be a nonwork day for federal employees by statute or Executive order, would be extended to the first day thereafter which is not a Saturday, Sunday, legal holiday, or any other day all or part of which is declared to be a nonwork day for federal employees by statute or Executive order.

We proposed to revise our policy regarding submission deadlines at existing § 419.46(c)(2), redesignated § 419.46(d)(2). The newly redesignated paragraph (d)(2) would specify that all deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order are extended to the first day thereafter which is not a Saturday, Sunday or legal holiday or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order. We invited public comment on our proposal. The following is a summary of the comments we received and our responses to those comments.

Comment: A few commenters supported our proposal to codify in order to make it consistent with section 216(j) of the Act. One commenter also stated that it would reduce the need for employees to work on holidays or weekends in order to submit Hospital OQR Program measures.

Response: We thank the commenters for their support. We agree with commenters that this policy change would lessen the need for employees to work on holidays or weekends.

After consideration of public comments, we are finalizing our proposal as proposed.

2. Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS for the CY 2023 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68481 through 68484) for a discussion of the form, manner, and timing for data submission requirements of chart-abstracted measures for the CY 2014 payment determination and subsequent years. We did not propose any changes to these policies.

The following previously finalized Hospital OQR Program chart-abstracted measures will require patient-level data to be submitted for the CY 2022 payment determination and subsequent years:

- *OP–2:* Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival (NQF #0288);
- *OP–3:* Median Time to Transfer to Another Facility for Acute Coronary Intervention (NQF #0290);
- *OP–18:* Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496); and
- *OP–23:* Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT Scan Interpretation Within 45 Minutes of ED Arrival (NQF #0661).

3. Claims-Based Measure Data Requirements for the CY 2023 Payment Determination and Subsequent Years

Currently, the following previously finalized Hospital OQR Program claims-based measures are required for the CY 2022 payment determination and subsequent years:

- *OP–8:* MRI Lumbar Spine for Low Back Pain (NQF #0514);
- *OP–10:* Abdomen CT—Use of Contrast Material;
- *OP–13:* Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low Risk Surgery (NQF #0669);
- *OP–32:* Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539);
- *OP–35:* Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy; and
- *OP–36:* Hospital Visits after Hospital Outpatient Surgery (NQF #2687).

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59106 through 59107), where we established a 3-year reporting period for OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy beginning with the CY 2020 payment determination and for subsequent years. In that final rule with comment period (83 FR 59136 through 59138), we established a similar policy under the ASCQR Program. We did not propose any changes to these policies.

4. Data Submission Requirements for the OP–37a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures for the CY 2023 Payment Determination and Subsequent Years

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79792 through 79794) for a discussion of the previously finalized requirements related to survey administration and vendors for the OAS CAHPS Survey-based measures. In addition, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59432 through 59433), where we finalized a policy to delay implementation of the OP–37a–e OAS CAHPS Survey-based measures beginning with the CY 2020 payment determination (2018 reporting period) until further action in future rulemaking. We did not propose any changes to the previously finalized requirements related to survey administration and vendors for the OAS CAHPS Survey-based measures.

5. Data Submission Requirements for Measures for Data Submitted via a Web-based Tool for the CY 2022 Payment Determination and Subsequent Years

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75112 through 75115), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70521), and the CMS QualityNet website (*www.qualitynet.org* for a discussion of the requirements for measure data submitted via the CMS QualityNet Secure Portal (also referred to as the HQR system secure portal) for the CY 2017 payment determination and subsequent years. In addition, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75097 through 75100) for a discussion of the requirements for measure data submitted via the CDC NHSN website. We did not propose any changes to these policies.

The following previously adopted quality measures will require data to be submitted via a CMS web-based tool for the CY 2023 payment determination and subsequent years with the exception of OP–31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) for which data submission remains voluntary:

- *OP–22:* Left Without Being Seen (NQF #0499);
- *OP–29:* Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658); and
- *OP–31:* Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536).

6. Population and Sampling Data Requirements for the CY 2021 Payment Determination and Subsequent Years

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72100 through 72103) and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74482 through 74483) for discussions of our population and sampling requirements. We did not propose any changes to these policies.

7. Review and Corrections Period for Measure Data Submitted to the Hospital OQR Program

a. Chart-Abstracted Measures

We refer readers to the CY 2015 OPPS/ASC final rule with comment period (79 FR 66964 and 67014) where we formalized a review and corrections period for chart-abstracted measures in the Hospital OQR Program. Per the previously finalized policy, the Hospital OQR Program implemented a 4-month review and corrections period for chart-abstracted measure data, which runs concurrently with the data submission period. During the review and corrections period for chart-abstracted data, hospitals can enter, review, and correct data submitted directly to CMS for the chart-abstracted measures.

b. Web-Based Measures

In the CY 2021 OPPS/ASC proposed rule (85 FR 48772), we proposed to expand our review and corrections policy to apply to measure data submitted via the CMS web-based tool beginning with data submitted for the CY 2023 payment determination and subsequent years. Hospitals would have a review and corrections period for web-based measures, which would run concurrently with the data submission period. The review and corrections period for web-based measures is from the time the submission period opens to the submission deadline. During this review and corrections period, hospitals can enter, review, and correct data submitted directly to CMS. However, after the submission deadline, hospitals would not be allowed to change these data. The expansion of the existing policy for chart-abstracted measures to data submitted via the CMS web-based tool would accommodate a growing diversity of measure types in the Hospital OQR Program. We solicited public comment on our proposal. The following is a summary of the comments we received and our responses to those comments.

Comment: A few commenters supported our proposal to expand the review and corrections policy for chart-abstracted measures to apply to measure data submitted via the CMS web-based tool. The commenters stated that it is appropriate for hospitals to have an opportunity to review and correct data submitted on any existing and future measures using a web-based tool.

Response: We thank the commenters for their support. As the diversity of measure types continues to increase, we agree that hospitals should have an opportunity to enter, review and correct data submitted to our web-based tool. This begins with data submitted during CY 2022 for the CY 2023 payment determination.

After consideration of public comments, we are finalizing our proposal as proposed.

c. Codification of the Review and Corrections Periods for Measure Data Submitted to the Hospital OQR Program

We note that the previously finalized policy relating to the review and corrections period for chart-abstracted measures has not yet been codified. Therefore, in the CY 2021 OPPS/ASC proposed rule (85 FR 48772), we proposed to codify the review and corrections period policy for measure data submitted to the Hospital OQR Program for chart-abstracted measure data, as well as for the proposed policy for measure data submitted directly to CMS via the CMS web-based tool. Specifically, we proposed to add a new paragraph (c)(4) to § 419.46, redesignated § 419.46(d). The new paragraph (d)(4) would provide that for both chart-abstracted and web-based measures, hospitals have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, hospitals can enter, review, and correct data submitted. However, after the submission deadline, this data cannot be changed. We solicited public comment on our proposal. The following is a summary of the comment we received and our response to that comment.

Comment: One commenter supported our proposed updates to codify the review and corrections period policy for chart-abstracted measure data submitted to the Hospital OQR Program, as well as the proposed policy for measure data submitted directly to CMS via the CMS web-based tool.

Response: We thank the commenter for their support.

After consideration of public comments, we are finalizing our proposal as proposed.

7. Hospital OQR Program Validation Requirements

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72105 through 72106), the CY 2013 OPPS/ASC final rule with comment period (77 FR 68484 through 68487), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66964 through 66965), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441 through 59443), and § 419.46(e) for our policies regarding validation. In the CY 2021 OPPS/ASC proposed rule (85 FR 48772), while we did not propose changes to our validation policies, we proposed to codify certain previously finalized policies. These policies are discussed in detail in section XIV.D.8.b of the proposed rule.

a. Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures

(1) Background

In the CY 2018 final rule (82 FR 59441 through 59443), we finalized a policy to formalize the Educational Review Process for Chart-Abstracted Measures, including Validation Score Review and Correction. Under the informal process, hospitals that were selected and received a score for validation may request an educational review to better understand the results. A hospital has 30 calendar days from the date the validation results are made available via the QualityNet Secure Portal (also referred to as the HQR System) to contact the CMS designated contractor, currently known as the Validation Support Contractor (VSC), to request an educational review (82 FR 59442). In response to a request, the VSC obtains and reviews medical records directly from the Clinical Data Abstraction Center (CDAC) and provides feedback (82 FR 59442). CMS, or its contractor, generally provides educational review results and responses via a secure file transfer to the hospital (82 FR 59442). In the CY 2018 final rule (82 FR 59441 through 59443), we (1) formalized this process; and (2) specified that if the results of an educational review indicate that we incorrectly scored a hospital's medical records selected for validation, the corrected quarterly validation score would be used to compute the hospital's final validation score at the end of the calendar year. We did not propose any changes to this finalized policy.

(2) Codification of Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures

The previously finalized policy to formalize the Educational Review Process for Chart-Abstracted Measures, including Validation Score Review and Correction finalized in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59441 through 59442), has not yet been codified at § 419.46. In the CY 2021 OPPS/ASC proposed rule (85 FR 48772), we proposed to codify those policies by adding a new paragraph (e)(4) to § 419.46, redesignated § 419.46(f). The new paragraph (f)(4) would specify that hospitals that are selected and receive a score for validation of chart-abstracted measures may request an educational review in order to better understand the results within 30 calendar days from the date the validation results are made available. If the results of an educational review indicate that a hospital's medical records selected for validation for chart-abstracted measures was incorrectly scored, the corrected quarterly validation score will be used to compute the hospital's final validation score at the end of the calendar year.

We invited public comment on this proposal. We did not receive any comments on this proposal. We are finalizing our proposal as proposed.

8. Extraordinary Circumstances Exception (ECE) Process for the CY 2021 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75119 through 75120), the CY 2015 OPPS/ASC final rule with comment period (79 FR 66966), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79795), the CY 2018 OPPS/ASC final rule with comment period (82 FR 59444), and 42 CFR 419.46(d) for a complete discussion of our extraordinary circumstances exception (ECE) process under the Hospital OQR Program. We did not propose any changes to these policies.

9. Hospital OQR Program Reconsideration and Appeals Procedures for the CY 2021 Payment Determination and Subsequent Years

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68487 through 68489), the CY 2014 OPPS/ASC final rule with comment period (78 FR 75118 through 75119), the CY 2016 OPPS/ASC final rule with comment period (80 FR 70524), the CY 2017 OPPS/ASC final rule with comment period (81 FR 79795), and § 419.46(f) for our reconsideration and appeals procedures.

In alignment with our proposal to change submission deadlines, in section XIV.D.1. of the CY 2021 OPPS/ASC proposed rule (85 FR 48772), we proposed a change to our reconsideration deadlines. We proposed that all deadlines falling on a nonwork day be moved forward consistent with section 216(j) of the Act, 42 U.S.C. 416(j), ''Periods of Limitation Ending on Nonwork Days,'' beginning with the effective date of this rule. Section 1872 of the Act, incorporates section 216(j) of the Act, to apply to Title XVIII, the Medicare program to which the Hospital OQR Program is administered. Under this proposal, all deadlines occurring on a Saturday, Sunday, legal holiday, or on any other day all or part of which is declared to be a nonwork day for federal employees by statute or Executive order, would be extended to the first day thereafter which is not a Saturday, Sunday, legal holiday or any other day all or part of which is declared to be a nonwork day for federal employees by statute or Executive order. Specifically, we proposed to remove ''the first business day on or after'' from existing § 419.46(f)(1), redesignated § 419.46(g)(1), to ensure consistency with section 216(j) of the Act. The redesignated paragraph (g)(1) would provide that a hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital OQR Program for a particular calendar year. Except as provided in paragraph (e), a hospital must submit a reconsideration request to CMS via the QualityNet website, no later than March 17, or if March 17 falls on a nonwork day, on the first day after March 17 which is not a nonwork day as defined in § 419.46(d)(2), of the affected payment year as determined using the date the request was mailed or submitted to CMS.

We invited public comment on our proposal. However, we did not receive any comments on this proposal. We are finalizing our proposal as proposed.

E. Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2021 Payment Determination

1. Background

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on measures selected by the Secretary, in the form and manner, and at a time, specified by the Secretary will incur a 2.0 percentage point reduction to their Outpatient Department (OPD) fee schedule increase factor; that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment year involved and will not be taken into account in computing the applicable OPD fee schedule increase factor for a subsequent year.

The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data in order to receive the full payment update factor and that fail to meet the Hospital OQR Program requirements. Hospitals that meet the reporting requirements receive

the full OPPS payment update without the reduction. For a more detailed discussion of how this payment reduction was initially implemented, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative payment weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to the proposed rule, which is available via the internet on the CMS website): ''J1'', ''J2'', ''P'', ''Q1'', ''Q2'', ''Q3'', ''R'', ''S'', ''T'', ''V'', or ''U''. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79796), we clarified that the reporting ratio does not apply to codes with status indicator ''Q4'' because services and procedures coded with status indicator ''Q4'' are either packaged or paid through the Clinical Laboratory Fee Schedule and are never paid separately through the OPPS. Payment for all services assigned to these status indicators will be subject to the reduction of the national unadjusted payment rates for hospitals that fail to meet Hospital OQR Program requirements, with the exception of services assigned to New Technology APCs with assigned status indicator ''S'' or ''T''. We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770 through 68771) for a discussion of this policy.

The OPD fee schedule increase factor is an input into the OPPS conversion factor, which is used to calculate OPPS payment rates. To reduce the OPD fee schedule increase factor for hospitals that fail to meet reporting requirements, we calculate two conversion factors—a full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the ''reporting ratio'' to indicate that it applies to payment for hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative payment weights by the reduced conversion factor. For example, to determine the reduced national unadjusted payment rates that applied to hospitals that failed to meet their quality reporting requirements for the CY 2010 OPPS, we multiplied the final full national unadjusted payment rate found in Addendum B of the CY 2010 OPPS/ASC final rule with comment period by the CY 2010 OPPS final reporting ratio of 0.980 (74 FR 60642).

We note that the only difference in the calculation for the full conversion factor and the calculation for the reduced conversion factor is that the full conversion factor uses the full OPD update and the reduced conversion factor uses the reduced OPD update. The baseline OPPS conversion factor calculation is the same since all other adjustments would be applied to both conversion factor calculations. Therefore, our standard approach of calculating the reporting ratio as described earlier in this section is equivalent to dividing the reduced OPD update factor by that of the full OPD update factor. In other words:

Full Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor)

Reduced Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor − 0.02)

Reporting Ratio = Reduced Conversion Factor/Full Conversion Factor

Which is equivalent to:

Reporting Ratio = (1 + OPD Update factor − 0.02)/(1 + OPD update factor)

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for services provided by hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: The wage index adjustment, the multiple procedure adjustment, the interrupted procedure adjustment, the rural sole community hospital adjustment, and the adjustment for devices furnished with full or partial credit or without cost. Similarly, OPPS outlier payments made for high cost and complex procedures will continue to be made when outlier criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. We established this policy in the OPPS beginning in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G. of the CY 2021 OPPS/ASC proposed rule.

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2021

We proposed to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2021 annual payment update factor. For the CY 2021 OPPS/ASC proposed rule, the proposed reporting ratio was 0.9805, which when multiplied by the proposed full conversion factor of $83.697 equaled a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of $82.016. We proposed to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2021 OPPS/ASC proposed rule, we proposed to continue to apply the reporting ratio, when applicable, to all HCPCS codes to which we have proposed status indicator assignments of ''J1'', ''J2'', ''P'', ''Q1'', ''Q2'', ''Q3'', ''R'', ''S'', ''T'', ''V'', and ''U'' (other than new technology APCs to which we have proposed status

indicator assignment of ''S'' and ''T''). We proposed to continue to exclude services paid under New Technology APCs. We proposed to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. We also proposed to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we proposed to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements. In addition to our proposal to implement the policy through the use of a reporting ratio, we also proposed to calculate the reporting ratio to four decimals (rather than the previously used three decimals) to more precisely calculate the reduced adjusted payment and copayment rates.

For the CY 2021 OPPS/ASC final rule with comment period, the final reporting ratio is 0.9805, which when multiplied by the final full conversion factor of 82.797 equals a final conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of 81.183. We are finalizing our proposal to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements. We are also finalizing our proposals to implement the policy through the use of a reporting ratio, and to calculate the reporting ratio to four decimals (rather than the previously used three decimals) to more precisely calculate the reduced adjusted payment and copayment rates for hospitals that fail to meet the Hospital OQR Program requirements for CY 2021 payment.

XV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background

1. Overview

We refer readers to section XIV.A.1. of the CY 2020 final rule with comment period (84 FR 61410) for a general overview of our quality reporting programs and to the CY 2019 OPPS/ASC final rule with comment period (83 FR 58820 through 58822) where we previously discussed our Meaningful Measures Initiative and our approach for evaluating quality program measures.

2. Statutory History of the ASCQR Program

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74494) for a detailed discussion of the statutory history of the ASCQR Program.

3. Regulatory History of the ASCQR Program

We refer readers to the CYs 2014 through 2020 OPPS/ASC final rules with comment period (78 FR 75122; 79 FR 66966 through 66987; 80 FR 70526 through 70538; 81 FR 79797 through 79826; 82 FR 59445 through 59476; 83 FR 59110 through 59139; and 84 FR 61420 through 61434, respectively) for an overview of the regulatory history of the ASCQR Program. We have codified certain requirements under the ASCQR Program at 42 CFR, part 16, subpart H (42 CFR 416.300 through 416.330). In the CY 2021 OPPS/ASC proposed rule (85 FR 48993), we proposed to update certain currently codified program policies and propose a review and corrections period as well as other administrative changes. We discuss these proposals and applicable public comments in more detail below in sections XV.C. and XV.D.

B. ASCQR Program Quality Measures

1. Considerations in the Selection of ASCQR Program Quality Measures

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68493 through 68494) for a detailed discussion of the priorities we consider for the ASCQR Program quality measure selection. We did not propose any changes to these policies.

2. Policies for Retention and Removal of Quality Measures From the ASCQR Program

a. Retention of Previously Adopted ASCQR Program Measures

We previously finalized a policy that quality measures adopted for an ASCQR Program measure set for a previous payment determination year be retained in the ASCQR Program for measure sets for subsequent payment determination years except when such measures are removed, suspended, or replaced as indicated (76 FR 74494 and 74504; 77 FR 68494 through 68495; 78 FR 75122; and 79 FR 66967 through 66969). We did not propose any changes to this policy.

b. Removal Factors for ASCQR Program Measures

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59111 through 59115), we clarified, finalized, and codified at 42 CFR 416.320 an updated set of factors [108] and the process for removing measures from the ASCQR Program. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59111 through 59115) for a detailed discussion of our process regarding measure removal. We did not propose any changes to this policy.

3. Summary of ASCQR Program Quality Measure Set Previously Finalized for the CY 2024 Payment Determination and for Subsequent Years

In the CY 2021 OPPS/ASC proposed rule (85 FR 48992), we did not propose to remove any existing measures or to adopt any new measures for the CY 2023 payment determination. Table 64 summarizes the previously finalized ASCQR Program measure set for the CY 2024 payment determination and subsequent years.

[108] We note that we previously referred to these factors as ''criteria'' (for example, 79 FR 66967 through 66969); we now use the term ''factors'' to align the ASCQR Program terminology with the terminology used in other CMS quality reporting and pay-for-performance (value-based purchasing) programs.

TABLE 64: Finalized ASCQR Program Measure Set for the CY 2024 Payment Determination and Subsequent Years

ASC #	NQF #	Measure Name
ASC-1	0263†	Patient Burn*
ASC-2	0266†	Patient Fall*
ASC-3	0267†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant*
ASC-4	0265†	All-Cause Hospital Transfer/Admission*
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-11	1536†	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery**
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-15a	None	OAS CAHPS – About Facilities and Staff***
ASC-15b	None	OAS CAHPS – Communication About Procedure***
ASC-15c	None	OAS CAHPS – Preparation for Discharge and Recovery***
ASC-15d	None	OAS CAHPS – Overall Rating of Facility***
ASC-15e	None	OAS CAHPS – Recommendation of Facility***
ASC-17	3470	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	3366	Hospital Visits after Urology Ambulatory Surgical Center Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers****

† NQF endorsement was removed.
* Measure finalized for suspension in reporting beginning with the CY 2021 payment determination (CY 2019 data collection) until further action in future rulemaking as discussed in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59117 through 59123).
** Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).
*** Measure finalized for delay in reporting beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking as discussed in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59450 through 59451).
**** Measure will be added beginning with the CY 2024 payment determination as set forth in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61421 through 61428).

The following is a summary of the comment we received and our response that comment.

Comment: A few commenters supported retaining the current measure set.

Response: We thank commenters for their support; we agree that at this time no changes to the ASCQR Program measure set are necessary.

4. Maintenance of Technical Specifications for Quality Measures

We refer readers to the CYs 2012 through 2016 OPPS/ASC final rules with comment period (76 FR 74513 through 74514; 77 FR 68496 through 68497; 78 FR 75131; 79 FR 66981; and 80 FR 70531, respectively) for detailed discussion of our policies regarding the maintenance of technical specifications for the ASCQR Program which are codified at 42 CFR 416.325. We did not propose any changes to these policies.

5. Public Reporting of ASCQR Program Data

We refer readers to the CYs 2012, 2016, 2017 and 2018 OPPS/ASC final rules with comment period (76 FR 74514 through 74515; 80 FR 70531 through 70533; 81 FR 79819 through 79820; and 82 FR 59455 through 59470, respectively) for detailed discussion of our policies regarding the public reporting of ASCQR Program data which are codified at 42 CFR 416.315 (80 FR 70533). We did not propose any changes to these policies.

6. ASCQR Program Measures and Topics for Future Considerations

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making regarding care and quality improvement in the ASC setting. We also seek measures that would facilitate meaningful comparisons between ASCs and hospitals providing comparable services. Therefore, we invited public comment on new measures for our consideration that address care quality in the ASC settings as well as on additional measures that could facilitate comparison of care provided in ASCs and hospitals.

The following is a summary of the comments we received and our responses to those comments.

Comment: Several commenters provided recommendations regarding both new quality measures for CMS to consider as well as measures to facilitate the comparison of care provided in ASCs and hospitals. One commenter requested that we require measures for surgical procedures that occur in both the ASC and outpatient hospital settings be reflected in the measure sets of both programs. For example, currently the Hospital OQR Program contains measures of surgical procedures that

also occur in ASCs, but there is no comparable measure in the ASCQR Program. The commenter recommended that such measures be specified so that for in common surgical procedures analysis for both settings was possible.

Response: We thank the commenters for their recommendations regarding measures to facilitate the comparison of care provided in ASCs and hospitals and the request for measures of surgical procedures that occur in both settings to be reflected in the measure sets of both programs. We understand the commenters concern that such measures be specified to allow for an analysis of both settings for common surgical procedures. We agree that there are surgical procedures that occur in both ASC and outpatient hospital settings that may not be currently reflected in both programs' measure sets. We will evaluate the feasibility of the commenters' recommendations and take them into consideration as we determine future updates to the ASCQR Program measure set.

Comment: A few commenters recommended we adopt measures related to patient and caregiver engagement, experience, and safety. Commenters suggested these measures to ensure providers deliver equitable, patient-centered care and provide patients and their caregivers a standardized way to compare providers and organizations. A few commenters also suggested CMS broaden the focus on safety to include workforce safety measures as a way to examine workforce burnout and turnover. One of these commenters requested that CMS employ an annual web-based workforce engagement survey to allow quality performance to be factored into payment and performance-based incentives.

Response: We thank the commenters for their recommendations regarding the adoption of measures related to patient and caregiver engagement, experience, and workforce safety. We refer readers to the CY 2017 OPPS/ASC final rule with comment period where we adopted ASC–15a–e (81 FR 79803 through 79817), and finalized data collection and data submission timelines (81 FR 79822 through 79824). These measures assess patients' experience with care following a procedure or surgery in an ASC by rating patient experience as a means for empowering patients and improving the quality of their care. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59450 through 59451), we finalized a delay in the implementation of the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-based Measures (ASC–15a–e) beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking. We will investigate the feasibility of the commenters' recommendation to focus on workforce safety measures for consideration toward future updates to the ASCQR Program measure set.

Comment: Several commenters had specific suggestions of measures for future consideration. These measures include: Normothermia (ASC–13), Unplanned Anterior Vitrectomy (ASC–14), Toxic Anterior Segment Syndrome (TASS) (ASC–16), Hospital-level Risk-standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550), and Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome (NQF #3025).

Response: We note that in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79801 through 79803), the Normothermia (ASC–13) and Unplanned Anterior Vitrectomy (ASC–14) were adopted into the ASCQR Program for the CY 2020 payment determination and subsequent years; we thank the commenter for their support of these measures. While we proposed the adoption of Toxic Anterior Segment Syndrome (TASS) (ASC–16) for the ASCQR Program (82 FR 52594), we did not finalize the adoption of this measure due to concerns that the burden of the measure would outweigh the benefits. We will consider the suggested measures not currently included in the ASCQR Program as well as reconsider the Toxic Anterior Segment Syndrome (TASS) (ASC–16) measure as we develop and refine the ASCQR Program measure set.

C. Administrative Requirements

1. Requirements Regarding QualityNet Account and Security Administrator

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75132 through 75133) for a detailed discussion of the QualityNet security administrator requirements, including setting up a QualityNet account and the associated timelines for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70533), we codified the administrative requirements regarding the maintenance of a QualityNet account and security administrator for the ASCQR Program at § 416.310(c)(1)(i).

In the CY 2021 OPPS/ASC proposed rule with comment period (85 FR 48993), we proposed to use the term ''security official'' instead of ''security administrator'' to denote the exercise of authority invested in the role. The term ''security official'' refers to ''the individual(s)'' who have responsibilities for security and account management requirements for a facility's QualityNet account. To be clear, this proposed update in terminology would not change the individual's responsibilities or add burden. We also proposed to revise § 416.310(c)(1)(i) by replacing the term ''security administrator'' with the term ''security official''. The new sentence would read ''A QualityNet security official is necessary to set up such an account for the purpose of submitting this information.'' We invited public comment on our proposals.

The following is a summary of the comment we received and our response that comment.

Comment: One commenter expressed concern with the terminology change of ''security administrator'' to ''security official,'' despite no changes in responsibility of the individual(s). The commenter suggested that the current term is sufficient and any changes to the title may cause undue confusion.

Response: We thank the commenter for their input and acknowledge the commenter's concern about potential confusion. However, we believe the term ''security official'' more clearly conveys the exercise of authority invested in the role and want to ensure adequate recognition. While an administrator is a person who performs official duties in a sphere, an official is a person having official duties, specifically as a representative of an organization. Thus, the term ''security official'' more aptly describes this role as a representative one.

After consideration of the comment received, we are finalizing our proposal as proposed.

2. Requirements Regarding Participation Status

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75133 through 75135) for a complete discussion of the participation status requirements for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70533 through 70534), we codified these requirements regarding participation status for the ASCQR Program at 42 CFR 416.305. We did not propose any changes to these policies.

D. Form, Manner, and Timing of Data Submitted for the ASCQR Program

1. Data Collection and Submission

a. Update of Language Generally

We previously codified our existing policies regarding data collection and submission under the ASCQR Program at 42 CFR 416.310. We currently use the phrases ''data collection period'' and ''data collection time period'' interchangeably in § 416.310(a) through (c). We believe that using one, consistent phrase will streamline and simplify the section and our policies to help avoid potential confusion. As such, we proposed to remove the phrase ''data collection time period'' in all instances where it appears in § 416.310, and replace it with the phrase ''data collection period''—specifically at § 416.310(a)(2), (b), (c)(1)(ii), and (c)(2), as well as replacing the phrase ''time period'' with ''period'' in § 416.310(c)(1)(ii) for language consistency. We invited comment on our proposal.

The following is a summary of the comment we received and our response that comment.

Comment: One commenter supported the proposal to remove the phrase ''data collection time period'' in all instances where it appears in § 416.310 and replace it with the phrase ''data collection period''. The commenter agreed that using one consistent phrase will help avoid potential confusion.

Response: We thank the commenter for their support. We agree that the change will reduce confusion and believe that using one consistent phrase will streamline the language across policies.

After consideration of the public comment received, we are finalizing our proposals as proposed.

b. Requirements Regarding Data Processing and Collection Periods for Claims-Based Measures Using Quality Data Codes (QDCs)

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75135) for a complete summary of the data processing and collection periods for the claims-based measures using QDCs for the CY 2014 payment determination and subsequent years. In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70534), we codified the requirements regarding data processing and collection periods for claims-based measures using QDCs for the ASCQR Program at 42 CFR 416.310(a)(1) and (2).

We did not propose any changes to these requirements. We note that data submission for the following claims-based measures using QDCs was suspended as finalized in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59117 through 59123 and 83 FR 59134 through 59135) until further action in rulemaking:

- *ASC–1:* Patient Burn;
- *ASC–2:* Patient Fall;
- *ASC–3:* Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and
- *ASC–4:* Hospital Transfer/Admission.

Furthermore, we noted that the previously finalized data processing and collection period requirements will apply to any future claims-based-measures using QDCs adopted in the ASCQR Program.

c. Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims-Based Measures Using QDCs

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59472) (and the previous rulemakings cited therein), as well as 42 CFR 416.310(a)(3) and 42 CFR 416.305(c) for our policies about minimum threshold, minimum case volume, and data completeness for claims-based measures using QDCs. We did not propose any changes to these policies.

As noted above, while data submission for certain claims-based measures using QDCs was suspended, our policies for minimum threshold, minimum case volume, and data completeness requirements will apply to any future claims-based-measures using QDCs adopted in the ASCQR Program.

d. Requirements Regarding Data Processing and Collection Periods for Non-QDC Based, Claims-Based Measure Data

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59136 through 59138), for a complete summary of the data processing and collection requirements for the non-QDC based, claims-based measures. We codified the requirements regarding data processing and collection periods for non-QDC, claims-based measures for the ASCQR Program at 42 CFR 416.310(b). We note that these requirements for non-QDC based, claims-based measures apply to the following previously adopted measures:

- *ASC–12:* Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy.
- *ASC–19:* Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357)

We did not propose any changes to the requirements for non-QDC based, claims-based measures.

e. Requirements for Data Submitted via an Online Data Submission Tool

(1). Requirements for Data Submitted via a CMS Online Data Submission Tool

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59473) (and the previous rulemakings cited therein) and 42 CFR 416.310(c)(1) for our requirements regarding data submitted via a CMS online data submission tool. We are currently using the CMS QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) secure portal) to host our CMS online data submission tool: *https://www.qualitynet.org.* We note that in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59473), we finalized expanded submission via the CMS online tool to also allow for batch data submission and made corresponding changes at 42 CFR 416.310(c)(1)(i).

The following previously finalized measures require data to be submitted via a CMS online data submission tool for the CY 2021 payment determination and subsequent years:

- *ASC–9:* Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
- *ASC–11:* Cataracts: Improvement in Patients' Visual Function within 90 Days Following Cataract Surgery
- *ASC–13:* Normothermia Outcome
- *ASC–14:* Unplanned Anterior Vitrectomy

We did not propose any changes to these policies for data submitted via a CMS online data submission tool.

(2). Requirements for Data Submitted via a Non-CMS Online Data Submission Tool

We refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75139 through 75140) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66985 through 66986) for our requirements regarding data submitted via a non-CMS online data submission tool (specifically, the CDC NHSN website). We codified our existing policies regarding the data collection periods for measures involving online data submission and the deadline for data submission via a non-CMS online data submission tool at 42 CFR 416.310(c)(2).

As we noted in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59135), no measures submitted via a non-CMS online data submission tool remain in the ASCQR Program beginning with the CY 2020 payment determination. We did not propose any changes to our non-CMS online data submission tool reporting requirements; these requirements would apply to any future non-CMS online data submission tool measures adopted in the ASCQR Program.

f. Requirements for Data Submission for ASC–15a–e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measures

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79822 through 79824) for our previously finalized policies regarding survey administration and vendor requirements for the CY 2020 payment determination and subsequent years. In addition, we codified these policies at 42 CFR 416.310(e). However, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59450 through 59451) we delayed implementation of the ASC15a–e: OAS CAHPS—Survey-based-measures beginning with the CY 2020 payment determination (CY 2018 data submission) until further action in future rulemaking, and we refer readers to that discussion for more details. We did not propose any changes to this policy.

g. ASCQR Program Data Submission Deadlines

While the ASCQR Program has established submission deadlines (42 CFR 416.310), there is no specified policy for deadlines falling on nonwork days. Therefore, we proposed that all program deadlines falling on a nonwork day be moved forward consistent with section 216(j) of the Social Security Act (the Act), 42 U.S.C. 416(j), ''Periods of Limitation Ending on Nonwork Days.'' Specifically, the Act indicates that all deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day, all or part of which is declared to be a nonwork day for federal employees by statute or Executive order, shall be extended to the first day thereafter which is not a Saturday, Sunday or legal holiday or any other day all or part of which is declared to be a nonwork day for federal employees by statute or Executive order (42 U.S.C. 416(j)). Section 1872 of the Act, incorporates section 216(j) of the Act, to apply to Title XVIII, the Medicare program under which the ASCQR Program is administered. As such, in the CY 2021 OPPS/ASC proposed rule (85 FR 48994), we proposed to add this policy for the submission deadlines associated with the ASCQR Program beginning with the effective date of this rule. We also proposed to codify this policy by adding a new paragraph (f) at § 416.310, which would provide that all deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order are extended to the first day thereafter which is not a Saturday, Sunday or legal holiday or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order. We invited public comment on our proposals.

The following is a summary of the comments we received and our responses to those comments.

Comment: A few commenters supported the proposal to move forward all program deadlines falling on a nonwork day consistent with section 216(j) of the Act, 42 U.S.C. 416(j), ''Periods of Limitation Ending on Nonwork Days.'' The commenters also supported the proposal to codify this policy by adding a new paragraph (f) at § 416.310.

Response: We thank the commenters for their support.

Comment: One commenter recommended that CMS continue to publish the revised deadline when the routinely established deadline falls on a nonwork day.

Response: We thank the commenter for this input. We will continue to publish revised reporting deadlines, which can be monitored and verified via the QualityNet website (*https://www.qualitynet.org*).

After consideration of the public comments received, we are finalizing our proposal as proposed.

2. Review and Corrections Period for Data Submitted via a CMS Online Data Submission Tool in the ASCQR Program

Under the ASCQR Program, for measures submitted via a CMS online data submission tool, ASCs submit measure data to CMS from January 1 through May 15 during the calendar year subsequent to the current data collection period (84 FR 61432).[109] For example, ASCs collect measure data from January 1, 2019 through December 31, 2019 and submit these data to CMS from January 1, 2020 through May 15, 2020. ASCs may begin submitting data to CMS as early as January 1. ASCs are encouraged, but not required, to submit data early in the submission period so that they can identify errors and resubmit data before the established submission deadline.

In the CY 2021 OPPS/ASC proposed rule with comment period (85 FR 48994), we proposed to formalize that process and establish a review and corrections period similar to that being proposed for the Hospital OQR Program in section XIV.D.7 of the CY 2021 OPPS/ASC proposed rule. For the ASCQR Program, we proposed to implement a review and corrections period which would run concurrently with the data submission period beginning with the effective date of this rule. During this review and corrections period, ASCs could enter, review, and correct data submitted directly to CMS. However, after the submission deadline, ASCs would not be allowed to change these data. We also proposed to codify this review and corrections period at new paragraph (c)(1)(iii) in § 416.310, which would provide that for measures submitted to CMS via a CMS online tool, ASCs have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, ASCs can enter, review, and correct data submitted. After the submission deadline, this data cannot be changed. We invited public comment on our proposals, including on the burden and benefits of such a review and corrections period. The following is a summary of the comments we received and our responses to those comments.

Comment: A few commenters supported our proposal to create and codify a review and corrections period for data submitted through a CMS online data submission tool. One commenter stated that this policy would give ASCs an opportunity to review their data and correct errors prior to a submission deadline.

Response: We thank the commenters for their support of this proposed policy change. We agree that it will provide ASCs time to review their data and identify errors prior to submission deadlines. We continue to encourage providers to submit data as early as possible, leaving adequate time to make any necessary corrections.

Comment: One commenter suggested that we extend the timeline for the review period. Specifically, the commenter recommended that we give ASCs one additional month following the data submission deadline to review and correct their data. The commenter

[109] ASCQR Program Data Submission Deadlines. Available at: *https://www.qualitynet.org/asc/data-submission#tab2*.

emphasized that recent natural disasters have caused practices to prioritize patient care and facility operations over data submission, such that data may not be submitted until late in the submission period. The commenter further explained that allowing a one-month review period after the submission deadline would help to mitigate the impact of natural disasters and facilitate the improved integrity of ASCQR Program data.

Response: We thank the commenter for this policy recommendation and the insights about the impact of natural disasters on ASCs. As noted previously, the current data submission period for measures submitted via a CMS online data submission tool is from January 1 through May 15 during the calendar year subsequent to the current data collection period (84 FR 61432). We believe that four and a half months should provide ample time to review, correct, and submit data from the prior year. However, we note that if an ASC is not able to submit data because it has experienced an extraordinary circumstance, such as a natural disaster, the ASC may request an exception under the ASCQR Program Extraordinary Circumstance Exceptions (ECE) policy. As described in section XV.D.4 of this final rule with comment period, ASCs must complete and submit the ECE form, along with any required information and supporting documentation, within 90 calendar days of the date of the extraordinary circumstance.[110]

After consideration of the comments received, we are finalizing our proposal as proposed.

3. ASCQR Program Reconsideration Procedures

We refer readers to the CY 2016 OPPS/ASC final rule with comment period (82 FR 59475) (and the previous rulemakings cited therein) and 42 CFR 416.330 for the ASCQR Program's reconsideration policy. We did not propose any changes to this policy.

4. Extraordinary Circumstances Exception (ECE) Process for the CY 2020 Payment Determination and Subsequent Years

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59474 through 59475) (and the previous rulemakings cited therein) and 42 CFR 416.310(d) for the ASCQR Program's policies for extraordinary circumstance exceptions (ECE) requests. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59474 through 59475), we: (1) Changed the name of this policy from ''extraordinary circumstances extensions or exemption'' to ''extraordinary circumstances exceptions'' for the ASCQR Program, beginning January 1, 2018; and (2) revised 42 CFR 416.310(d) of our regulations to reflect this change. We will strive to complete our review of each request within 90 days of receipt. We did not propose any changes to these policies.

E. Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499) for a detailed discussion of the statutory background regarding payment reductions for ASCs that fail to meet the ASCQR Program requirements.

2. Policy Regarding Reduction to the ASC Payment Rates for ASCs That Fail To Meet the ASCQR Program Requirements for a Payment Determination Year

The national unadjusted payment rates for many services paid under the ASC payment system are equal to the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. For CY 2021, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the multifactor productivity (MFP)-adjusted hospital market basket update factor. The MFP adjustment is set forth in section 1833(i)(2)(D)(v) of the Act. The MFP-adjusted hospital market basket update is the annual update for the ASC payment system for a 5-year period (CY 2019 through CY 2023). Under the ASCQR Program in accordance with section 1833(i)(7)(A) of the Act and as discussed in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499), any annual increase shall be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction applied beginning with the CY 2014 payment rates (77 FR 68500). For a complete discussion of the calculation of the ASC conversion factor and our finalized proposal to update the ASC payment rates using the inpatient hospital market basket update for CYs 2019 through 2023, we refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59073 through 59080).

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we finalized our proposal that we would calculate two conversion factors: A full update conversion factor and an ASCQR Program reduced update conversion factor. We finalized our proposal to calculate the reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for that calendar year payment determination. We finalized our proposal that application of the 2.0 percentage point reduction to the annual update may result in the update to the ASC payment system being less than zero prior to the application of the MFP adjustment.

The ASC conversion factor is used to calculate the ASC payment rate for services with the following payment indicators (listed in Addenda AA and BB to the proposed rule, which are available via the internet on the CMS website): ''A2'', ''G2'', ''P2'', ''R2'' and ''Z2'', as well as the service portion of device-intensive procedures identified by ''J8'' (77 FR 68500). We finalized our proposal that payment for all services assigned the payment indicators listed above would be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR Program reduced update conversion factor (77 FR 68500).

The conversion factor is not used to calculate the ASC payment rates for separately payable services that are assigned status indicators other than payment indicators ''A2'', ''G2'', ''J8'', ''P2'', ''R2'' and ''Z2.'' These services include separately payable drugs and biologicals, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPPS payment rates, and certain office-based procedures, radiology services and diagnostic tests where payment is based on the PFS nonfacility PE RVU-based amount, and a few other specific services that receive cost-based payment (77 FR 68500). As a result, we also finalized our proposal that the ASC payment rates for these services would not be reduced for failure to meet the ASCQR Program requirements because the payment rates for these services are not calculated using the ASC conversion factor and, therefore, not affected by reductions to the annual update (77 FR 68500).

[110] For more information on the ECE policy, we refer stakeholders to the QualityNet website at *https://www.qualitynet.org/asc/data-submission#tab2.*

Office-based surgical procedures (generally those performed more than 50 percent of the time in physicians' offices) and separately paid radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents) are paid at the lesser of the PFS nonfacility PE RVU-based amounts or the amount calculated under the standard ASC ratesetting methodology. Similarly, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized our proposal that payment for certain diagnostic test codes within the medical range of CPT codes for which separate payment is allowed under the OPPS will be at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the standard ASC ratesetting methodology when provided integral to covered ASC surgical procedures. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the standard ASC ratesetting methodology for this type of comparison would use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity. This is necessary so that the resulting ASC payment indicator, based on the comparison, assigned to these procedures or services is consistent for each HCPCS code, regardless of whether payment is based on the full update conversion factor or the reduced update conversion factor.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, we believe that it is both equitable and appropriate that a reduction in the payment for a service should result in proportionately reduced coinsurance liability for beneficiaries (77 FR 68500). Therefore, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the Medicare beneficiary's national unadjusted coinsurance for a service to which a reduced national unadjusted payment rate applies will be based on the reduced national unadjusted payment rate.

In that final rule with comment period, we finalized our proposal that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program (77 FR 68500). For example, the following standard adjustments would apply to the reduced national unadjusted payment rates: The wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; and the adjustment for devices furnished with full or partial credit or without cost (77 FR 68500). We believe that these adjustments continue to be equally applicable to payment for ASCs that do not meet the ASCQR Program requirements (77 FR 68500).

In the CY 2015 through CY 2020 OPPS/ASC final rules with comment period we did not make any other changes to these policies. We proposed the continuation of these policies for CY 2021 in the CY 2021 OPPS/ASC proposed rule (85 FR 48995 through 48996), did not receive any public comments on these policies, and are finalizing the continuation of these policies for CY 2021.

XVI. Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years

A. Background

The Overall Star Rating provides a summary of certain existing hospital quality information based on publicly available quality measure results reported through CMS programs, in a way that is simple and easy for patients to understand, by assigning hospitals between one and five stars. The Overall Star Rating was first introduced and reported on *Hospital Compare* in July 2016 [111] and has been refreshed six times,[112] [113] [114] [115] two of which included minor methodology updates,[116] [117] over the past 3 years. *Hospital Compare,* and any successor site, is a public website hosted by CMS with transparent information and data on over 100 quality measures for over 5,300 hospitals, nationwide in the United States (U.S.), for consumers and researchers. In this rule, for the Overall Star Rating, the term ''publish'' refers to the public posting of the Overall Star Rating and ''refresh'' refers to the public posting quality measure and program data on *Hospital Compare* or its successor website.

During development of the Overall Star Rating, we established guiding principles to use methods that were scientifically valid, inclusive of hospitals and measure information, accounted for the heterogeneity of available measures and hospital reporting, and accommodated changes in the underlying measures.[118] In addition, we aimed to provide alignment with the information displayed on *Hospital Compare* and the measures and methods used within CMS programs, transparency of Overall Star Rating methods, and responsiveness to stakeholder input. After the launch of the Overall Star Rating in July 2016 and as the Overall Star Rating gained broader use by multiple stakeholders, we added new guiding principles to guide reevaluation of the methodology.[119]

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed a methodology which includes elements of the current methodology as well as updates (we refer readers to section E. Current and Proposed Overall Star Rating Methodology of the proposed rule) that aim to increase simplicity of the methodology, predictability of measure emphasis within the methodology over time, and comparability of ratings among hospitals. We also proposed to include Veterans Health Administration (VHA) hospitals (we refer readers to section C. Veterans Health Administration Hospitals in Overall Star Rating) and proposed to include Critical Access Hospitals (CAHs) (we refer readers to section B. Critical Access Hospitals in the Overall Star Rating) in

[111] Centers for Medicare & Medicaid Services. (2016, July 27). *First Release of the Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from *www.cms.gov/newsroom*: *https://www.cms.gov/newsroom/fact-sheets/first-release-overall-hospital-quality-star-rating-hospital-compare.*

[112] Centers for Medicare & Medicaid Services. (2016, May). *Overall Hospital Quality Star Rating on Hospital Compare: July 2016 Updates and Specifications Report.*

[113] Centers for Medicare & Medicaid Services. (2016, October). *Overall Hospital Quality Star Rating on Hospital Compare: December 2016 Updates and Specifications Report.*

[114] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare: July 2017 Updates and Specifications Report.*

[115] Centers for Medicare & Medicaid Services. (2019, November 4). Overall Hospital Quality Star Rating on Hospital Compare: January 2020 Updates and Specifications Report. Retrieved from *qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2.*

[116] Centers for Medicare & Medicaid Services. (2018, November 30). Overall Hospital Quality Star Rating on Hospital Compare: February 2019 Updates and Specifications Report. Retrieved from *qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2.*

[117] Centers for Medicare & Medicaid Services. (2017, November). *Star Methodology Enhancement for December 2017 Public Release.* Retrieved from *www.qualitynet.org*: *https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources.*

[118] Centers for Medicare & Medicaid Services. (2017, December). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from *www.qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1.*

[119] Ibid.

the Overall Star Rating. In addition, we proposed to establish the Overall Hospital Quality Star Rating and methodology at subpart J of part 412 (proposed § 412.190).

Because of our production timeline to calculate and distribute Overall Star Rating results in time for hospitals to preview the ratings in advance of publication, we used the CY 2021 OPPS/ASC proposed rule to propose the methodology for the Overall Star Rating even though it includes not only hospital outpatient measures, but also hospital inpatient measures, which are generally discussed in the Inpatient Prospective Payment System (IPPS) rule. We plan to reference the finalized policies for the Overall Star Rating from this CY 2021 OPPS/ASC final rule in the coming FY 2022 IPPS/LTCH rule.

1. Purpose, Authority, and Applicable Hospital Quality Data

a. Purpose

In 2014, to inform the initial methodology for the Overall Star Rating, we conducted a review of the literature as well as a review of prior and current star rating efforts. This review supported the notion that patients care about information on hospital quality, but that patient use of this information is limited by low understanding of quality information. Additionally, we heard feedback that hospital quality information is often intimidating as displayed and is not user-friendly in comparison to other consumer ratings. The key findings of the review were consistent with consumer priorities to bring a wide variety of measures together into a single overall star rating. Therefore, we sought to help consumers understand hospital quality information through development of a summary measure, which combines publicly reported quality information in an easy-to-understand rating that is familiar to consumers.

The primary objective of the Overall Star Rating was to use an established, evidence-based statistical approach to summarize hospital quality measure results reported on *Hospital Compare* with the goal of assigning acute care hospitals and facilities that provide acute inpatient and outpatient care in the U.S. to an overall rating between one and five whole stars.[120] The Overall Star Rating is meant to complement other hospital quality information publicly posted on *Hospital Compare* or its successor website, including the individual measure scores and the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Star Rating.[121] The original guiding principles of the Overall Star Rating was to use scientifically valid methods that are inclusive of hospitals and measure information, able to account for different hospitals reporting on different measures, and able to accommodate changes in the underlying measures over time.[122] We also aimed to create alignment with *Hospital Compare* and CMS programs, transparency of the methods for calculating the Overall Star Rating, and responsiveness to stakeholder input through various and ongoing engagement activities.

The goal of the Overall Star Rating is to summarize hospital quality information in a way that is simple and easy for patients to understand, by assigning hospitals between one and five stars, to increase transparency and empower stakeholders to make more informed decisions about their healthcare. To this end, we proposed that (1) the Overall Star Rating is a summary of certain publicly reported hospital measure data for the benefit of stakeholders, such as patients, consumers, and hospitals, (2) the guiding principles of the Overall Star Rating are to use scientifically valid methods, inclusive of hospitals and measure information and able to accommodate measure changes; alignment with *Hospital Compare* or its successor websites and CMS programs; provide transparency of the methods for calculating the Overall Star Rating; be responsive to stakeholder input; and (3) to codify this at § 412.190(a).

We invited public comment on our proposals as discussed previously. The following is a summary of the comments we received and our responses to those comments.

Comment: One commenter supported the purpose of the Overall Star Rating and appreciated that the tool consolidates and streamlines the various hospital quality measures into a single metric.

Response: We thank the commenter for their support and agree that the Overall Star Rating effectively combines multiple dimensions of hospital quality into an overall rating. Review of the literature and engagement with patients and patient advocates confirmed that patients care about hospital quality information but find it difficult to understand. Therefore, the Overall Star Rating is meant to provide a summary of hospital quality information based on publicly available quality measure results in a way that is simple and easy for patients to understand.

Comment: Many commenters opposed the purpose of the Overall Star Rating, noting that a single composite rating oversimplifies the various complex factors that must be considered when assessing hospital quality of care. Commenters further stated that an overall composite rating obscures details about care and does not allow for an accurate comparison of hospitals.

Several commenters questioned the usefulness of the Overall Star Rating for patients as a tool to make informed decisions about where to seek care. Specifically, some commenters noted the Overall Star Rating cannot be used by patients to compare hospitals based on their specific condition or treatment needs and alternatively suggested reported star ratings or information based on service lines. One commenter recommended that CMS focus on measures specific to clinical conditions or treatments and patient clinical or demographic characteristics, which may be more helpful to patients than an overall rating.

Response: As stated in section A.1.a. Purpose of this final rule, review of the literature and consumer engagement supported the notion that patients care about information on hospital quality, but that quality measurement, often in the form of multiple measure scores as rates and ratios, is intimidating and difficult to understand. The primary purpose of the Overall Star Rating is to provide a summary of certain existing hospital quality information in a way that is easy for patients to understand, by assigning hospitals between one and five stars, to increase transparency and empower stakeholders to make more informed decisions about their healthcare. The Overall Star Ratings methodology is designed to summarize the underlying measures in a manner that maintains the validity of the underlying measures that have undergone rigorous development and reevaluation processes, including testing, stakeholder vetting, National Quality Forum (NQF) evaluation, and rulemaking. Furthermore, the Overall Star Rating is meant to complement, not replace, the existing individual

[120] Centers for Medicare & Medicaid Services. (2017, December). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from *www.qualitynet.org*: *https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1.*

[121] Centers for Medicare & Medicaid Services. (2017, November). *Star Methodology Enhancement for December 2017 Public Release.* Retrieved from *www.qualitynet.org*: *https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources.*

[122] Centers for Medicare & Medicaid Services. (2017, December). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from *www.qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1.*

measures reported on *Hospital Compare* or its successor website and accommodate stakeholder needs to either or concurrently view an overall rating and individual measures, which may be more pertinent to a specific condition or hospital service of interest. We also provide performance summaries for the Overall Star Rating measure groups for patients and stakeholders wishing more granular information on hospital Overall Star Rating performance.

We appreciate commenter suggestions for the development of star ratings by service lines, rather than overall. CMS and its development contractor had previously investigated the feasibility of star ratings for different measure groupings including by condition, procedure, or service line. CMS' development contractor brought the concept, options, and findings to the Technical Expert Panel (TEP), Patient & Patient Advocate Work Group, and a public comment period.[123] While stakeholders, including providers and patients, were interested in the concept of creating star ratings for individual clinical domains, we ultimately found insufficient existing measures to group measures or calculate star ratings by conditions, procedures, or service lines. However, we will continue to explore the possibility of calculating star ratings based on clinical domains as the available measures within CMS hospital quality programs evolve.

Comment: Commenters also suggested continued stakeholder engagement to gain a better understanding of how to make the Overall Star Rating useful to patients, with some commenters recommending user-customized star ratings for which patients can set measure or measure group weights based on their own values and needs.

Response: We appreciate commenter suggestions for user-customized star ratings, which we also evaluated and brought in front of stakeholders during work group meetings, as well as a public comment period.[124] Ultimately, a majority of stakeholders did not support the concept of user-customized star ratings. Prior comments suggested that user-customized star ratings would be too confusing for patients, difficult for hospitals to explain, require elaborate testing, and not allow hospitals to use the Overall Star Rating for quality improvement.

After consideration of the public comments received, we are finalizing our proposals as proposed.

b. Subsection (d) Hospitals

The Overall Star Rating includes measures that (1) capture quality of care at hospitals and facilities providing acute inpatient and outpatient care and (2) are publicly reported on *Hospital Compare* or its successor websites. CMS currently publicly reports information regarding the performance of individual hospitals in the following CMS quality programs: Hospital Inpatient Quality Reporting (IQR) Program, Hospital Readmission Reduction Program (HRRP), Hospital-Acquired Condition (HAC) Reduction Program, Hospital Value-Based Purchasing (VBP) Program, and Hospital Outpatient Quality Reporting (OQR) Program. Such authority is granted under applicable sections 1833 and 1886 of the Act.[125]

Specifically, under sections 1886(b)(3)(B)(viii)(VII) and 1833(t)(17)(E) of the Act for the Hospital IQR and OQR Programs respectively, the Secretary of the Department of Health and Human Services (Secretary) is required to make quality information available to the public. Section 1886(b)(3)(B)(viii)(VII) of the Act states that ''The Secretary shall establish procedures for making information regarding measures submitted under this clause available to the public. Such procedures shall ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to furnished in inpatient settings in on the internet website of the Centers for Medicare & Medicaid Services.'' Section 1833(t)(17)(E) of the Act states that ''The Secretary shall establish procedures for making data submitted under this paragraph available to the public. Such procedures shall ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in outpatient settings in hospitals on the internet website of the Centers for Medicare and Medicaid Services.'' We believe that these requirements allow the agency to create the Overall Star Rating as a means to summarize existing publicly reported quality measure data from the Hospital IQR and OQR Programs, along with quality measure data from other hospitals, in a form and manner that improves accessibility of hospital quality information for the benefit of patients and consumers.

In addition, the HRRP (under section 1886(q)(6)(A) of the Act) and the HAC Reduction Program (under section 1886(p)(6)(A) of the Act) require that the Secretary must make information regarding readmission and hospital acquired condition rates for hospitals available to the public. Specifically, section 1886(q)(6)(A) of the Act states that ''The Secretary shall make information available to the public regarding readmission rates of each subsection (d) hospital under the program'' and section 1886(p)(6)(A) of the Act states that ''The Secretary shall make information available to the public regarding hospital acquired conditions of each applicable hospital.'' Similar to Hospital IQR and OQR Programs, we believe that these requirements allow the agency to create and publicly release the Overall Star Rating as a means to summarize existing publicly reported quality measure data from the HRRP and HAC Reduction Program, along with quality measure data from other hospitals, in a form and manner that improves accessibility of hospital quality information for the benefit of patients and consumers.

Our use of data reported by hospitals under the Hospital VBP Program in the Overall Star Ratings is supported by section 1886(o)(10)(A)(i) of the Act. Specifically, section 1886(o)(10)(A) of the Act states that the Secretary shall make information available to the public regarding the performance of individual hospitals under the Program, including (i) the performance of the hospital with respect to each measure that applies to the hospital; (ii) the performance of the hospital with respect to each condition or procedure; and (iii) the hospital performance score assessing the total performance of the hospital. Hospitals that participate in the Hospital VBP Program report data on each Hospital VBP Program measure for a specified performance period that applies to the program year. Under our proposed Overall Star Rating methodology, which we describe in detail below, we would use these Hospital VBP Program measure rates, in combination with measure rates reported by various hospitals under the Hospital IQR

[123] Centers for Medicare & Medicaid Services. (2019, June). Public Comment Summary Report. Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[124] Centers for Medicare & Medicaid Services. (2019, June). Public Comment Summary Report. Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[125] U.S. Congress. (1934) *United States Code: Social Security Act, 18 U.S.C. 1833 and 1886.*

Program, Hospital OQR Program, HRRP, and HAC Reduction Program to calculate and make public a star rating that applies to the hospital for a corresponding star rating period, making that star reflective of the hospital's measured level of quality in all of these programs.

The Overall Star Rating does not use data reported by hospitals under the Prospective Payment System-Exempt Cancer Hospitals Quality Reporting (PCHQR) Program, the Inpatient Psychiatric Facilities (IPF) Quality Reporting Program, or the Ambulatory Surgical Centers Quality Reporting (ASCQR) Program.

Beginning with publication of Overall Star Rating in CY 2021 and subsequent years, we proposed to: (1) Continue to use data publicly reported on a CMS website from the programs described above as a basis to calculate the Overall Star Rating, and (2) codify this at § 412.190(b)(2).

We invited public comment on our proposals. However, we did not receive any comment. We are finalizing our proposals as proposed.

B. Critical Access Hospitals in the Overall Star Rating

1. Current Critical Access Hospitals in the Overall Star Rating

The current Overall Star Rating is calculated based on certain data that is publicly reported on a CMS website and includes data from hospitals and facilitates that provide acute inpatient and outpatient care, including CAHs. Many CAHs currently voluntarily submit measure data consistent with certain CMS quality programs and elect to have their quality measure data publicly reported through their QualityNet account by selecting Optional Public Reporting Notice of Participation. We note, however, that the Hospital OQR Program no longer uses a Notice of Participation form (83 FR 59103 through 59104). Submission of data through the Hospital OQR Program is considered participation specifically in that program. If a CAH elects to voluntarily submit data and have their quality measure data publicly reported, they are subsequently eligible to receive a star rating so long as they meet the specified reporting thresholds, discussed in detail in section E.6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating of this final rule.

We note that many CAHs do not meet the minimum threshold to receive a star rating due to serving too few patients to report some of the underlying measures. To date, typically anywhere from 48 to 55 percent of CAHs report enough measures to receive a star rating.

2. Inclusion of Critical Access Hospitals in the Overall Star Rating

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to continue to include voluntary measure data from CAHs for the purpose of calculating Overall Star Rating through authority in section 1704 of the Public Health Service Act (PHSA).[126] Section 1704 of the PHSA states that the Secretary is authorized to conduct and support by grant or contract (and encourage others to support) such activities as may be required to make information respecting health information and health promotion, preventive health services, and education in the appropriate use of health care available to the consumers of medical care, providers of such care, schools, and others who are or should be informed respecting such matters. We believe that this authority allows the agency to include CAHs in Overall Star Rating because the purpose of the Overall Star Rating is to summarize hospital quality information in a way that is simple and easy for patients to understand, by assigning hospitals between one and five stars, to increase transparency and empower stakeholders to make informed decisions about their healthcare. We have an existing contract mechanism through our current Healthcare Quality Analytics and Reports (HCQAR) contract, which would continue under a future similar contract vehicle as appropriate, for the calculation of the Overall Star Rating for all hospitals that provide acute inpatient and outpatient care, including CAHs, and for the dissemination of reports to these hospitals prior to publication. Any hospital or facility providing acute inpatient and outpatient care, including CAHs, with measure or measure group scores reported on *Hospital Compare* or its successor websites are given a confidential hospital-specific report (HSR) during the Overall Star Rating preview where they may review their measure, measure group, and star rating results prior to public release. The Overall Star Rating preview period and confidential hospital-specific reports are discussed in more detail in section F. Preview Period of this final rule.

In addition, section 1851(d) of the Act allows the Secretary to disseminate information to Medicare beneficiaries to promote informed choice among coverage options.[127] Many CAHs are located in remote areas that face unique challenges in resources and are often one of the only options for patients to seek care.[128] We believe it is important to include CAH data when available because it aligns with CMS goals of healthcare transparency, consumer choice, and the guiding principle of the Overall Star Rating, which is to include as much information as possible about hospital quality. The inclusion of CAHs in the Overall Star Rating has been supported by the Health Resources and Services Administration (HRSA) through their ongoing work with rural hospitals and facilities that provide acute inpatient and outpatient care, including CAHs. HRSA encourages CAHs to report quality measure data as part of quality improvement and public reporting and supports the inclusion of publicly reported measure scores for CAHs within the Overall Star Rating. Additionally, as part of ongoing stakeholder engagement activities, we have heard from some CAHs that they are interested in receiving a star rating and that voluntary measure reporting places no additional burden on CAHs.

Therefore, we proposed that CAHs that wish to be voluntarily included in the Overall Star Rating must have elected to both (a) voluntarily submit quality measures included in and as specified by CMS hospital programs and (b) publicly report their quality measure data on one of CMS' public websites. We proposed to codify this at § 412.190(b)(3). CAHs that do not elect to participate or that elect to withhold their data from public reporting will not be included in the Overall Star Rating calculation. Since CAHs voluntarily report measures, CAHs may have their Overall Star Rating withheld from public release provided they submit a timely request, as described in more detail under section G. Overall Star Rating Suppressions of this final rule.

Of note, the proposal to peer group hospitals by the number of measure groups, as outlined in section E.7. Approach to Peer Grouping Hospitals of this final rule, was dependent on CAH participation in the Overall Star Rating since CAHs make up approximately half of the hospitals within the three measure peer group and excluding CAHs from the Overall Star Rating would not provide a sufficient amount

[126] Public Health Service Act of 2019, Public Law 116–69, Page 133 Stat. 1134, codified as amended at 42 U.S.C. 201.

[127] U.S. Congress. (1934) United States Code: Social Security Act, 42 U.S.C. 1851.

[128] Centers for Medicare & Medicaid Services. (2013, April 9). *Critical Access Hospitals.* Retrieved from *www.cms.gov*: *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/CAHs.*

of hospitals to make peer group comparisons.

We invited public comment on our proposals to: (1) Include CAHs in the Overall Star Rating that wish to be voluntarily included in the Overall Star Rating and have elected to both (a) voluntarily submit quality measures included in and specified under CMS hospital programs and (b) publicly report their quality measure data on Hospital Compare or its successor site; and (2) to codify these at § 412.190(b)(3). We note that for the purposes of the rest of this discussion, we will refer to both subsection (d) hospitals and CAHs as ''hospitals.'' The following is a summary of the comments we received and our responses to those comments.

Comment: Many commenters expressed general support for the inclusion of CAHs in the Overall Star Rating. Commenters noted that inclusion of CAHs will improve transparency and increase usability for consumers while also incentivizing CAHs to participate in measure reporting.

Response: We thank commenters for their support and agree that continuing to include CAHs within the Overall Star Rating improves the transparency and usability of the Overall Star Rating for patients. Most CAHs do participate in measure reporting but have too few cases to meet the minimum case counts to receive publicly reported scores for some narrowly focused quality measures, such as condition- and procedure-specific measures, and therefore do not meet the reporting thresholds to receive a star rating (section E.6.b. Minimum Reporting Thresholds for Receiving a Star Rating of this final rule).

Comment: Some commenters particularly supported the inclusion of CAHs if it resulted in peer grouping and comparison of CAHs separately from other hospitals. However, several commenters expressed concerns about the inclusion of the CAHs in the Overall Star Rating, recommending that CMS refrain from comparing CAHs to other acute care hospitals. Some commenters requested separate measurement or ratings for CAHs, noting that any other risk adjustment would not appropriately capture differences in demographics and healthcare resources for CAHs and other acute care hospitals. Some commenters recommended improved consumer interpretability of the Overall Star Rating for CAHs versus other types of hospitals. Specifically, commenters suggested that CMS provide clear details on the services available for each hospital and the number of hospitals assigned to each star rating based on these services.

Response: Feedback from stakeholders, including the Patient & Patient Advocate Work Group, stated that critical access status is not a meaningful approach to grouping hospitals to patients and it is important to be able to compare star ratings across hospital types. As discussed under section E.7.b. Peer Grouping of this final rule, we are finalizing our proposal to peer group hospitals by the number of measure groups in which at least 3 measures are reported. We had considered CAH status as a peer grouping variable, but found appreciable differences in summary score cutoffs for each star rating category between CAHs and non-CAHs, which would make differences in star rating assignments difficult for stakeholders, including providers, to understand and explain. Furthermore, feedback from the Patient & Patient Advocate Work Group consistently indicated that peer grouping by CAH status would be misleading and unhelpful to patients, particularly for patients with limited hospital options in their community. We also heard from stakeholders that it is important for patients to be able to compare star ratings across hospital types. We note that *Hospital Compare* or its successor websites does provide general information on the hospital type and services provided at each hospital alongside the Overall Star Rating, including for example, emergency care services. Historically, we have publicly posted the Overall Star Rating input file and SAS pack at the time of the Overall Star Rating publication so that stakeholders may review and replicate the methodology and thus, coupled with hospital characteristic data, have the ability to review the types of hospitals assigned to each star rating.

After consideration of the public comments received, we are finalizing our proposals as proposed.

C. Veterans Health Administration Hospitals in the Overall Star Rating

In the CY 2021 OPPS/ASC proposed rule, we proposed to include quality measure data from Veterans Health Administration hospitals (VHA hospitals) for the purpose of calculating Overall Star Rating beginning with the CY 2023. CMS has an existing contract mechanism with the Veterans Health Administration (VHA) through an Interagency Agreement to publish their hospitals' quality measure data on *Hospital Compare* [129] in accordance with section 206(c) of the Veterans Access, Choice, and Accountability Act (Choice Act) of 2014 (Pub. L. 113–146).[130]

Furthermore, section 1704 of the PHSA [131] allows the Secretary to make health information available to consumers of medical care through grant or contract mechanism including, but not limited to, the publication of health information. In addition, section 1851(d) of the Act allows the Secretary to disseminate information to Medicare beneficiaries to promote informed choice among coverage options.[132] We believe this includes the publication of quality measure data and Overall Star Rating for VHA hospitals.

Therefore, in the CY 2021 OPPS/ASC proposed rule, we proposed to include VHA hospitals in the Overall Star Rating beginning in CY 2023. Including VHA hospitals in the Overall Star Rating beginning in CY 2023 allows CMS to establish the methodology through the CY 2021 OPPS/ASC proposed rule and host confidential reporting of the Overall Star Rating for VHA hospitals prior to public release of VHA star ratings. In order to be eligible to receive a star rating, VHA data would be subject to the same reporting threshold as subsection (d) hospitals and CAHs included in the Overall Star Rating (finalized as three measure groups, one of which must be Mortality or Safety of Care, with at least three measures in each measure group, as discussed in section E.6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating of this final rule).

We anticipate that adding VHA hospital data to the Overall Star Rating calculation would influence national results due to several steps in the Overall Star Rating methodology that inherently assess quality measure performance in a relative manner, or by comparing hospitals to other hospitals. This influence is present in three places of the Overall Star Rating methodology: in the standardization of individual measure scores, in the standardization of measure group scores, and in the calculation of star ratings using k-means

[129] Centers for Medicare & Medicaid Services. (2016, October 19). *Veterans Health Administration Hospital Performance Data.* Retrieved July 6, 2020, from *www.cms.gov*; *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/VA-Data.*

[130] Veterans Access, Choice, and Accountability Act of 2014, Public Law 113–146, Page 128 Stat. 1754, codified as amended at 38 U.S.C. 1703C(b)(1).

[131] Public Health Service Act of 2019, Public Law 116–69, Page 133 Stat. 1134, codified as amended at 42 U.S.C. 201.

[132] U.S Congress. (1934) United States Code: Social Security Act, 42 U.S.C. 1851.

clustering. The addition of VHA hospitals has no direct influence on CMS-administered programs, however. CMS program impacts, including payment and burden, are assessed based on hospitals participating in CMS' programs and do not include VHA hospitals in those determinations. CMS intends to provide more information about the statistical impact of adding VHA hospitals to the Overall Star Rating and discuss procedural aspects in a future rule.

We invited public comment on our proposal to include VHA hospitals in the Overall Star Rating beginning with CY 2023. The following is a summary of the comments we received and our responses to those comments.

Comment: One commenter supported the inclusion of VHA hospitals within the Overall Star Rating since it will allow veterans to compare non-VHA and VHA hospitals when making healthcare decisions. Regardless of support, commenters requested impact analyses of the inclusion of VHA hospitals on the Overall Star Rating results.

Response: We thank commenters for their feedback. We agree that including VHA hospitals within the Overall Star Rating promotes transparency and provides veterans with the ability to compare hospitals and make empowered decisions about their healthcare. Details of the inclusion of VHA hospitals within the Overall Star Rating as well as impact analyses will be addressed through future rulemaking.

Comment: Most commenters opposed the inclusion of VHA hospitals within the Overall Star Rating because they treat patients with an inherently different case mix, demographics, and often for select clinical conditions.

Response: We acknowledge that VHA hospitals treat a unique patient population. However, the Veterans' Access to care through Choice, Accountability, and Transparency Act (Choice Act) of 2014 (Pub. L. 113–146) allows veterans to seek healthcare at non-VHA hospitals under certain circumstances,[133] section 1704 of the PHSA allows the Secretary to make health information available to consumers of medical care,[134] and section 1815 (d) of the Act allows the Secretary to disseminate information to Medicare beneficiaries to promote informed choice among coverage options.[135] Including VHA hospitals within the Overall Star Rating executes these provisions by providing veterans and Medicare beneficiaries with star ratings for VHA hospitals, effectively allowing them to compare VHA and non-VHA hospitals when making decisions about where to seek care.

After consideration of the public comments received, we are finalizing our proposal as proposed. As stated above, details of the inclusion of VHA hospitals within the Overall Star Rating, including impact analyses, will be addressed through future rulemaking.

D. History of the Overall Hospital Quality Star Rating

Prior to introduction of the Overall Star Rating on the *Hospital Compare* website in July 2016, we engaged stakeholders throughout development of the methodology. CMS' Overall Star Rating development contractor convened both a TEP, consisting of national statistical experts, providers, purchasers, and patient advocates, and a Patient & Advocate Work Group, as well as hosted two public input periods[136] [137] to gain stakeholder feedback on aspects of the methodology. Specifically, feedback was solicited on topics such as measure inclusion and groupings, statistical and non-statistical approaches to summarizing measures, weightings for individual measures and measure groups, and approaches to classifying hospitals to star ratings. In 2015, we hosted a confidential hospital dry run to provide all hospitals and facilities that provide acute inpatient and outpatient care with a private report on their measure performance, measure group scores, and star ratings results, which allowed hospitals to preview their preliminary results without public posting and to familiarize themselves with the methodology.[138] Concurrent with the July 2016 preview period, we also hosted a National Provider Call to present the final methodology and answer stakeholder questions.[139]

For the initial July 2016 and each subsequent release of the Overall Star Rating, including October 2016, December 2016, December 2017, February 2019, and January 2020, we have continuously provided resources to maintain transparency and facilitate understanding of the methods, including three National Provider Calls[140] [141] [142] as well as methodology reports,[143] hospital-specific reports,[144] and open access datasets with quality measure data used to calculate the Overall Star Rating (referred to as the public input file), and SAS programing code used to calculate the Overall Star Rating, along with supporting documents to allow stakeholders to understand and replicate the Overall Star Rating results.

Since the introduction of the Overall Star Rating on the *Hospital Compare* website in July 2016, the Overall Star Rating development contractor has continued to engage stakeholders by convening two additional TEPs, maintaining the Patient & Advocate Work Group, convening a new Provider Leadership Work Group, consisting of hospital quality and medical staff, and hosting two additional public input periods.[145] [146] As a result of ongoing

[133] Veterans Access, Choice, and Accountability Act of 2014, Public Law 113–146, Page 128 Stat. 1754, codified as amended at 38 U.S.C. 1703C(b)(1).

[134] Public Health Service Act of 2019, Public Law 116–69, Page 133 Stat. 1134, codified as amended at 42 U.S.C. 201.

[135] U.S Congress. (1934) United States Code: Social Security Act, 42 U.S.C. 1851.

[136] Centers for Medicare & Medicaid Services. (2015, January). *Hospital Compare Star Ratings Public Comment Report 1: Measure Selection for Hospital Star Ratings.*

[137] Centers for Medicare & Medicaid Services. (2015, June). *Hospital Quality Star Ratings on Hospital Compare Public Comment Report #2: Methodology of Overall Hospital Quality Star Ratings.*

[138] Centers for Medicare & Medicaid Services. (2018, September 18). *Hospital Compare Overall Star Ratings Dry Run Q&A.* Retrieved from *www.qualitynet.org: https://www.qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab4.*

[139] Centers for Medicare & Medicaid Services. (2015, August 13). *Centers for Medicare & Medicaid Services Hospital Compare Overall Star Ratings Methodology MLN Connects National Provider Call.* Retrieved from *www.cms.gov: https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2015-08-13-Star-Ratings.*

[140] Ibid.

[141] Centers for Medicare & Medicaid Services. (2016, May 12). *Centers for Medicare & Medicaid Services Overall Hospital Quality Star Ratings on Hospital Compare National Provider Call.* Retrieved from: *https://www.qualityreportingcenter.com/en/inpatient-quality-reporting-programs/hospital-inpatient-quality-reporting-iqr-program/archived-events/hiqr-event134/.*

[142] Centers for Medicare & Medicaid Services. (2017, November 30). *Centers for Medicare & Medicaid Services Hospital Quality Star Ratings on Hospital Compare December 2017 Methodology Enhancements National Provider Call.* Retrieved from: *https://www.qualityreportingcenter.com/en/inpatient-quality-reporting-programs/hospital-inpatient-quality-reporting-iqr-program/archived-events/hiqr-event107/.*

[143] Centers for Medicare & Medicaid Services. (2018, January). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from: *https://www.qualitynet.org/files/5d0d3a1b764be766b0103ec1?filename=Star_Rtngs_CompMthdlgy_010518.pdf.*

[144] Centers for Medicare & Medicaid Services. *Hospital-Specific Reports.* Retrieved from: *https://www.qualitynet.org/inpatient/public-reporting/overall-ratings/reports.*

[145] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

[146] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov*: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

reevaluation and stakeholder engagement, we updated the methodology in December 2017 and February 2019. CMS also hosted a National Provider Call [147] to facilitate the December 2017 methodology enhancements and nine listening sessions to facilitate the February 2019 methodology enhancements. The current methodology includes enhancements made in December 2017 [148] and February 2019.[149]

1. Reevaluation of the Overall Hospital Quality Star Rating Methodology

The Overall Star Rating is a summary of certain existing hospital quality information, which is collected and reported as part of several CMS programs to improve and make transparent the quality of care provided at hospitals that provide acute inpatient and outpatient care. As the underlying measures reported on *Hospital Compare* have been added, updated, and removed, and as stakeholders have begun using the methodology for purposes beyond consumer transparency, including provider quality improvement efforts, we have refined the methodology of the Overall Star Rating. Since the first reporting of the Overall Star Rating in July 2016, we have maintained an active monitoring and re-evaluation process for the methodology, as well as engaged stakeholders for continuous feedback. Based on this ongoing reevaluation work, we have released multiple, iterative updates to the methodology in December 2017 [150] and February 2019 [151] that addressed stakeholder concerns revealed through previous stakeholder engagement by the TEP [152] [153] and during public input. We refer readers to section E.4.a.(2) Latent Variable Modeling Measure Loadings of this final rule for an overview of the February 2019 methodology updates.

Between 2018 and 2019, CMS' Overall Star Rating development contractor received input on several potential methodology updates through two TEP meetings,[154] three Patient & Advocate Work Group meetings, two Provider Leadership Work Group meetings, nine public listening sessions,[155] and one public input period.[156] Through these reevaluation analyses and stakeholder engagement, we identified three aforementioned overarching areas of improvement for the Overall Star Rating methodology—simplicity of the methodology, predictability of measure emphasis within the methodology over time, and comparability of ratings among hospitals that provide acute inpatient and outpatient care.[157] [158] Simplicity of the methodology means we aim to reduce the statistical complexity of the methodology, while maintaining a representative summary of hospital quality data, so that stakeholders can better understand how the Overall Star Rating is calculated. Predictability of measure emphasis within the methodology over time means we aim to create a methodology that assigns similar measure weight, or emphasis, to each measure to calculate measure group scores and Overall Star Rating over time (each Overall Star Rating publication). Comparability of ratings among hospitals means we aim to create a methodology that compares hospitals that are more similar to each other, such as the measures they report or services they provide, when calculating the Overall Star Rating.

[147] Centers for Medicare & Medicaid Services. (2016, 12 May). *Overall Hosptial Quality Star Ratings on Hospital Compare.* Retrieved from *www.qualityreportingcenter.com*: *https://www.qualityreportingcenter.com/globalassets/migrated-pdf/iqr_20160512_npc-overall-star-rating_vfinal5.9.16.508.pdf.*

[148] Centers for Medicare & Medicaid Services. (2017, November). *Star Methodology Enhancement for December 2017 Public Release.* Retrieved from *www.qualitynet.org*: *https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources.*

[149] Centers for Medicare & Medicaid Services. (2018, November 30). *Quarterly Updates and Specifications Report (February 2019).* Retrieved from *www.qualitynet.org: https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources#tab2.*

[150] Centers for Medicare & Medicaid Services. (2017, November). *Star Methodology Enhancement for December 2017 Public Release.* Retrieved from *www.qualitynet.org*: *https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources.*

[151] Centers for Medicare & Medicaid Services. (2018, November 30). *Quarterly Updates and Specifications Report (February 2019).* Retrieved from *www.qualitynet.org*: *https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources#tab2.*

[152] Centers for Medicare & Medicaid Services. (2017, June). *Hospital Quality Star Ratings on Hospital Compare Technical Expert Panel.*

[153] Centers for Medicare & Medicaid Services. (2018, June). *Summary of Technical Expert Panel (TEP): Hospital Quality Star Rating on Hospital Compare.*

[154] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[155] Centers for Medicare & Medicaid Services. (2019, November). *Overall Hospital Quality Star Rating Listening Session Meeting Summary Report.* Retrieved from *https://www.cms.gov/files/document/overall-hospital-quality-star-ratings-listening-session-summary-report.*

[156] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[157] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[158] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

Since the original introduction of the Overall Star Rating, stakeholders have requested a less complex, or simplified, methodology so that providers can better understand the methodology, interpret their star rating, and use the Overall Star Rating to identify areas for quality improvement.[159] We developed the current methodology under the original principles of the Overall Star Rating, which was to use a statistical approach to summarize quality measures for patients.[160]The current methodology aims to prioritize patient usability and employs data-driven statistical modeling approaches, including latent variable modeling [161] and k-means clustering,[162] to calculate measure group scores and to assign hospital summary scores to star ratings. In summary, the current methodology is designed to rely on data for several critical steps in the star ratings calculation. A couple of the proposed methodology updates aim to increase the simplicity of the methodology for health care providers seeking to replicate, better understand, or communicate an interpretation of the Overall Star Rating, including (1) regrouping measures into five measure groups, rather than seven, due to measure removals as a result of the Meaningful Measure Initiative discussed below in section E.3.b.(2) New Measure Group: Timely and Effective Care of this final rule and (2) using a simple average of measure scores to calculate measure group scores discussed below in section E.4. Step 3: Calculation of Measure Group Scores of this final rule.

Several proposed refinements aim to address the predictability of measure emphasis within the methodology over time. Between the December 2017 and the intended July 2018 publication of the Overall Star Rating, there were no Overall Star Rating methodology updates; however, there were several measure-level updates, including the introduction of two new measures (Severe Sepsis and Septic Shock: Early Management Bundle and Pneumonia Excess Days in Acute Care), the removal of one measure (Pneumonia 30-day Readmission), and updated specifications for the CMS Patient Safety Indicator Composite (CMS PSI–90) measure.[163] The updates to the underlying measures for the July 2018 confidential preview period resulted in differences in the emphasis of measure contributions to the star rating calculation from previous releases.[164] These observed changes in star ratings were similar to star rating increases and decreases observed between reporting periods for other CMS star rating programs, however greater than the increases and decreases observed in prior Overall Star Rating publications. While some increases and decreases in star ratings are expected as hospital performance worsens or improves relative to other hospitals in the nation and as measures are added, updated, and removed from the Overall Star Rating calculation, results from the July 2018 confidential preview period illuminated the extent of the sensitivity of a data-driven statistical model to underlying measure updates. As a result of this unexpected change in measure emphasis, we did not move forward with public release of the July 2018 Overall Star Rating and instead focused on potential improvements to the methodology and stakeholder engagement. Several of the proposed methodology updates, including (1) regrouping measures into five measure groups, rather than seven, due to measure removals as a result of the Meaningful Measure Initiative, discussed below in section E.3.b.(2) New Measure Group: Timely and Effective Care of this final rule; (2) use of a simple average of measure scores to calculate measure group scores, discussed below in section E.4.b. Use of a Simple Average of Measure Scores to Calculate Measure Group Scores of this final rule; and (3) requiring at least three measures in three measure groups, one of which must be Mortality or Safety of Care, to receive a star rating discussed below in section E.6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating of this final rule, aim to address concerns around the predictability of measure emphasis, and in turn star ratings, over time.

Comparability of the Overall Star Rating is a commonly expressed priority by stakeholders.[165] [166] Hospitals that provide acute inpatient and outpatient care differ in size or patient volume, geographical location, urban or rural location, patient populations treated, and services offered. In turn, hospitals differ in the number and type of quality measures reported. All hospitals providing acute inpatient and outpatient care, regardless of differences in any of these characteristics, are included within the Overall Star Rating calculation and are eligible to receive a star rating. Stakeholders, primarily providers on the TEP, Provider Leadership Work Group, and during a public input period, have highly recommended that the Overall Star Rating account for differences in hospital case-mix or type to increase comparability of hospital star ratings.[167] [168] Several of the proposed methodology updates, including (1) stratifying the Readmission measure group according to proportion of dual-eligible patients at each hospital discussed below in section E.4.d.(2) Proposal to Stratify Only the Readmission Measure Group Scores of this final rule; (2) requiring at least three measures in three measure groups, one of which must be Mortality or Safety of Care, to receive a star rating discussed below in section E.6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating of this final rule; and (3) peer grouping hospitals by number of measure groups, discussed below in section E.7. Approach to Peer Grouping Hospitals of this final rule, aim to increase the comparability of hospitals for patients and providers.

[159] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov*: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[160] Centers for Medicare & Medicaid Services. (2018, January). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from: *https://www.qualitynet.org/files/5d0d3a1b764be766b0103ec1?filename=Star_Rtngs_CompMthdlgy_010518.pdf.*

[161] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

[162] Illowsky, B., & Dean, S. (2013). *Introductory Statistics.* Houston, TX: 12th Media Services. Retrieved from: *https://openstax.org/details/books/introductory-statistics.*

[163] Centers for Medicare & Medicaid Services. *Hospital-Specific Reports.* Retrieved from: *https://www.qualitynet.org/inpatient/public-reporting/overall-ratings/reports.*

[164] Centers for Medicare & Medicaid Services. (2018, May). Quarterly Updates and Specifications Report: July 2018. Retrieved from: *https://www.qualitynet.org/files/5d0d3abf764be766b0104a21?filename=StarRatingsJul18_UpdtSpecsRpt.pdf.*

[165] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[166] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov*: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[167] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov*: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[168] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

In 2019, we conducted extensive analyses and engaged multiple stakeholder groups to evaluate each of the proposed methodology updates outlined below. Most notably, CMS' Overall Star Rating development contractor recruited and convened a third TEP to provide technical input,[169] a second Provider Leadership Work Group to provide policy input, and a second Patient & Advocate Work Group to provide input on usability, and we hosted a public listening session,[170] all to gain a range of new perspectives on the current methodology and potential methodology updates.

E. Current and Proposed Overall Star Rating Methodology

1. Overview

The current Overall Star Rating methodology can be outlined within six steps briefly described here and, in more detail, further below. In the first step, the measures are selected from among those reported on *Hospital Compare* to include as much information as possible while considering whether the measures are suitable for combination within the Overall Star Rating. In the first step, the measure scores are also standardized to be consistent in terms of direction (that is, higher scores are better) and numerical magnitude. In the second step, the measures are grouped into one of seven measure groups. Third, for each group, a statistical model, called a latent variable model (LVM), is used to determine a group score for each hospital reporting on measures in that group. In the fourth step, a weight is applied to each measure group score and all available measure groups are averaged to calculate the hospital summary score. In the fifth step, hospitals that provide acute inpatient and outpatient care reporting too few measures and measure groups are excluded. Finally, hospital summary scores are organized into five categories, representing the five star ratings, using an algorithm process called k-means clustering. K-means clustering is a method to cluster data so that observations within one cluster are more similar to each other than observations in another cluster.[171]

In the CY 2021 OPPS/ASC proposed rule, for public release of the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to both retain and update certain aspects of the current Overall Star Rating methodology, as outlined below within each of the six steps of the current methodology. Generally, we proposed to retain the following aspects of the current Overall Star Rating methodology:

- An annual publication cycle using data posted on *Hospital Compare* or its successor site from data publicly reported within the prior year; for example, the Overall Star Rating published in January 2020 used data publicly reported from the October 2019 refresh;
- Suppression policy for subsection (d) hospitals;
- Inclusion of measures publicly reported on *Hospital Compare* or its successor sites that meet specific inclusion and exclusion criteria and standardization of measure score within Step 1: Selection and Standardization of Measures for Inclusion in the Overall Star Rating;
- Publicly displaying measure group level information for measure groups for which a hospital has at least three measures, use of weighted average of measure group scores to calculate summary scores and measure group reweighting to account for measure group scores which are not reported within Step 4: Calculation of Hospital Summary Scores as a Weighted Average of Group Scores; and
- Use of k-means clustering to assign hospitals that provide acute inpatient and outpatient care to one of five star ratings within Step 6: Application of Clustering Algorithm to Obtain a Star Rating.

We proposed to make the following methodology updates:

- Regroup measures as a result of the Meaningful Measure Initiative (83 FR 41147 through 41148) by combining the three process measure groups into one group, Timely and Effective Care, within Step 2: Assignment of Measures to Groups;
- Update the calculation of measure group scores to include standardization of measure group scores and to use a simple average of measure scores, rather than latent variable modeling;
- Stratify the Readmission measure group scores using the proportion of dual-eligible patients at each hospital within Step 3: Calculation of Measure Group Scores;
- Change the reporting thresholds to receive a star rating to three measures within three measure groups, one of which must be Mortality or Safety of Care, within Step 5: Application of Minimum Thresholds for Receiving a Star Rating; and
- Apply peer grouping of hospitals that provide acute inpatient and outpatient care based on number of measure groups between Step 5: Application of Minimum Thresholds for Receiving a Star Rating and Step 6: Application of Clustering Algorithm to Obtain a Star Rating. These are discussed in more detail in section E.7. Approach to Peer Grouping Hospitals of this final rule.

We received numerous comments on the overall concept of methodology updates. The comments were not specific to any individual update. The following is a summary of the comments we received and our responses to those comments.

Comment: Some stakeholders provided broad comments on CMS' proposals in entirety. Most of those commenters supported CMS' proposals and the efforts to increase simplicity, predictability, and comparability of the Overall Star Rating methodology as a result of previous stakeholder input. Commenters stated that they believe a more simple and predictable methodology would result in more transparency, the ability for stakeholders to understand, predict, and replicate results, and reduced administrative burden for providers while increasing the accuracy and usability of the Overall Star Rating for patients. Commenters stated that the methodology proposals result in comparisons of more similar providers, such as large vs small hospitals.

Response: We thank the commenters for their support. We agree that the proposals will increase simplicity and predictability of the Overall Star Rating methodology. We also agree that the proposals provide more transparency and understanding of the methodology for stakeholders, including both providers and patients, and will increase the comparability of hospital star ratings.

Comment: One commenter requested that CMS conduct further reliability and validity testing before finalizing the proposed methodology.

Response: We analyzed each methodology proposal both independently, as well as collectively. We presented findings within each section of the Overall Star Rating proposals, as well as overall impact analyses to facilitate public understanding and comments. Most

[169] Ibid.

[170] Centers for Medicare & Medicaid Services. (2019, November). *Overall Hospital Quality Star Rating Listening Session Meeting Summary Report.* Retrieved from *https://www.cms.gov/files/document/overall-hospital-quality-star-ratings-listening-session-summary-report.*

[171] Huang, Z. Extensions to the k-Means Algorithm for Clustering Large Data Sets with Categorical Values. *Data Mining and Knowledge Discovery* 2, 283–304 (1998) doi:10.1023/A:1009769707641.

sections of the Overall Star Ratings proposals contained reliability and validity considerations, for example consistency of hospital assignments to peer groups over time (see section E.7. Approach to Peer Grouping Hospitals of this final rule). While there is currently no consensus standard for measuring reliability and validity for summary measures, such as the Overall Star Rating, we have historically conducted reliability and validity testing that has been shared in detail with TEPs and work groups as well as in public documentation.[172] [173] We will continue to provide updated reliability and validity testing within the methodology report, which will be posted for the preview period (see section F. Preview Period of this final rule). In addition, through ongoing reevaluation, we will continue to monitor the reliability and validity of the Overall Star Rating methodology.

2. Step 1: Selection and Standardization of Measures for Inclusion in the Overall Star Rating

a. Timeframe

(1) Current Timeframe

Generally, for CMS quality programs, we update measure data results on the *Hospital Compare* or its successor websites quarterly in January, April, July, and October of each year. In the past, the Overall Star Rating was published on *Hospital Compare* both quarterly and biannually. Beginning in February 2019, the Overall Star Rating was published annually. In January 2020, the Overall Star Rating continued the annual publication cycle with the additional approach of using data publicly posted on *Hospital Compare* in a quarter prior to the update to calculate star ratings. For example, we used October 2019 publicly reported measure data on *Hospital Compare* to calculate Overall Star Rating results for the January 2020 publication.[174] Note that the data collection period for each measure varies depending on measure specifications that set minimum case requirements to ensure individual measure reliability and meet the requirements of CMS quality programs, as detailed in each program's respective rules as well as on *Hospital Compare* or its successor website.

(2) Retain Current Timeframe With Modification

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027) for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to retain the current timeframe with modification, such that the Overall Star Rating would continue to be published once annually; however, instead of using data from the same quarter as or the quarter prior to the publication of the Overall Star Rating, we would use publicly available measure results on *Hospital Compare* or its successor websites from a quarter within the prior year. As mentioned above, for CMS quality programs, we generally update measure data results on the *Hospital Compare* or its successor websites quarterly in January, April, July, and October of each year. Therefore, we would use publicly reported data from one of those four *Hospital Compare* refreshes to calculate the Overall Star Rating. For example, for a January 2021 Overall Star Rating release, we could use data refreshed on *Hospital Compare* in April, July or October of 2020. We proposed to codify this timeframe at § 412.190(c).

We believe publishing the Overall Star Rating once a year is appropriate because it may minimize period to period changes in hospital star ratings that may result from small changes in individual hospital and national performance for the underlying measures. Furthermore, publishing the Overall Star Rating once a year would allow time for the star ratings to reflect improvements or updates in hospital performance on the underlying measures. It also is aligned with the current cycle of many underlying measures, particularly highly weighted outcome measures that are also refreshed annually.[175] Also, using data publicly reported on *Hospital Compare* or its successor websites within the prior year, rather than data publicly reported concurrent with the Overall Star Rating, would allow providers more time, beyond the standard 30 days, to review their star rating as well as the measure and measure group results that contribute to their star rating during the confidential preview period (we refer readers to section F. Preview Period of this final rule). Hospitals that provide acute inpatient and outpatient care may use this additional time to more thoroughly anticipate and understand their results, as well as generate communication or improvement strategies.

We invited public comment on our proposals to: (1) Publish the Overall Star Rating once annually using data publicly reported on *Hospital Compare* or its successor websites from a quarter within the prior year, and (2) codify this at § 412.190(c). The following is a summary of the comments we received and our responses to those comments.

Comment: Several commenters supported CMS' proposal to continue an annual publication of the Overall Star Rating, with some commenters expressing appreciation for the codification of the annual publication within a rule to increase predictability of Overall Star Rating publications.

Response: We appreciate commenters support for our proposal to continue an annual publication of the Overall Star Rating. Publishing the Overall Star Rating once a year allows for sufficient time between ratings to reflect improvements or updates in hospital performance on the underlying measures. Updating the Star Ratings annually also aligns with the current cycle of many underlying measures, particularly highly weighted outcomes measures, that are also refreshed annually, for example in July of each year.

Comment: Some commenters recommended that CMS prioritize using the most recent available data over providing hospitals extra time to review their underlying measure performance and expressed concern that the data used to determine the Overall Star Rating does not reflect current quality of care. One commenter recommended CMS designate a specific prior quarter's data rather than ''any prior quarter'', unless there are extreme circumstances.

Response: As requested by providers,[176] publishing the Overall Star

[172] Centers for Medicare & Medicaid Services. (2018, January). Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0). Retrieved from: *https://www.qualitynet.org/files/5d0d3a1b764be766b0103ec1?filename=Star_Rtngs_CompMthdlgy_010518.pdf.*

[173] Centers for Medicare & Medicaid Services. (2017, December). Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0). Retrieved from *www.qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1.*

[174] Centers for Medicare & Medicaid Services. (2019, November 4). Overall Hospital Quality Star Rating on Hospital Compare: January 2020 Updates and Specifications Report. Retrieved from qualitynet.org: *https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2.*

[175] For the Hospital VBP Program, this includes: MORT30–AMI, MORT30–CABG, MORT30–COPD, MORT30–HF, MORT30–HF, MORT30–PN; HAI1 through HAI6, and COMP–HIP–KNEE; For the Hospital IQR Program, this includes: MORT30–STK, PSI–4, READM30–HOSPWIDE, EDAC–AMI, EDAC–HF, EDAC–PN, and COMP–HIP–KNEE; For the Hospital OQR Program, this includes: OP–32, OP–35, OP–36; For the HRRP, this includes: READM30–CABG, READM30–COPD, and READM30-Hip/Knee; and for the HAC Reduction Program, this includes: PSI–90 and HAI–1 through HAI–6.

[176] Centers for Medicare & Medicaid Services. (2019, June). Public Comment Summary Report. Retrieved from *www.CMS.gov*: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

Rating using data publicly reported on *Hospital Compare* or its successor websites within the prior year will allow providers more time to review their measure scores, measure group scores, and star rating results during the confidential preview period. We acknowledge that the measures included in CMS payment programs and the Overall Star Rating use a range of data measurement periods with data reflecting outcomes from up to three years ago in order to collect enough data to calculate reliable hospital scores, however each measure is updated as often as quarterly and as seldom as annually to incorporate more recent data. Furthermore, using data from any quarter within the prior year provides CMS with flexibility to calculate the Overall Star Rating and maintain transparency for patient healthcare decisions in the event of potentially compromised measure score calculation or CMS program-level data disruption due to a public health emergency, for example.

Comment: Several commenters requested CMS update the Overall Star Rating more frequently, either quarterly or biannually, to provide consumers with more recent and meaningful data. Another commenter recommended that the annual Overall Star Rating publication align with the July *Hospital Compare* data refresh.

Response: We appreciate commenter requests for more frequency of the Overall Star Rating publications and acknowledge commenters' request to use more current data to calculate the Overall Star Ratings. We acknowledge that the measures included in CMS payment programs and the Overall Star Rating use a range of data measurement periods with data reflecting outcomes from up to three years ago. However, publishing the Overall Star Rating annually may minimize period to period shifts in hospital star ratings that may result in small changes in individual hospital and national performance on the underlying measures. We have received feedback from stakeholders [177] that hospitals increasing or decreasing star rating categories on a quarterly or bi-annual basis may encounter difficulties explaining the increase or decrease in star rating to hospital leadership and patients. An annual refresh will allow adequate time to reflect improvements or updates in hospital performance on the underlying measures. While a publication of the Overall Star Ratings in July of every year would align in timing with the scheduled refresh of many highly weighted outcome measures, such as readmission and mortality measures, the underlying data used to calculate the Overall Star Rating would not align since we will use data from a quarter within the prior year (see section E.2.a.(2) Retain Current Timeframe With Modification of this final rule). A publication of the Overall Star Rating in October or January could reflect July *Hospital Compare* data refreshes.

Comment: One commenter requested CMS suspend the proposed 2021 publication of the Overall Star Rating to finalize the methodology changes and include an independent audit of the methodology prior to publication in 2022.

Response: The Overall Star Rating proposals were vetted through extensive reevaluation activities and stakeholder engagement, including TEP,[178] [179] Provider Leadership Work Group, and Patient & Patient Advocate Work Group meetings, a public input period,[180] and CMS listening sessions.[181] In addition, the NQF convened a separate, independent TEP [182] that also reviewed and provided broad support for these proposals.

After consideration of the public comments received, we are finalizing our proposals as proposed.

b. Measure Inclusion

(1) Current Measure Inclusion

Generally, measures publicly reported on *Hospital Compare* or its successor site through CMS quality programs, specifically the Hospital IQR Program, Hospital OQR Program, HRRP, HAC Reduction Program, and Hospital VBP Program, were used to calculate Overall Star Rating. We did not include publicly reported measures from any CMS programs not measuring acute inpatient or outpatient care or pertaining to specialty hospitals, such as cancer hospitals, and ambulatory surgical centers, such as the PCHQR Program, IPFQR Program, or Ambulatory ASCQR Program. The goal of Overall Star Rating is to summarize quality of care at hospitals providing acute inpatient and outpatient care and thus, only include measure scores representing quality of acute inpatient and outpatient care.

Any measures that were removed or suspended from one of the listed quality programs and not displayed on *Hospital Compare* or successor websites were not included.

(2) Retain Current Measure Inclusion

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), we proposed to continue the same practice by incorporating measures summarizing quality of care at inpatient and outpatient care hospitals in the Overall Star Rating. Specifically, for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to use certain measures publicly reported on the *Hospital Compare* or successor websites through certain CMS quality programs, specifically the Hospital IQR Program, Hospital OQR Program, HRRP, HAC Reduction Program, and Hospital VBP Program, to calculate the Overall Star Rating. We also proposed to codify this policy at § 412.190(b)(1).

We believe hospital inpatient and outpatient measures publicly reported on *Hospital Compare* or its successor websites are appropriate for the Overall Star Rating because they capture the quality of care at hospitals providing acute inpatient and outpatient care and provide a snapshot of quality when combined together. We recognize that measures reported on *Hospital Compare* or its successor websites undergo a rigorous development process which includes extensive measure testing, vetting by stakeholders, evaluation by the NQF, and undergo rulemaking for inclusion in CMS programs and public reporting. As such, the Overall Star Rating methodology uses the measures as specified under the CMS programs, and measure scores as reported on *Hospital Compare* or its successor websites at the time of the Overall Star Rating calculation. As noted above, any measures that are removed or suspended from one of the listed quality programs and not displayed on *Hospital Compare* or successor websites are not

[177] Centers for Medicare & Medicaid Services. (2019, June). Public Comment Summary Report. Retrieved from *www.CMS.gov*: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[178] Centers for Medicare & Medicaid Services. (2018, June). Summary of Technical Expert Panel (TEP): Hospital Quality Star Rating on Hospital Compare.

[179] Centers for Medicare & Medicaid Services. (2019, November). Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare. Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[180] Centers for Medicare & Medicaid Services. (2019, June). Public Comment Summary Report. Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[181] Centers for Medicare & Medicaid Services. (2019, November). Overall Hospital Quality Star Rating Listening Session Meeting Summary Report. Retrieved from *https://www.cms.gov/files/document/overall-hospital-quality-star-ratings-listening-session-summary-report.*

[182] National Quality Forum. (2019, November 6). National Quality Forum Hosptial Quality Star Ratings Summit. Retrieved from *www.qualityforum.org: http://www.qualityforum.org/NQF_Hospital_Quality_Star_Rating_Summit.aspx.*

included. Additional measure exclusions are discussed in the next section. Also, we refer readers to sections B. Critical Access Hospitals in the Overall Star Rating and C. Veterans Health Administration Hospitals in Overall Star Rating of this final rule for our discussions about CAHs and VHA hospitals.

We invited public comment on our proposals: (1) Use measures publicly reported on *Hospital Compare* or its successor websites through certain CMS quality programs, specifically the Hospital IQR Program, Hospital OQR Program, HRRP, HAC Reduction Program, and Hospital VBP Programs, for the Overall Star Rating in CY 2021 and subsequent years, and (2) codify this policy at § 412.190(b)(1). The following is a summary of the comments we received and our responses to those comments.

Comment: Several commenters expressed general support for the continued Overall Star Rating measure selection criteria, as proposed.

Response: We thank commenters for their support and agree that the measure selection criteria ensures the inclusion of existing measures reported within CMS quality programs and on *Hospital Compare* or its successor website for hospitals that provide acute inpatient and outpatient care.

Comment: Some commenters recommended changes to the measure selection criteria, specifically recommending removing measures with annual volatility and only including NQF-endorsed measures that are valid, reliable, and aligned with other existing measures. Several commenters provided further feedback on specific measures included within the Overall Star Rating with some commenters expressing concern with healthcare-associated infection (HAI) measure risk adjustment, recommending the removal of the PSI–90 measure, and one commenter supporting the inclusion of electronic clinical quality measures. Those that commented specifically on the PSI–90 measure expressed concern that the measure was developed as a tool for hospitals to identify potential safety events, rather than quality measurement within CMS programs, utilizes administrative claims, rather than chart-abstracted data, disadvantages hospitals that have high volume of surgeries, results in surveillance bias, and has inadequate risk adjustment and poor reliability. They requested that CMS implement better alternative safety quality measures or update, benchmark, and audit the PSI–90 measure.

Response: One of the guiding principles of the Overall Star Rating is to use methods that are inclusive of measure information publicly available on *Hospital Compare* or its successor websites through CMS quality programs. As measures are updated within, removed from, or added to CMS quality programs and *Hospital Compare* or its successor website, the measures are subsequently updated within, removed from, or added to the Overall Star Rating, unless the measures meet one of the specified measure exclusion criteria.

While changes in results that reflect updates in individual and national hospital performance are expected, we agree that extreme volatility on the individual measures and Overall Star Rating poses challenges for hospitals and consumers interpreting results. To increase the predictability and reduce extreme volatility of the Overall Star Rating, in the CY 2021 OPPS/ASC proposed rule, we proposed to establish an annual publication of the Overall Star Rating, preventing shifts in star ratings within a given year, and to use a simple average of measure scores to calculate measure group scores, for more balanced and consistent measure emphasis within groups.

Measures that are included within CMS quality programs and reported on *Hospital Compare* or its successor websites undergo a rigorous development process which include extensive measure testing, stakeholder vetting, evaluation by the NQF, and rulemaking. While most measures included within the Overall Star Rating are NQF-endorsed, NQF endorsement is not required.

Existing measures within CMS quality programs were developed and implemented to fulfill important gaps in measurement and areas for quality improvement. We continuously monitor and reevaluate measures for evidence, opportunities for performance improvement, and potential methodology updates. For example, under the Hospital IQR Program, we adopted updates to the PSI–90 measure for the FY 2018 payment determination and subsequent years, which addressed stakeholder feedback on the component weighting within the composite measure (81 FR 57128– 57133). We appreciate support for the inclusion of electronic measures within CMS quality programs and the Overall Star Rating. Although electronic measures are not currently required for public reporting and therefore are not included in the Overall Star Rating at this time, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58437), CMS finalized proposal policy to begin public display of electronic quality measure data starting with data reported by hospitals for the CY 2021 reporting period/FY 2023 payment determination and for subsequent years. As electronic measures become required within CMS quality programs, electronic measures will be subsequently included within the Overall Star Rating.

Comment: One commenter recommended that CMS evaluate measures for validity and reliability if data from CY 2020 are excluded and the measurement periods are extended to enhance sample size as a result of COVID–19.

Response: On March 27, 2020, we granted exceptions under certain Medicare quality reporting and value-based purchasing programs.[183] [184] In addition, the 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 Interim Final Rule (IFC) (85 FR 54820) updated the extraordinary circumstances exceptions granted for the Hospital Acquired Condition (HAC) Reduction Program, Hospital Readmissions Reduction Program (HRRP), and Hospital VBP Program for the PHE for COVID–19 as a result of the PHE for COVID–19. This IFC also announced that with respect to the Hospital VBP Program, HRRP, HAC Reduction Program, if, as a result of a decision to grant a new nationwide ECE without request or a decision to grant a substantial number of individual ECE requests, we do not have enough data to reliably compare national performance on measures, we may propose to not score facilities, hospitals based on such limited data or make the associated payment adjustments for the affected program year.

We are currently analyzing how our exemptions granted and the COVID–19 pandemic impact the measures within

[183] CMS Press Release, dated March 22, 2020, CMS Announces Relief for Clinicians, Providers, Hospitals and Facilities Participating in Quality Reporting Programs in Response to COVID–19. Located at *https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting.*

[184] CMS Guidance Memo, dated March 27, 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. Located at *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

various CMS quality programs. We note that the Overall Star Rating is calculated using individual measures publicly reported through CMS quality programs and on *Hospital Compare* or its successor website. The Overall Star Rating uses data publicly reported through CMS quality programs and thus, data excluded from those CMS quality programs, will be subsequently excluded from the Overall Star Rating. Hospitals can also utilize established processes under each program in order to review and correct individual measure scores. We refer readers to the QualityNet website: *https://qualitynet.org/* for additional program-related information. We also refer readers to section G. of this final rule; we may also consider suppression of the Overall Star Rating if we determine that due to a public health emergency underlying measure data were substantially affected.

After consideration of the public comments received, we are finalizing our proposals as proposed.

c. Measure Exclusions

(1) Current Measure Exclusions

Of the measures publicly reported on the *Hospital Compare* website through the CMS quality programs listed in a previous section, in the past, we have excluded some measures from the Overall Star Rating methodology for various reasons. The measures excluded fall into the following categories:

- Measures with no more than 100 hospitals reporting performance publicly, as these measures would not produce reliable measure group scores based on so few hospitals;
- Structural measures not amenable to inclusion in a summary scoring calculation alongside process and outcome measures, as these measures cannot be as easily combined with other measures captured on a continuous scale with more granular data;
- Non-directional measures (for which it is unclear whether a higher or lower score is better, such as payment measures), as these measures cannot be standardized to form an aggregate measure group score;
- Measures not required for reporting on *Hospital Compare* or its successor websites through CMS programs, that is the Hospital IQR Program, Hospital OQR Program, HRRP, HAC Reduction Program and Hospital VBP Program, due to the purpose of Overall Star Rating being a summary of measure information as displayed on *Hospital Compare* or its successor websites;
- Overlapping measures (for example, measures that are identical to another measure, measures with substantial overlap in cohort and/or outcome, and measures that are part of an already-included composite measure), in order to avoid duplicative measure results within the methodology; and
- Measures with statistically significant negative loadings estimated by the LVM as described further in section E.4.a.(2) Latent Variable Model Measure Loadings of this final rule.

In February 2019, we excluded measures for which the LVM estimates a statistically significant negative loading, which indicated the measure had an inverse relationship with other measures in the group.[185] LVM is the a statistical method for combining information that represents a latent trait, in this case measures within a measure group that represent an aspect of hospital quality, to estimate a numerical score, in this case measure group scores.[186] Measure loadings are the contribution, or emphasis, of each measure as assigned by the LVM.[187] Latent variable modeling and measure loadings are described in more detail under section E.4. Step 3: Calculation of Measure Group Scores of this final rule.

(2) Retention and Update of Select Measure Exclusions

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for the Overall Star Rating beginning in CY 2021 and subsequent years, we intended to continue to exclude certain measures used to calculate the Overall Star Rating. We believe these measure exclusions remain appropriate moving forward because the Overall Star Rating is a summary of the existing publicly reported measures of hospital quality of care but not all measure scores can be reliably or appropriately combined with other measure scores. These are discussed in more detail below.

1. We proposed to continue to exclude measures that only 100 hospitals or less publicly report. These measures would not produce reliable measure group scores based on too few hospitals.

2. We proposed to continue to exclude measures that are not able to be standardized and otherwise not amenable to inclusion in a summary score calculation alongside process and outcome measures or measures that cannot be combined in a meaningful way. This includes measures that cannot be as easily combined with other measures captured on a continuous scale with more granular data.

3. We proposed to continue to exclude non-directional measures for which it is unclear whether a high or lower score is better. Without directional scores these measures cannot be standardized to be combined with other measures and form an aggregate measure group score as detailed in section E.2.d Measure Score Standardization of this final rule.

4. We proposed to continue to exclude measures not required for reporting on *Hospital Compare* or its successor websites through CMS programs.

5. We proposed to continue to exclude measures that overlap with another measure in terms of cohort or outcome; this includes component measures that are part of an already-included composite measure. This exclusion criterion avoids duplicative measure results within the Overall Star Rating methodology. In general, we would determine which measures to include or exclude based on the level of information provided by the measure. For example, we would include a composite measure, such as PSI–90, over the component measures, such as PSI–03. As another example, we would include the excess days in acute care (EDAC) measures over the readmission measures, because while both measure sets have the same cohort, the EDAC measures capture a broader outcome inclusive of emergency department visits and observation stays in addition to the unplanned readmissions captured by both measures.

We also proposed to codify these exclusions at § 412.190(d)(1)(i). We noted that we did not propose to continue to exclude measures with statistically significant negative loadings estimated by the LVM. (Measure loadings are the contribution, or emphasis, of each measure as assigned by the LVM.[188] and are further discussed in section E.4.a.(2) Latent Variable Model Measure Loadings of this final rule). This is because, in section E.4.b. of the CY 2021 OPPS/ASC proposed rule, we proposed to calculate measure group scores using a simple average of measure scores, instead of latent variable modeling. Should that proposal be finalized, measure loadings would no longer be produced as a product of latent variable modeling and, therefore, the exclusion criteria of

[185] Centers for Medicare & Medicaid Services. (2018, November 30). *Quarterly Updates and Specifications Report (February 2019).* Retrieved from *www.qualitynet.org*: *https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources#tab2.*

[186] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

[187] Ibid.

[188] Ibid.

measures with statistically significant negative loadings would no longer be necessary. However, should that proposal not be finalized, we would continue using LVM to calculate measure group scores and exclude measures with statistically significant negative loadings as discussed in section E.4.a.(2) Latent Variable Modeling Measure Loadings of this final rule.

We invited public comment on our proposal as discussed previously. The following is a summary of the comments we received and our responses to those comments.

Comment: Several commenters expressed general support for the continued Overall Star Rating measure exclusion criteria, as proposed.

Response: We thank commenters for their support and agree that the measure exclusion criteria ensures the measures included within the Overall Star Rating can be easily standardized and combined in a meaningful way with other measures to form aggregate measure group scores.

We are finalizing our proposals as proposed.

d. Measure Score Standardization

(1) Current Measure Score Standardization

In the past, once the relevant measures were excluded, the remaining measures are standardized to a single, common scale to account for differences in measure score units, such as ratios or rates, and direction, specifically whether a higher or lower score indicates better quality.[189] It is necessary to standardize all measure scores to the same scale (that is, units and direction) for combination into and calculation of measure group scores. To standardize, we used a statistical technique to calculate Z-scores for each measure.[190] A Z-score is a standard deviation score, which relays the amount of variation in a dataset, or in this case, the variation in hospital measure scores. In the Overall Star Rating, Z-scores were produced by subtracting the national mean measure score from each hospital's measure score and dividing by the standard deviation [191] across hospitals. Standard deviation is a number that measures how far data values are from their average.[192] See the measure score standardization example and Table 65. In addition, we changed the direction of all measures that indicate better performance with a lower score so that they were reversed to uniformly indicate that a higher score indicates better performance for all the measures prior to combination with other measures to calculate measure group scores.

(2) Retention of Current Measure Score Standardization

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to continue to standardize measure scores as it allows for measures, which are different in units and direction, to be combined into aggregate measure group scores. Specifically, we proposed that once applicable measures are excluded, we would standardize the remaining measures by calculating Z-scores for each measure prior to being combined in an aggregate measure group score so that all measures are on a single, common scale. That is, we would subtract the national mean measure score from each hospital's measure score and divide the difference by the measure standard deviation in order to standardize measures. We also proposed to codify this at § 412.190(d)(2).

Example of Standardization of Measure Score

Standardized measures score (HAI–6) = − (0.470 − 0.694)/0.49 = 0.46

[189] Centers for Medicare & Medicaid Services. (2017, December). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from *www.qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1.*

[190] DeVore, G.R. (2017, January 17). ''Computing the Z score and centiles for cross-sectional analysis: a practical approach.'' Journal of Ultrasound in Medicine 36.3: 459–473.

[191] Illowsky, B., & Dean, S. (2013). *Introductary Statistics.* Houston, TX: 12th Media Services. Retrieved from: *https://openstax.org/details/books/introductory-statistics.*

[192] Ibid.

TABLE 65: Example of Standardization of Measure Scores Within Safety of Care Measure Group

Measure Name	Measure Score	Measure National Mean Score	Measure Standard Deviation	Standardized Measure Score
COMP-HIP-KNEE Hospital-Level Risk Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA)	3.22%	2.66%	0.005	-1.13
HAI-1 Central-Line Associated Bloodstream Infection (CLABSI)	1.233	0.736	0.66	-0.75
HAI-2 Catheter-Associated Urinary Tract Infection (CAUTI)	0.747	0.806	0.64	0.09
HAI-3 Surgical Site Infection (SSI) from Colon Surgery	0.000	0.826	0.68	1.21
HAI-4 Surgical Site Infection (SSI) Abdominal Hysterectomy	0.000	0.867	0.89	0.97
HAI-5 Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteremia	0.166	0.843	0.69	0.98
HAI-6 Clostridium Difficile (C. difficile)	0.470	0.694	0.49	0.46
PSI-90 Complication/Patient Safety for Selected Indicators	0.999	0.996	0.18	0.02

We invited public comment on our proposals to standardize measure scores and codify this policy at § 412.190(d)(2). However, we received no comments on these proposals.

We are finalizing our proposals as proposed.

e. Measure Score Winsorization

(1) Current Measure Score Winsorization

In the past, to avoid extreme outlier performance that may be potentially inaccurate or pose technical challenges to statistical estimates, the standardized measure scores were Winsorized [193] at the 0.125th and 99.875th percentiles of a standard normal distribution so that all measure scores range from negative 3 to positive 3 (−3 to 3). Winsorization [194] is a common strategy used to set extreme outliers to a specified percentile of the data. This step was necessary in order to minimize the impact of extreme measure score outliers on the performance of the latent variable modeling (LVM) (we refer readers to section E.4.a.(1) Latent Variable Modeling Overview of this final rule for details). We chose to Winsorize the 0.125th and 99.875th percentiles to minimize the number of scores requiring Winsorization, while also allowing the models to perform properly and produce results. This approach to measure inclusion and standardization within the Overall Star Rating has been vetted previously through the TEP,[195] [196] Patient & Advocate Work Group, and a public input period.[197]

(2) Elimination of Measure Score Winsorization Moving Forward

We refer readers to section E.4.b. Use of a Simple Average of Measure Scores to Calculate Measure Group Scores of this final rule, where we finalized to calculate measure group scores using a simple average of measure scores for the Overall Star Rating beginning in CY 2021 and subsequent years, instead of latent variable modeling, as was used in the past. Because Winsorization was only necessary to minimize the impact of extreme outliers prior to statistical modeling to ensure model stability, the absence of LVM would eliminate the need for Winsorization. Eliminating Winsorization would be consistent with the proposal to replace the LVM with a

[193] Kwak, S.K., & Kim, J.H. (2017, July 27). ''Statistical data preparation: Management of missing values and outliers.'' Korean journal of anesthesiology 70.4: 407.

[194] Ibid.

[195] Centers for Medicare & Medicaid Services. (2015, February). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[196] Centers for Medicare & Medicaid Services. (2014, December). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[197] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

simple average of measure scores, would support the goal of refinements to simplify the methodology, and would retain the original, observed performance of outlier hospitals within the calculations. However, in the proposed rule, we stated that should we not finalize our proposal to adopt the simple average of measure scores and retain LVM to calculate measure group scores, as discussed in section E.4.a. Current Approach to Calculating Measure Group Scores Using Latent Variable Modeling of this final rule, we would continue to Winsorize measure scores to minimize the impact of extreme outliers. We refer readers to section E.4.b. Use of a Simple Average of Measure Scores to Calculate Measure Group Scores of this final rule where we are finalizing the policy to use a simple average of measure scores.

We invited public comment on our proposals as discussed previously. The following is a summary of the comments we received and our responses to those comments.

Comment: Several commenters supported the removal of measure score Winsorization with the use of simple average of measure scores.

Response: We thank commenters for their support and agree that measure score Winsorization is no longer necessary with a simple average of measure scores to calculate measure group scores.

Comment: A few commenters suggested that CMS retain measure score Winsorization with the simple average of measure scores approach to reduce potential measurement error or effect of a single measure within the Overall Star Rating calculation.

Response: We refer readers to section E.4.b. Use of a Simple Average of Measure Scores to Calculate Measure Group Scores of this final rule where we are adopting use of a simple average of measure scores to calculate measure group scores and disagree with commenters that measure score Winsorization should be retained with the use of a simple average of measure scores. Winsorization of measure scores was previously necessary with LVM in order to minimize the impact of extreme measure score outliers prior to statistical modeling to ensure model stability but it is no longer necessary with a simple average of measure scores. Removing Winsorization is consistent with our intent to simplify the Overall Star Rating methodology and use a simple average of measure scores to calculate measure group scores. In addition, removing measure score Winsorization allows CMS to retain the underlying measure scores, as calculated, to be used within the Overall Star Rating, better reflecting measure performance for outlier hospitals. The Overall Star Rating includes measure scores reported within CMS quality programs and reported on *Hospital Compare* or its successor websites, which underwent and continue to undergo rigorous development and reevaluation processes that include substantial validation testing to minimize measurement error. Furthermore, use of a simple average of measure scores to calculate measure group scores will create equal weighting within measure groups, therefore, diminishing the possibility of one or a few measures from having more effect on a hospital's star rating.

3. Step 2: Assignment of Measures to Groups

a. Past Assignment of Measures to Groups

In the past, we have grouped measures into one of seven measure groups: Mortality, Safety of Care, Readmission, Patient Experience, Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging. Measures were grouped this way to align with the Hospital VBP Program [198] and the previous display of *Hospital Compare,*[199] to clinically reflect shared components of hospital quality, allow for measures to be added or removed as they are added or removed from public reporting, and to be useful to patients in making healthcare decisions as communicated by the Patient & Advocate Work Group. Grouping measures is also consistent with other CMS star rating initiatives, including Nursing Home Compare Star Ratings,[200] Medicare Plan Finder Star Ratings,[201] and Dialysis Facility Compare.[202]

b. New Measure Group and Continuation of Certain Groups

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to consolidate the three process measure groups—Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging—into one process measure group: Timely and Effective Care. We also proposed to retain the current structure of the Mortality, Safety of Care, and Readmission, and the Patient Experience measure groups. These are discussed in more detail below.

(1) Continuation of the Mortality, Safety of Care, Readmission, and Patient Experience Measure Groups

The Mortality, Safety of Care, Readmission, and Patient Experience measure groups were used in the past as noted above. The Mortality, Safety of Care, Readmission, and Patient Experience measure groups contain an adequate number of publicly reported measures to produce robust measure group scores, reflective of differences in hospital quality. These measure groups were not as affected as the process of care measure groups, discussed in the next section, by the Meaningful Measure Initiative (83 FR 41147 through 41148).[203] In the CY 2021 OPPS/ASC proposed rule, for the Overall Star Rating beginning CY 2021 and subsequent years, we proposed to continue to use these measure groups. We also proposed to codify these measure groups at § 412.190(d)(3).

We invited public comment on our proposals as discussed previously. The following is a summary of the comments we received and our responses to those comments.

Comment: Several commenters recommended that CMS continue to assess the various measure groups and group weights, now and in the future, to ensure measure groups and weights are balanced and reflect areas of importance to patients. One commenter noted that the composition of measures available on *Hospital Compare* or its successor websites will continue to evolve, and that CMS should consider longer-term solutions for measure groupings to prevent frequent regroupings and subsequent instability in scores. One commenter supported CMS' measure groups but also recommended that CMS review other existing metrics as an

[198] Centers for Medicare & Medicaid Services. (2017, December). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from *www.qualitynet.org*: *https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1.*

[199] Centers for Medicare & Medicaid Services. (2019) *Hospital Compare.* Retrieved from: *www.medicare.gov/hospitalcompare*: *https://www.medicare.gov/hospitalcompare/search.html*?.

[200] Centers for Medicare and Medicaid Services (2019, October). Design for Nursing Home Compare. Retrieved from *www.cms.gov*: *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Downloads/usersguide.pdf.*

[201] Centers for Medicare and Medicaid Services (2019, October 1). Medicare 2020 Part C & D Star Ratings Technical Notes. Retrieved from *www.cms.gov*: *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/Prescription DrugCovGenIn/Downloads/Star-Ratings-Technical-Notes-Oct-10–2019.pdf.*

[202] Centers for Medicare and Medicaid Services (2016, June). Technical Notes on the Updated Dialysis Facility. Retrieved from dialysisdata.org: *https://dialysisdata.org/sites/default/files/content/Methodology/UpdatedDFCStarRating Methodology.pdf.*

[203] Ibid.

example of aggregating quality, safety, and patient experience and engaging hospitals on improvement efforts on specific target areas and service lines. Another commenter specifically expressed concern with the Safety of Care measure group being comprised of HAI measures, the PSI–90 measure, and the Total Knee Arthroplasty/Total Hip Arthroplasty complication measure, which all have dissimilar risk adjustment approaches, making it difficult for consumers to understand and hospitals to target improvement within the Safety of Care measure group.

Response: We appreciate the commenters' suggestions for ongoing reevaluation of measure groupings over time and as *Hospital Compare* or its successor websites evolve. We will continue to monitor the number and groupings of the underlying measures that comprise the Overall Star Rating. While measures within a group may differ in specifications, including risk adjustment, the measure regroupings were identified and implemented based on alignment with clinical components of hospital quality, the Hospital VBP Program, the previous display of *Hospital Compare,* and input received from stakeholders during TEP and Patient & Patient Advocate Work Group meetings and public input periods. The Overall Star Rating is meant to summarize and reflect the existing measures on *Hospital Compare* or its successor website. As part of ongoing reevaluation, we will continue to monitor the available measures reported within CMS quality programs for inclusion and grouping within the Overall Star Rating. The best way for hospitals to improve on the Overall Star Rating is to improve performance on the underlying measures. The adoption of a simple average of measure scores to calculate measure group scores would assign equal weights within measure groups, allow hospitals to better predict measure contributions, and target quality improvement efforts for improved measure group scores and star ratings (see section E.4.b. Use of a Simple Average of Measure Scores to Calculate Measure Group Scores of this final rule).

After consideration of the public comments we received, we are finalizing our proposals as proposed.

(2) New Measure Group: Timely and Effective Care

Since the first release of the Overall Star Rating, measures have been: (1) Developed and adopted in CMS programs to address measurement gaps, and also (2) removed as a result of the Meaningful Measures Initiative (83 FR 41147 through 41148).[204] However, there has been a steady overall reduction in both the number of measures in CMS quality programs, as well as the number of measures publicly reported and available for inclusion in the Overall Star Rating—from 64 measures in the first publication of Overall Star Rating in 2016, to 51 measures for the most recent January 2020 publication.

More specifically, as finalized in the CY 2018 [205] and CY 2019 OPPS/ASC [206] final rules, and the FY 2019 IPPS/LTCH PPS final rule,[207] resulting from the Meaningful Measure Initiative (83 FR 41147 through 41148),[208] the following 12 process measures have been removed from the Hospital IQR and Hospital OQR Programs, and therefore, also from public reporting and the Overall Star Rating process measure groups between CY 2019 and CY 2021.

From the Effectiveness of Care measure group:

- Influenza Immunization (IMM–2) (83 FR 41151),
- Influenza Vaccination Coverage Among Healthcare Personnel (OP–27) (83 FR 37179 through 37186),
- Aspirin at Arrival (OP–4) (82 FR 59430),
- Colonoscopy Interval for Patients with a History of Adenomatous Polyps (OP–30) (83 FR 37179 through 37186), and
- Incidence of potentially preventable VTE (VTE–6) (83 FR 41151).

From the Timeliness of Care measure group:

- Median Time from ED Arrival to ED Departure for Admitted ED Patients (ED–1b) (83 FR 41151),
- Median Time to ECG (OP–5) (83 FR 37179 through 37186),
- Door to Diagnosis Evaluation by a Qualified Medical Professional (OP–20) (82 FR 59430),
- Median Time to Pain Management for Long Bone Fracture (OP–21) (82 FR 59428), and
- Median Time to Fibrinolysis (OP–1) (83 FR 37179 through 37186).

From the Efficient Use of Medical Imaging group:

- Thorax CT—Use of Contrast Material (OP–11) (83 FR 37179 through 37186), and
- Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT) (OP–14) (83 FR 37179 through 37186).

The aforementioned measure removals from CMS quality programs and public reporting ultimately result in two of the previously used measure groups, Timeliness of Care and Efficient Use of Medical Imaging, being comprised each of only three measures, which would not produce robust or predictable measure group scores.

Therefore, in the CY 2021 OPPS/ASC proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed combining three previously used measure groups—Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging—into one group entitled Timely and Effective Care. We also proposed to codify this new group at § 412.190(d)(3). This new consolidated group would reflect the principles of measure reduction under the Meaningful Measures Initiative and align with the current display of measures on *Hospital Compare.*[209] This consolidation would be necessary to ensure that a sufficient number of measures exist in this group.[210] [211] [212] In general, the TEP supported regrouping of measures into five measure groups with one process measure group (Timely and Effective Care) given the available measures and scheduled removal of measures in the upcoming years.[213]

[204] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 83 FR 41147 (Aug 17, 2018) (to be codified at 42 CFR parts 412, 413, 424 and 495).

[205] Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (OPPS/ASC), 83 FR 59216 (Dec 14, 2017) (to be codified at 42 CFR parts 414, 416, and 419).

[206] Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (OPPS/ASC), 83 FR 58818 (Nov 21, 2018) (to be codified at 42 CFR parts 416 and 419).

[207] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 83 FR 41151 (Aug 17, 2018) (to be codified at 42 CFR parts 412, 413, 424 and 495).

[208] Ibid.

[209] Centers for Medicare & Medicaid Services. *Hospital Compare.* (2019). Retrieved from *www.medicare.gov/hospitalcompare*: *https://www.medicare.gov/hospitalcompare/search.html?*.

[210] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 83 FR 41151 (Aug 17, 2018) (to be codified at 42 CFR parts 412, 413, 424 and 495).

[211] Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (OPPS/ASC), 83 FR 59216 (Dec 14, 2017) (to be codified at 42 CFR parts 414, 416, and 419).

[212] Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (OPPS/ASC), 83 FR 58818 (Nov 21, 2018) (to be codified at 42 CFR parts 416 and 419).

[213] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

In order to simulate the potential effects of these proposals, we used October 2019 publicly reported measure data on *Hospital Compare* to test the January 2020 Overall Star Rating to determine how many hospitals would be eligible to receive a star under the proposed measure grouping. Of the 4,576 hospitals that provide acute inpatient care, including CAHs, and reported measures on *Hospital Compare* in October 2019, 180 more hospitals (3,780 hospitals total) would have met the current reporting thresholds (that is, at least three measures in at least three measure groups, one of which must be an outcome group) to receive a star rating with the proposed five measure groups as compared to the original seven measure groups (3,600 hospitals). Additionally, the proposed new grouping would allow approximately 157 additional CAHs, of the 1,306 CAHs with measure scores included within the Overall Star Rating, to receive a star rating. To note, with the current methodology of seven measure groups, these 157 CAHs usually do not meet the minimum threshold to receive a star rating due to serving too few patients to report the underlying measures in each of the individual process groups. The minimum reporting threshold requirements are discussed in section E.6.b. Minimum Reporting Thresholds for Receiving a Star Rating of this final rule.

The above estimations of how many hospitals would receive a star rating are based on the measure regrouping methodology proposed in this rule; we note that other proposals may also influence hospitals meeting or not meeting reporting thresholds for star ratings. This measure regrouping proposal aligns with the guiding principles of the Overall Star Rating,[214] which include being inclusive of hospitals and measure information, accommodating changes in the underlying measures, and accounting for the heterogeneity of available measures. We invited public comment on our proposed measure groupings and codification of those groupings. The following is a summary of the comments we received and our responses to those comments.

Comment: Many commenters expressed support for grouping the Effectiveness of Care, Timelines of Care, and Efficient Use of Medical Imaging into one Timely and Effective Care measure group, especially considering the recent and future measure removals from public reporting as a result of the Meaningful Measures Initiative. Several commenters noted that combining these measure groups would allow more hospitals to qualify for scoring, particularly small hospitals and CAHs, and would align with CMS' goal of being inclusive of hospitals and measure information.

Response: We appreciate the support for our proposal and agree that combining the Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging measure groups into one measure group, Timely and Effective Care, aligns with the guiding principle for inclusivity of measure and hospital information within the Overall Star Rating (see section A.1.a. Purpose of this final rule) by allowing more hospitals to meet the reporting thresholds to receive a star rating (see section E.6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating of this final rule). Using January 2020 Overall Star Rating data (October 2019 public reporting data), when isolated, regrouping process measures into one measure group, Timely and Effective Care, results in 180 more hospitals meeting the reporting threshold to receive a star rating.

After consideration of the public comments we received, we are finalizing our proposals as proposed.

4. Step 3: Calculation of Measure Group Scores

In the past, we have used latent variable modeling (LVM) to calculate measure group scores. In the CY 2021 OPPS/ASC proposed rule, we proposed to replace LVM with a simple average of measure group scores to increase the simplicity of the methodology and predictability of measure weights within the methodology. LVM and the proposal to utilize a simple average of measure group scores is discussed in detail below.

a. Current Approach to Calculating Measure Group Scores Using Latent Variable Modeling

Latent Variable Modeling[215] (LVM) is a statistical approach used to combine or summarize multiple pieces of information, such as hospital quality measures, into a single number, such as measure group scores. LVM is described further within section E.4.a.(1) Latent Variable Modeling Overview of this final rule. Notably, LVM estimates loadings, or the contribution of each measure within each of the measure groups, using the data from hospitals that provide acute inpatient and outpatient care, as described in section E.4.a.(2) Latent Variable Modeling Measure Loadings of this final rule. LVM also produces point estimates and standard errors for each hospitals' measure group score, allowing for the calculation of confidence intervals to assign hospitals with at least three measures in a measure group to ''above,'' ''same as,'' or ''below the national average,'' as described in section E.4.a.(3) Measure Group Performance Categories.

(1) Latent Variable Modeling Overview

Latent Variable Modeling[216] (LVM) is a statistical approach used to combine or summarize multiple pieces of information and has been used to summarize information in a variety of settings ranging from education to healthcare.[217] [218] [219] The purpose for using LVM is to quantify the underlying quality trait, or an aspect of quality, as a number which best explains the correlation and variation of measures in a given group.

In the past, we have employed LVM to estimate measure group scores for each of the seven measure groups. In this context, LVM accounted for the relationship, or correlation, between measures for a given hospital so that measures that are more consistent with each other have a greater influence on the underlying aspect of quality calculated as a measure group score.[220] In addition, the LVM also accounted for differences in the size of each hospital's measure denominator so that measures with larger denominators also have more influence on the measure group score.[221]

When we developed the initial methodology for Overall Star Rating, we investigated multiple approaches to calculating measure group scores,

[214] Centers for Medicare & Medicaid Services. (2018, January). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from: *https://www.qualitynet.org/files/5d0d3a1b764be766b0103ec1?filename=Star_Rtngs_CompMthdlgy_010518.pdf.*

[215] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

[216] Ibid.

[217] Henderson CR. Best Linear Unbiased Estimation and Prediction under a Selection Model. Biometrics 1975;31:423–47.

[218] Shwartz M, Ren J, Pekoz EA, Wang X, Cohen AB, Restuccia JD. Estimating a composite measure of hospital quality from the Hospital Compare database: differences when using a Bayesian hierarchical latent variable model versus denominator-based weights. Med Care 2008;46:778–85.

[219] Landrum M, Bronskill S, Normand S–L. Analytic Methods for Constructing Cross-Sectional Profiles of Health Care Providers. Health Services and Outcomes Research Methodology 2000;1:23–47.

[220] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

[221] Ibid.

including simple or weighted averages of measures, as well as more complex approaches such as LVM and factor analyses.[222] Both the simple and weighted average approaches take the sum of measures, either with equal (that is, simple) or varying weights (that is, weighted), and divide by the number of measures a hospital reports in the measure group. Both LVM[223] and factor analysis[224] attempt to identify underlying traits, in this case quality of acute inpatient and outpatient care, within large datasets, such as hospital measure scores. Each approach was reviewed by the TEP and presented for public input prior to the launch of Overall Star Rating in 2016. We ultimately chose LVM to calculate measure group scores based on support from the TEP,[225] which favored the ability of LVM to utilize data to account for the relationship between measures, measures which are not reported, and sampling variation.[226]

Each LVM assumes that each measure in a measure group reflects information about an underlying aspect or domain of hospital quality as represented by each of the measure groups. For example, safety, mortality, or readmission are each aspects of quality represented by a distinct set of individual measures. Previously, we constructed a separate LVM for each of the seven measure groups. Each LVM estimated a quantitative value, or measure group score, for the group's underlying aspect of quality for each hospital that reports enough measures in each group.

LVM accounts for the correlation between measures by allowing measures that are more consistent with each other to have a greater influence on the measure group scores.[227] The LVM also accounts for differences in the size of each hospital's measure denominator so that measures with larger denominators have more influence on the measure group score, since their measure scores are considered more precise.[228] A measure's influence on the measure group score, or loading, is derived by the LVM, ultimately by using the national performance of each measure, as well as the correlation between measures to find the best combination of measure emphasis for each measure group.[229] Measure loadings are further discussed below in section E.4.a.(2) Latent Variable Model Measure Loadings of this final rule. The loading represents the measure's relationship to the underlying aspect of quality and therefore, the measure's contribution to the measure group score.[230] Measure loadings were re-estimated for each publication of the Overall Star Rating and were the same value for all hospitals that provide acute inpatient and outpatient care. In other words, LVM accounts for measures which are not reported by estimating and assigning the same measure loading values to all hospitals, regardless of differences in the number of measures hospitals report.

The LVM for each measure group can be explained using the below path diagram presented in Figure 1. In the sample path diagram, the ovals represent the measure group scores, calculated using LVM, and hospital summary scores, calculated by a weighted average of measure group scores. The measure group score is not directly observed but estimated from the LVM using the individual measures. The arrows between the measure group scores and each individual measure represent the relationship of that measure to the aspect of quality reflected by each measure with respect to the other measures in that group; each arrow has a different degree of association, also known as a ''loading'' or coefficient, which is explained in detail within section E.4.a.(2) Latent Variable Modeling Measure Loadings of this final rule. The small circles on the left represent the residual error within each hospital for each of the measures included in the Overall Star Rating. The residual error (ε) is the variation which could not be explained by the measure group score (random effect).

Figure 1. Sample Path Diagram of Group Specific LVM

The LVM equation used to derive a hospital's measure group score is as follows:

$$Y_{khd} = \mu_{kd} + \gamma_{kd}\alpha_{hd} + \varepsilon_{khd},\ k=1,\ldots,N_d$$

$$\alpha_{hd} \sim N(0,1) \text{ and } \varepsilon_{khd} \sim N(0, \sigma_{kd}^2)$$

Let Y_{khd} denote the standardized score for hospital h and measure k in measure group d. α_{hd} is the hospital-specific group-level latent trait (random effect) for hospital h and measure group d and follows a normal distribution[231] with mean 0 and variance 1. The estimated value of α_{hd} will be used as a measure group score. γ_{kd} is the loading (regression coefficient of the latent variable) for measure k, which shows the relationship with the measure group score of measure group d. N_d is the total number of measures in measure group d. The assumption of unit variance here is an innocuous choice of units required to identify the parameter μ_{kd} and γ_{kd}. For detailed descriptions of the LVM model parameters and equation, please see the Overall Hospital Quality Star Rating on *Hospital Compare* Methodology Report (v3.0).[232]

(2) Latent Variable Modeling Measure Loadings

In the past, the LVMs within the Overall Star Rating methodology estimate loadings for each measure within each of the measure groups. A measure's loading indicates its relative contribution to a hospital's measure group score, with higher loadings indicating measures with more influence.[233] A measure's loading is

[222] Oh, J.H., et al. (2016, October 17). ''A factor analysis approach for clustering patient reported outcomes.'' Methods of information in medicine 55.05: 431–439.

[223] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

[224] Oh, J.H., et al. (2016, October 17). ''A factor analysis approach for clustering patient reported outcomes.'' Methods of information in medicine 55.05: 431–439.

[225] Centers for Medicare & Medicaid Services. (2015, February). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[226] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

[227] Ibid.

[228] Ibid.

[229] Ibid.

[230] Ibid.

[231] Illowsky, B., & Dean, S. (2013). *Introductary Statistics.* Houston, TX: 12th Media Services. Retrieved from: *https://openstax.org/details/books/introductory-statistics.*

[232] Centers for Medicare & Medicaid Services. (2017, December). *Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0).* Retrieved from *www.qualitynet.org*: *https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1.*

[233] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

specific to the measure and the same for all hospitals reporting that measure.

A measure loading is a regression coefficient,[234] which is estimated through the LVM by using a statistical approach called maximum likelihood. Maximum likelihood[235] uses the observed data for each measure in a group, including the national performance on the measure and the measure's relationship to other measures in the group, to find the best combination of measure emphasis for the aspect of quality represented by the measure group. In other words, measure score variation nationally and the correlation between measures in a measure group influence measure loadings. Measures with more variation nationally and higher correlations with other measures in a measure group have higher measure loadings because such measures are assumed to convey more information about a given aspect of acute inpatient and outpatient quality of care than measures with limited variation or less correlation with other measures in the same group.

The LVM also accounts for sampling variation, or differences in the amount of information available for different hospitals to estimate loadings. For example, for each measure, some hospitals may report a score based on data from fewer cases while other hospitals report scores based on more cases, resulting in differing precision for each hospital's individual measure score. We accounted for these differences in case size by giving more weight to measures with larger denominators. Measure scores based on larger denominators are assumed to have more precise measure scores and therefore contribute more when estimating measure loadings. The weighted likelihood equation for accounting for sampling variation within each measure group is as follows:

$$L = \prod_{k=1}^{K} \prod_{h=1}^{H} (L(Y_{khd}))^{w_{khd}} \quad w_{khd} = \frac{n_{khd}}{\sum_{h=1}^{N_{kd}} n_{khd}} \times N_{kd}$$

L is the likelihood function. N_{kd} is the total number of hospitals for measure k in measure group d and N_{kd} is the denominator for hospital h and measure k in measure group d. A hospital with a larger denominator will be weighted more in the LVM. The specified weighted likelihood is maximized with respect to all the parameters in the first LVM equation.

Measures with higher loadings have a greater association and impact on the measure group score than measures with lower loadings. Measures highly correlated with other measures in the measure group and the measure group score, measures with large denominators, and measures more commonly reported are likely to have higher loadings because they are generally expected to provide more information about a hospital's quality profile than other measures.

In February 2019, we made an update to remove measures with statistically significant negative loadings from the LVM calculations.[236] Measure loadings can be positive or negative. Measures with statistically significant negative loadings have an inverse relationship with other measures in the group. Although negative loadings rarely occur and are almost always statistically insignificant, some stakeholders, including those on the TEP, and during a public input period, expressed concern that measures with negative loadings could be perceived to promote lower quality with respect to measure group scores.[237] [238] [239] [240] [241] While internal analyses have not identified any substantial effect of measures with negative loadings on hospital star ratings, CMS understood the theoretical concern and decided to remove measures with statistically significant negative loadings, beginning in February 2019.[242]

Measure loadings were re-estimated for each publication of the Overall Star Rating and could change dynamically as the measure methodologies, hospitals' performance, and the relationship between measures evolved.

(3) Measure Group Performance Categories

We reported Overall Star Rating measure group performance categories to individual hospitals that provide acute inpatient and outpatient care and on *Hospital Compare* in order to provide context for measure group scores in comparison to all other hospitals in the nation. Performance categories were not calculated by the LVM, nor did they have influence on star ratings. Rather, they were assigned categories of ''above'', ''same as'', or ''below the national average'' as additional public information on each of the measure groups a hospital reports by comparing a hospital's measure group score to the national average measure group score.

These measure group performance categories were assigned using information from the LVM, separate from measure loadings. For each measure group, LVM produced a point estimate[243] and standard error[244] for each hospital's measure group score that we used to construct a 95 percent confidence interval.[245] A point estimate is a statistic close to the exact value in a dataset, whereas the standard error is a measure of the variability, or how spread out individual points are around the average in the dataset, and both are used to construct a confidence interval, or a range of reasonable values in which we expect a value to fall.[246] We compared this 95 percent confidence interval to the national mean measure group score. Measure group scores with confidence intervals that fall entirely

[234] Ibid.

[235] Cole, S.R., Chu, H., & Greenland, S. (2014, January 15) ''Maximum likelihood, profile likelihood, and penalized likelihood: a primer.'' American journal of epidemiology 179.2: 252–260.

[236] Centers for Medicare & Medicaid Services. (2018, November 30). *Quarterly Updates and Specifications Report (February 2019)*. Retrieved from *www.qualitynet.org*: *https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources#tab2*.

[237] Centers for Medicare & Medicaid Services. (2015, June 8). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare*.

[238] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report*.

[239] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report*. Retrieved from *www.CMS.gov*: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815*.

[240] Centers for Medicare & Medicaid Services. (2017, June). *Hospital Quality Star Ratings on Hospital Compare Technical Expert Panel*.

[241] Centers for Medicare & Medicaid Services. (2018, June). *Summary of Technical Expert Panel (TEP): Hospital Quality Star Rating on Hospital Compare*.

[242] Centers for Medicare & Medicaid Services. (2018, November 30). *Overall Hospital Quality Star Rating on Hospital Compare: February 2019 Updates and Specifications Report*. Retrieved from *qualitynet.org*: *https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2*.

[243] Illowsky, B., & Dean, S. (2013). Introductary Statistics. Houston, TX: 12th Media Services. Retrieved from: *https://openstax.org/details/books/introductory-statistics*.

[244] Ibid.

[245] Ibid.

[246] Ibid.

above the national average were considered ''above the national average'', confidence intervals that include the national average were considered ''same as the national average'', and confidence intervals that fall entirely below the national average were considered ''below the national average''.

b. Use of a Simple Average of Measure Scores To Calculate Measure Group Scores

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to eliminate use of the LVM and instead use a simple average of measure scores to calculate measure group scores.

We recognize that LVM may be challenging for stakeholders to understand and explain to others. Stakeholders, specifically providers, serving on the Provider Leadership Work Group and during a public input period,[247] have requested a less complex methodology that can be easily understood by their organization, explained to their patients, and used to identify areas for quality improvement. In addition, LVM is a data-driven statistical approach that relies on underlying measure data to re-estimate measure loadings[248] for each release of the Overall Star Rating. Since the underlying measure data is refreshed variably based on the measure and CMS quality program requirements—either quarterly, biannually, or annually—the estimated measure loadings based on the underlying data for each annual publication of the Overall Star Rating were unpredictable, further complicating understanding of the methodology and efforts to allocate resources for quality improvement.

Therefore, in the CY 2021 OPPS/ASC proposed rule, for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to discontinue the use of the LVM, and instead, propose to adopt a simple average of measure scores to calculate measure group scores. This method would average the measure scores a hospital reports within a given measure group, which have been standardized, to calculate the measure group scores. In other words, we would take 100 percent divided by the number of measures reported to give us the percentage each measure would weigh; this measure weight would then be multiplied by the standardized measure score to calculate the measure's weighted score. Then, all of the individual measure weighted scores within a group would be added together to calculate the measure group score. We also proposed to codify this policy at § 412.190(d)(4).

For example, if a hospital reports all eight measures in the Safety of Care measure group, the measure weights would be determined by calculating 100 percent divided by eight measures reported (100 percent / 8 reported measures = 12.5 percent) and each measure would be weighted 12.5 percent within the group. The standardized measure scores for each of the eight measures would then be multiplied by the weight of 12.5 percent and summed to determine the Safety of Care measure group score. See Table 66 for an example of measure weights in which a hospital reports all eight measures within Safety of Care. For the Readmission measure group for example, a hospital's score on the Hospital-Wide, All-Cause Unplanned Readmission measure, which includes most patient admissions at a hospital, would have the same influence as their score on the condition specific Chronic Obstructive Pulmonary Disease (COPD) Readmission measures, which includes significantly fewer patients.

Example of Simple Average of Measure Scores To Calculate Measure Group Scores

$$\text{Measure group score} = [(-1.13 * 0.125) + (-0.75 * 0.125) + (0.09 * 0.125) + (1.21 * 0.125) + (0.97 * 0.125) + (0.98 * 0.125) + (0.46 * 0.125) + (0.02 * 0.125)] = 0.23$$

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[247] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report*. Retrieved from *www.CMS.gov*: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815*.

[248] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

TABLE 66: Example of Simple Average of Measure Scores to Calculate of Safety of Care Measure Group Score

Measure Name	Example Measure Score	Standardized Measure Score	Measure Weights	Weighted Standardized Measure Scores*	Safety of Care Measure Group Score
COMP-HIP-KNEE Hospital-Level Risk Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA)	3.22%	-1.13	12.5%	-0.14	0.23
HAI-1 Central-Line Associated Bloodstream Infection (CLABSI)	1.233	-0.75	12.5%	-0.09	
HAI-2 Catheter-Associated Urinary Tract Infection (CAUTI)	0.747	0.09	12.5%	0.01	
HAI-3 Surgical Site Infection (SSI) from Colon Surgery	0.000	1.21	12.5%	0.15	
HAI-4 Surgical Site Infection (SSI) Abdominal Hysterectomy	0.000	0.97	12.5%	0.12	
HAI-5 Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteremia	0.166	0.98	12.5%	0.12	
HAI-6 Clostridium Difficile (C. difficile)	0.470	0.46	12.5%	0.06	
CMS PSI-90 Patient Safety and Adverse Events Composite	0.999	0.02	12.5%	0.003	

*Please note that measure group scores are continuous and rescaled. Negative and positive scores do not denote good or bad performance.

Under certain circumstances, hospitals may not report all measures within a measure group. However, we note that the proposed minimum threshold is three measures within three measure groups, one of which must be Mortality or Safety of Care. Once this threshold is met, any additional measures or groups may contribute to a hospital's star rating. We refer readers to section E.6. Step 5 Application of Minimum Thresholds for Receiving a Star Rating of this final rule. As an example, if a hospital reports three measures in the Safety of Care measure group, the measure weights would be determined by calculating 100 percent divided by three measures reported (100 percent / 3 reported measures = 33.3 percent) and each measure would be weighted 33.3 percent within the group. The standardized measure scores for each of the three measures would then be multiplied by the weight of 33.3 percent and summed to determine the Safety of Care measure group score. See Table 67 for an example of measure weights in which a hospital reports three measures within Safety of Care.

Example of Simple Average of Measures Scores To Calculate Measure Group Scores When Measures Are Not Reported

Measure group score = $[(-1.13 * 0.333) + (0.46 * 0.333) + (0.02 * 0.333)] = -0.22$

TABLE 67: Example of Simple Average of Measure Scores to Calculate Safety of Care Measure Group Score When Measures are not Reported

Measure Name	Example Measure Score	Standardized Measure Score*	Measure Weights	Weighted Standardized Measure Scores*	Safety of Care Measure Group Score*
COMP-HIP-KNEE Hospital-Level Risk Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA)	3.22%	-1.13	33.3 %	-0.38	-0.22
HAI-1 Central-Line Associated Bloodstream Infection (CLABSI)	NA	NA	NA	NA	
HAI-2 Catheter-Associated Urinary Tract Infection (CAUTI)	NA	NA	NA	NA	
HAI-3 Surgical Site Infection (SSI) from Colon Surgery	NA	NA	NA	NA	
HAI-4 Surgical Site Infection (SSI) Abdominal Hysterectomy	NA	NA	NA	NA	
HAI-5 Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteremia	NA	NA	NA	NA	
HAI-6 Clostridium Difficile (C. difficile)	0.470	0.46	33.3 %	0.15	
CMS PSI-90 Patient Safety and Adverse Events Composite	0.999	0.02	33.3 %	0.006	

*Please note that measure group scores are continuous and rescaled. Negative and positive scores do not denote good or bad performance.

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As previously noted, LVM accounted for measures which are not reported by uniformly assigning the same loading for a measure to hospitals that provide acute inpatient and outpatient care,[249] whereas use of a simple average of measure scores would result in hospitals having varying measure weights depending on differences in the number of measures reported. For example, if a hospital reports three of the eight measures in the Safety of Care measure group, each measure would be weighted at 33 percent within that group. On the other hand, a hospital that reports all eight measures in the Safety of Care measure group would have a different weighting of 12.5 percent for each measure within the measure group. We simulated the possible range of measure weights using the data used for January 2020 Overall Star Rating (October 2019 public reporting data), which included 51 measures. We simulated the results using the measure group weights proposed in section E.5.a.(2) Continue Current Calculation of Hospital Summary Scores Through a Weighted Average of Measure Group Scores of this final rule; outcome and patient experience measure groups were weighted 22 percent and the process group was weighted 12 percent. Taking into account the measure group weights applied later in the methodology, the minimum effective measure weight, or the percentage of the hospital summary score based on a single measure, would be 3 percent for a hospital reporting all 51 measures and the maximum effective measure weight would be 33 percent for another hospital reporting the minimum threshold number of nine measures (at least three measures in at least three groups). Hospitals with more measures will have lower measure weights for each measure, whereas hospitals with fewer measures will have higher measure weights for each measure. The number of measures included in the Overall Star Rating varies for each publication depending on measure removals from and additions for public reporting.

Using a simple average of measure scores to calculate measure group scores would be responsive to stakeholder feedback that requested CMS increase the simplicity of the methods and the predictability of measure emphasis between publications.[250] [251] [252] [253] Using a simple average of measure scores would increase the predictability of measure emphasis by allowing hospitals to anticipate equal measure weights across the measures they report within a given group. While there may be differences in measure emphasis between hospitals that provide acute inpatient and outpatient care based on differences in measure reporting, a simple average of measure scores will be responsive to stakeholder feedback and make the methodology easier for stakeholders to understand, interpret, and explain to patients.

Since measure loadings are an artifact of the LVM approach, they would no longer be calculated under the proposed new method using a simple average of measure scores. In addition, since the point estimates and standard errors used to calculate 95 percent confidence intervals and assign hospital measure group performance to ''above,'' ''same as,'' or ''below the national average'' were products of the LVM approach, measure group performance categories will no longer be available under the proposed new method using a simple average of measure scores. However, we intend to continue to publicly display alternative summaries of hospital performance within measure groups for transparency and patient usability. Should the proposal to use a simple average of measure scores to calculate measure group scores not be finalized, measure group performance categories would still be available in the same manner described above.

In crafting the proposal, we also considered continuing to utilize LVM as we have in the past and as discussed in the section above. Ultimately, we chose to propose to discontinue the use LVM because of the complexity associated with understanding how measure loadings are empirically assigned with the LVM and contribute to the measure group scores. We invited public comment on our proposals to use a simple average of measure scores to calculate measure group scores and to codify this policy at § 412.190(d)(4) as discussed. The following is a summary of the comments we received and our responses to those comments.

Comment: Many commenters supported the use of a simple average of measure scores to calculate measure group scores. They appreciated CMS' responsiveness to previous stakeholder input and emphasized advantages of a simple average of measure scores including transparency of methods, predictable and balanced measure emphasis within groups, reduced shifts in measure group scores and star ratings, and alignment with CMS programs. These advantages make the methodology easier for stakeholders to understand and for providers to react to and improve upon measurement and star ratings as well as explain to hospital leadership and patients.

Response: We thank commenters for their support. Being responsive to stakeholder input has been and continues to be a guiding principle of the Overall Star Rating since original development. We agree that the proposals would increase simplicity and predictability of the Overall Star Rating methodology, hopefully providing more transparency and understanding of the methodology for stakeholders, including both providers and patients.

Comment: A few commenters did not support CMS' proposal to use a simple average of measure scores advocated for the continued use of latent variable modeling (LVM) to calculate measure group scores because of the methodological advantages of LVM as a statistical model that accounts for important factors, including the relationship between measures and measure precision. They also pointed out that the original Overall Star Rating TEP favored LVM over other approaches for the same reasons.

Response: We acknowledge the known advantages to the LVM approach that had been favored by the original TEP and have been used to calculate measure group scores, including the ability of the model to account for the relationship between measures, differences in sampling variation, or measure precision, and missing measure scores.[254] However, subsequent application of the LVM approach has also revealed several challenges in implementation as measures and scores have evolved on *Hospital Compare* and its successor websites. Notably, several

[249] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

[250] Centers for Medicare & Medicaid Services. (2018, June). *Summary of Technical Expert Panel (TEP): Hospital Quality Star Rating on Hospital Compare.*

[251] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[252] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

[253] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[254] Cai, L. (2012, March 31). Latent variable modeling. Shanghai archives of psychiatry, 24(2), 118–120. doi:10.3969/j.issn.1002–0829.2012.02.010.

stakeholders,[255] particularly providers, indicated the use of LVM resulted in unpredictable measure loadings. This added greater uncertainty in anticipated changes in star ratings and was challenging for stakeholders to understand, explain to others, and use for quality improvement. A simple average of measure scores would assign equal weights within measure groups, allowing stakeholders to predict, interpret, and easily replicate measure group scores.

Comment: One stakeholder requested that the simple average of measure scores approach be evaluated by a TEP.

Response: The use of a simple average of measure scores was vetted through extensive stakeholder engagement, including TEP,[256] Provider Leadership Work Group, Patient & Patient Advocate Work Group meetings, a public input period,[257] and a CMS listening session.[258] In general, stakeholders supported the use of a simple average of measure scores to calculate measure group scores for a less complex methodology with more predictable measure emphasis that can be easily understood, explained to others, and used to identify areas for quality improvement.

Comment: One commenter recommended that CMS continue to use device days, number of procedures, or patient days as the HAI measure denominators, rather than predicted infections.

Response: One of advantages of LVM was its ability to account for sampling variation, or measure precision, through the use of measure denominator data. In February 2019,[259] we had updated the Overall Star Rating methodology to use alternative HAI denominators of device days, number of procedures, or patient days, instead of predicted infections, to better represent case volume and sampling variation in order to account for measure precision within LVM. It is important to note that the Overall Star Rating has used and will continue to use the HAI Standardized Infection Ratio (SIR) measure scores, as calculated for the HAC Reduction Program, which utilizes predicted infections as the denominator, within the Overall Star Rating methodology. The Overall Star Rating used alternative HAI denominators only to account for measure precision within the LVM. However, the Overall Star Rating methodology will no longer account for measure precision with the use of a simple average of measure scores to calculate measure group scores, therefore negating the need for alternative HAI denominators.

Comment: Some commenters noted disadvantages of a simple average of measure scores to calculate measure group scores and encouraged CMS to continue to consider alternative approaches, including template matching or relative measure weights based on measure volume, evidence, importance to or impact on patients, as the Agency for Health Research and Quality does with harm-based weights within the PSI–90 composite, or opportunity for provider improvement, which could be done through comparisons to the national average.

Response: During development and recent reevaluation of the Overall Star Rating, we considered multiple approaches to the weighting of individual measure scores when calculating measure group scores, including template matching and relative measure weighting. However, given that the Overall Star Rating summarizes aggregate hospital-level measure scores reported through CMS quality programs without the use of underlying patient-level data, approaches such as template matching[260] may be both infeasible as well as not align with the aim for a simple methodology that stakeholders can easily understand and explain to others. Also, relative measure weighting based on volume, in some cases, would result in measure group scores dominated by one measure, such as PSI–90 (81 FR 56761)[261] within the Safety of Care measure group and Hospital-Wide Readmission within the Readmission measure group. During engagement efforts,[262] stakeholders preferred more balanced measure emphasis within measure groups. In addition, relative weighting based on evidence or importance to patients may be subjective and resource intensive for CMS and stakeholders to monitor and maintain. Finally, TEP[263] and work group input also acknowledged that relative measure weighting approaches may have the unintended consequence of creating an incentive for hospitals to focus quality improvement efforts on few measures.

Comment: A few commenters requested impact analyses outlining the impact of the use of a simple average of measure scores on overall and individual hospital star rating results.

Response: We appreciate the commenters' request for impact analyses on the use of a simple average of measure scores to calculate measure group scores. We provided analytic considerations specific to the proposal to use a simple average of measure scores within section E.4.b. Use of a Simple Average of Measure Scores to Calculate Measure Group Scores of this final rule and we also provided overall impact analyses on hospital star ratings within section 8. Effects of Requirements for the Overall Hospital Quality Star Ratings of the proposed rule (85 FR 49057 through 49077). We simulated impacts using January 2020 Overall Star Rating data (October 2019 public reporting data) and the combined methodology proposals: Regroup measures, use a simple average of measure scores to calculate measure group scores, and update reporting thresholds to require at least three measures in at least three measure groups, one of which must be Mortality of Safety of Care, but not include peer grouping to isolate proposals and allow for informed public comments. As stated in section 8 of 85 FR 49057 through 49077), 1,796 (53 percent) hospitals would receive the same star

[255] Centers for Medicare & Medicaid Services. (2019, June). Public Comment Summary Report. Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815*.

[256] Centers for Medicare & Medicaid Services. (2019, November). Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare. Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6*.

[257] Centers for Medicare & Medicaid Services. (2019, June). Public Comment Summary Report. Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815*.

[258] Centers for Medicare & Medicaid Services. (2019, November). Overall Hospital Quality Star Rating Listening Session Meeting Summary Report. Retrieved from *https://www.cms.gov/files/document/overall-hospital-quality-star-ratings-listening-session-summary-report*.

[259] Centers for Medicare & Medicaid Services. (2018, November 30). Overall Hospital Quality Star Rating on Hospital Compare: February 2019 Updates and Specifications Report. Retrieved from *www.qualitynet.org*: *https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2*.

[260] Silber, J.H., Rosenbaum, P.R., Ross, R.N., Ludwig, J.M., Wang, W., Niknam, B.A., . . . & Fleisher, L.A. (2014). Template matching for auditing hospital cost and quality. Health services research, 49(5), 1446–1474.

[261] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 81 FR 56761 (Aug 22, 2016) (codified at 42 CFR parts 405, 412, 413, and 489).

[262] Centers for Medicare & Medicaid Services. (2019, November). Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare. Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6*.

[263] Centers for Medicare & Medicaid Services. (2018, June). Summary of Technical Expert Panel (TEP): Hospital Quality Star Rating on Hospital Compare.

rating. The results showed that 1,468 (43 percent) hospitals would shift up or down one star rating, 135 (4 percent) hospitals would shift up or down two star ratings, 9 (0.3 percent) hospitals would shift up or down three star ratings, and 1 (0.03 percent) hospital would shift up or down four star ratings. Since regrouping measures and updating reporting thresholds primarily resulted in modest impacts to the number of hospitals meeting the reporting thresholds to receive a star rating, the shift in hospital star ratings was primarily due to the use of a simple average of measure scores to calculate measure groups scores. We refer reads to section 8. Effects of Requirements for the Overall Hospital Quality Star Ratings of this final rule for the impact analyses using October 2020 public reporting data for the final Overall Star Rating methodology for 2021 and subsequent years.

After consideration of the public comments received, we are finalizing our proposals as proposed.

c. Standardize Measure Group Scores

Standardizing [264] scores is a way to make varying scores directly comparable by putting them on a common scale. While standardization is used in other parts of the methodology, particularly to standardize measure scores within the first step of methodology, it was previously not necessary to standardize measure group scores when using statistical modeling, such as LVM. In the absence of statistical modeling, under the use of a simple average of measure scores as discussed in section E.4.b. Use of a Simple Average of Measure Scores to Calculate Measure Group Scores of this final rule, the distributions and interpretations of measure group scores may differ. For example, a 0.5 measure group score in Safety of Care may not conceptually be similar to a 0.5 measure group score in Patient Experience, exaggerating the influence of some measure groups when calculating a weighted average of measure group scores.

Therefore, for the Overall Star Rating beginning with CY 2021 and subsequent years (85 FR 48996 through 49027), we proposed to standardize measure group scores. More specifically, we proposed to standardize measure group scores by calculating Z-scores for each measure group. As mentioned in section E.2.d. Measure Score Standardization of this final rule, a Z-score [265] is a standard deviation [266] score which relays the amount of variation in a dataset, or in this case, the variation in hospital measure scores. Z-scores would be calculated by subtracting the national average measure group scores from each hospital's measure group score and dividing by the standard deviation across hospitals. Standardization of measure group scores would occur prior to combining measure group scores through a weighted average to calculate summary scores, and would result in all measure group scores centered near zero with a standard deviation [267] of one. We also proposed to codify this policy at § 412.190(d)(4)(i).

See Table 68 for an example of how measures would be combined through a simple average of measure scores to calculate measure group scores and then how the measure group scores would be standardized. The standardization of measure group scores would not impact hospital performance within the measure group or the natural distribution of scores. As a result of standardization,[268] mean group scores and standard deviations would become more similar across measure groups. We simulated the potential effects of standardization using data from the January 2020 publication of Overall Star Rating and found that hospital summary scores with and without standardization of measure group scores are highly correlated with a Pearson correlation of 0.975, indicating that standardizing measure group scores does not substantially alter hospital performance assessment. We note that, should the proposal to use a simple average of measure scores to calculate measure group scores not be finalized, we would not need to standardize measure group scores.

We invited public comment on our proposals to standardize measure group scores and codify this policy at § 412.190(d)(4)(i). However, we did not receive any comments on these proposals. We are finalizing our proposals as proposed.

d. Stratify Readmission Measure Group Scores

(1) Current Measure Group Scores Without Stratification

In the past, we have not stratified or adjusted any of the measures, measure groups, summary scores, or star ratings by social risk factor variables within the Overall Star Rating methodology, primarily based on the original guiding principles of the Overall Star Rating. The Overall Star Rating is meant to summarize the existing quality measure information that is publicly reported through CMS programs, including Hospital IQR Program, Hospital OQR Program, HRRP, HAC Reduction Program, and Hospital VBP Program, on *Hospital Compare* or its successor websites. Individual measures undergo rigorous development and reevaluation processes under each program that include extensive analytic testing and stakeholder engagement. As such, individual measure methodologies as specified under each program, including approaches to risk adjustment, are included within the Overall Star Rating. As measure data and methodologies are updated under each of the programs, they are subsequently reflected within the Overall Star Rating methodology. CMS' Overall Star Rating development contractor has engaged stakeholders in discussion regarding the comparability of hospital star ratings for over five years throughout the development and reevaluation of the Overall Star Rating. Throughout that engagement, some stakeholders, primarily providers, requested incorporation of social risk factor adjustment within the Overall Star Rating, while other stakeholders expressed concerns regarding adjustment in general or the specific variables available for adjustment.[269] Specifically, some stakeholders have requested social risk factor adjustment of the readmission measures or the Readmission measure group.[270] [271] Recently a HHS Report to Congress has

[264] Illowsky, B., & Dean, S. (2013). *Introductory Statistics.* Houston, TX: 12th Media Services. Retrieved from: *https://openstax.org/details/books/introductory-statistics.*

[265] DeVore, G.R. (2017, January 17). ''Computing the Z score and centiles for cross-sectional analysis: a practical approach.'' Journal of Ultrasound in Medicine 36.3: 459–473.

[266] Illowsky, B., & Dean, S. (2013). *Introductory Statistics.* Houston, TX: 12th Media Services. Retrieved from: *https://openstax.org/details/books/introductory-statistics.*

[267] Ibid.

[268] Ibid.

[269] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[270] National Quality Forum. (2019, November 6). *National Quality Forum Hosptial Quality Star Ratings Summit.* Retrieved from *www.qualityforum.orgs http://www.qualityforum.org/NQF_Hospital_Quality_Star_Rating_Summit.aspx.*

[271] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

set forth a broad range of recommendations regarding social risk factors and Medicare's value-based purchasing programs, and the report does not recommend adjusting quality measures for social risk for public reporting.[272] We sought comment on our proposal to stratify the Readmission measure group based on the proportion of dual-eligible patients, and an alternative not to stratify the Readmission measure group based on the proportion of dual-eligible patients.

(2) Proposal To Stratify Only the Readmission Measure Group Scores

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to stratify only the Readmission measure group score by hospitals' proportion of dual-eligible patients and codify this at § 412.190(d)(4)(v). We proposed to specifically stratify only the Readmission measure group, and not other measure groups, based on hospitals' proportion of dual-eligible hospital discharges, to be responsive to select stakeholder concerns that some hospitals providing acute inpatient and outpatient care face unique challenges preventing readmissions among patients with complex social risk factors,[273] and to align with the payment adjustment recently implemented for HRRP payment determination (82 FR 38231 through 38237). We proposed to utilize and repurpose the same peer group quintiles assigned by the HRRP annually. We proposed to assign hospitals that do not participate in the HRRP, but have their proportion of dual-eligible patients available, to HRRP designated peer groups, as they would not have already been assigned to a peer group through the HRRP. We also proposed that in the event a hospital's proportion of dual-eligible patient data is missing, CMS would not adjust that hospital's Readmission measure group score and that hospital would retain its original, unadjusted Readmission measure group score, as calculated through a simple average of their measure scores.

The proposed stratification of the Overall Star Rating Readmission measure group score would use the same dual-eligible variable and a similar peer grouping approach as is used in the HRRP for payment determinations (82 FR 38231 through 38237). To be clear, the Overall Star Rating is not used to determine hospital payments. Dual-eligible[274] patients are those that are dually eligible for Medicare and full-benefit Medicaid among a hospital's total Medicare Fee-for-Service and Medicare Advantage patient discharges (42 U.S. Code 1315b(f)). Dual-eligible status is consistently captured for patients and available through enrollment files, which are updated annually, and does not require extrapolation from area of residence variables, such as census or community surveys.

In 2016, the 21st Century Cures Act mandated that CMS determine hospital penalties for readmissions that account for social risk factors through a transitional methodology that calculates excess readmissions ratios within hospital peer groups defined by the percentage of dual-eligible patients served by the hospital within the HRRP (Pub. L. 114–255). Section 15002 of the 21st Century Cures Act, adding a new section 1886(q)(3)(D) and (E) to the Act, also indicated this methodology could be characterized as a ''transitional adjustment'' and that the Secretary may revise the stratification methodology, taking into account recommendations made on risk-adjustment methodologies for HRRP based on the studies conducted under the IMPACT Act by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) on the role of socioeconomic status in Medicare's value-based purchasing program.

In the FY 2018 IPPS/LTCH PPS rule, we finalized our HRRP proposal to implement a methodology that categorizes participating hospitals that provide acute inpatient care into five peer groups by quintiles, based on the proportion of dual-eligible patients to total patients served by the hospital. The methodology uses the median excess readmission ratio of hospitals within each of the five peer groups as the threshold to assess hospital performance on each measure (82 FR 38231 through 38237). The excess readmission ratio measures a hospital's relative performance and is the ratio of predicted-to-expected readmissions.[275] This methodology was implemented within HRRP in FY 2019 as announced in the associated correction notification (82 FR 46138). The individual readmission measures included within HRRP and publicly reported on *Hospital Compare* or its successor websites are not adjusted for social risk factors.

The proposal to stratify the Readmission measure group based on the proportion of dual-eligible patients is intended to provide consistency between the current stratification method used for the HRRP and the Overall Star Rating methodology. It is not in any way intended to suggest a new policy direction for the more general question of whether CMS programs should employ social risk factor adjustment methods of any kind. The rationale for this proposal is based on alignment between the two CMS efforts. If changes are made in the future to the HRRP stratification approach, CMS may consider similar changes to the Overall Star Rating methodology through future rulemaking. Recently a HHS Report to Congress has set forth a broad range of recommendations regarding social risk factors and Medicare's value-based purchasing programs, which do not recommend adjusting quality measures for social risk for public reporting.[276] The stratification approach in the HRRP has been recommended for removal based on HHS recommendations in a second Report to Congress, mandated by the IMPACT Act of 2014, titled ''Social Risk Factors and Performance in Medicare's Value-Based Purchasing Programs'' submitted by ASPE on June 29, 2020.[277] The report recommends not adjusting outcome measures for social risk factors in CMS programs and recommends that,

[272] Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation (ASPE). (2020) *Second Report to Congress: Social Risk Factors and Performance in Medicare's Value-based Purchasing Programs.* Retrieved from: *https://aspe.hhs.gov/system/files/pdf/263676/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report.pdf.* Accessed July 2, 2020.

[273] National Quality Forum. (2014, August). Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors. Retrieved from: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=77474.*

[274] Centers for Medicare & Medicaid Services. (2018, May). *Dual Eligible Beneficiaries Under Medicare and Medicaid.* Retrieved from *www.cms.gov: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Medicare_Beneficiaries_Dual_Eligibles_At_a_Glance.pdf.*

[275] Centers for Medicare & Medicaid Services. (2019, Novemebr 19). *Hospital Readmissions Reduction Program (HRRP).* Retrieved from *www.cms.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HRRP/Hospital-Readmission-Reduction-Program.*

[276] Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation (ASPE). (2020) *Second Report to Congress: Social Risk Factors and Performance in Medicare's Value-based Purchasing Programs.* Retrieved from: *https://aspe.hhs.gov/system/files/pdf/263676/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report.pdf.* Accessed July 2, 2020.

[277] Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation (ASPE). (2020) *Second Report to Congress: Social Risk Factors and Performance in Medicare's Value-based Purchasing Programs.* Retrieved from: *https://aspe.hhs.gov/system/files/pdf/263676/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report.pdf.* Accessed July 2, 2020.

eventually, stratification of hospitals by the proportion dual-eligible patients should be removed from the HRRP. CMS is currently reviewing the report recommendations and considering how to incorporate these recommendations within CMS programs.

The Overall Star Rating uses individual measure scores, as calculated under the quality programs and reported on *Hospital Compare* or its successor website, to calculate measure group scores. Individual measure methodologies, including current and future approaches to risk adjustment for each measure, as specified in the measures, are inherently included within the Overall Star Rating. Since the Overall Star Rating utilizes the individual measure scores as publicly reported, it is not appropriate to apply social risk factor adjustment to the individual measure scores for the purpose of the Overall Star Rating. In addition, stakeholders have agreed that social risk factor adjustment is not appropriate for all measure types, such as measures capturing healthcare-associated infections where the onset of adverse events occur in the hospital setting should not be influenced by a patient's socioeconomic status.[278] [279] The proposed stratification approach would stratify only the Readmission measure group scores based on a comparison to other hospitals with similar proportions of dual-eligible patients, as opposed to in comparison to all hospitals.

Since the Overall Star Rating is not used to determine hospital payment, we proposed calculating the readmission measure group score within each dual-eligible peer group. In the formula below, α_h is the readmission group score for hospital h, $\bar{\alpha}$ is the national average of readmission group score, $\bar{\alpha}_{peer\ group\ j}$ is the average readmission group score for dual-eligible peer group j (j = 1, 2, . . ., 5).

$$\tilde{\alpha}_{h|peer\ group\ j} = \alpha_h * \left\{1 + \frac{\bar{\alpha}}{\alpha_h}\left(1 - \frac{\bar{\alpha}_{peer\ group\ j}}{\bar{\alpha}}\right)\right\}$$
$$= \alpha_h + \bar{\alpha} - \bar{\alpha}_{peer\ group\ j}$$

During public input periods,[280] CMS' contractor received feedback from stakeholders, specifically providers, encouraging alignment between Overall Star Rating and CMS programs, with specific mention of alignment with HRRP's approach to peer grouping by dual-eligibility. In response to stakeholder feedback to promote alignment between programs and provide consistent measurement standards for providers, we proposed to utilize the same dual-eligible quintiles as HRRP for the Readmission measure group. Applying stratification to the Readmission measure group scores based on proportion of dual-eligible patients would align with HRRP (82 FR 38231 through 38237). Consistent with HRRP, stratifying the Overall Star Rating Readmission measure group would assign hospitals to one of five peer groups based on the proportion of dual-eligible patients. For FY 2019, the range of proportion of dual-eligible patients within each of the hospital peer group quintiles for HRRP are as follows: 0 to 13.69 percent, 13.70 to 18.40 percent, 18.41 to 23.23 percent, 23.24 to 30.98 percent, 30.99 to 100 percent for peer groups one, two, three, four, five, respectively. We proposed to utilize and repurpose the same peer group quintiles assigned by the HRRP, annually. Peer groups for the Overall Star Rating would not be exact quintiles, as a greater number of hospitals are included in Overall Star Rating than those participating in HRPP. The Overall Star Rating includes hospitals providing acute inpatient and outpatient care, including both subsection (d) hospitals and CAHs, whereas HRRP only includes subsection (d) hospitals. We refer readers to section A.1.b. Subsection (d) Hospitals and B. Critical Access Hospitals in the Overall Star Rating of this final rule for more information on the hospitals included within the Overall Star Rating. For the 2020 Overall Star Rating release, 4,384 hospitals received a Readmission group score, while 3,077 hospitals participated in HRRP received a readmission score. Since the hospitals within the Overall Star Rating that do not participate in HRRP would not already be assigned to a peer group by the HRRP methodology, we proposed to calculate their proportion of dual-eligible patients and assign them to one of the five peer groups based on the HRRP designated peer groups.

As stated above, we proposed to assign hospitals that do not participate in the HRRP, but have their proportion of dual-eligible patients available, to HRRP designated peer groups, as they would not have already been assigned to a peer group through the HRRP. This is necessary to maintain alignment with HRRP so that hospitals in HRRP are assigned to the same peer group within both HRRP and the Overall Star Rating. As also stated above, we proposed to not adjust a hospital's Readmission measure group score if that hospital has missing dual-eligible patient data. This is necessary because we would not have the dual-eligible data necessary to produce an adjusted score.

(i) Other Methods Considered

In developing our proposal, we also considered recalculating the peer group quintiles based on all hospitals in the Overall Star Rating dataset, and not solely based on those participating in HRRP. Using all hospitals to calculate peer group quintiles would be more consistent with other aspects of the methodology that use all hospital data, such as the calculation of measure group scores and weighted average of measure groups scores to calculate summary scores. However, calculating quintiles based on all hospitals would create potential misalignment between quintiles, and therefore peer group

[278] National Quality Forum. (2019, November 6). *National Quality Forum Hosptial Quality Star Ratings Summit.* Retrieved from *www.qualityforum.org: http://www.qualityforum.org/NQF_Hospital_Quality_Star_Rating_Summit.aspx.*

[279] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[280] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

assignment, for HRRP and the Overall Star Rating Readmission measure group. More specifically, if dual-eligible quintiles were recalculated based on all hospitals within the Overall Star Rating, some hospitals that are within both HRRP and the Overall Star Rating would be assigned to different peer groups in each of the two methodologies based on the different dual-eligible quintile cutoffs.

Using January 2020 Overall Star Rating release data (from October 2019 publicly reported measure data on *Hospital Compare*), we simulated calculation of quintiles based on all hospitals, 155 (5.04 percent) of the 3,174 HRRP hospitals would move down a peer group quintile; that is, they would move to a quintile with a lower proportion of patients that are dual-eligible, indicating their patient case mix has lower social risk. Under this simulation, specifically, 23 (3.67 percent) hospitals assigned dual-eligible quintiles in HRRP would move from peer group two to peer group one, with the lowest proportion of dual-eligible patients, 40 (6.46 percent) hospitals would move from peer group three to peer group two, 48 (7.74 percent) hospitals would move from peer group four to peer group three, and 44 (7.28 percent) hospitals would move from peer group five, with the highest proportion of dual-eligible patients, to peer group four.

For the January 2020 Overall Star Rating publication, 4,384 hospitals received a Readmission group score, while 1,307 hospitals did not participate in HRRP. Similarly, using the same simulated calculation of quintiles based on all hospitals, 90 (6.89 percent) of the 1,307 non-HRRP hospitals would move down a peer group quintile if calculating based on all hospitals than they would have if using only HRRP hospitals. Specifically, 9 (0.69 percent) hospitals would move from peer group two to peer group one, with the lowest proportion of dual-eligible patients, 31 (2.37 percent) hospitals would move from peer group three to peer group two, 27 (2.07 percent) hospitals would move from peer group four to peer group three, and 23 (1.76 percent) hospitals would move from peer group five, with the highest proportion of dual-eligible patients, to peer group four.

After calculation, mean Readmission measure group scores would be the same for each hospital peer group, resulting in more similar measure group scores across hospital peer groups. While stratifying results in more comparable measure group scores across peer groups of proportions of dual-eligible patients, the effect on the Overall Star Rating Readmission measure group is modest; our simulations showed a 0.967 correlation between unadjusted and adjusted Readmission measure group scores using January 2020 Overall Star Rating release data (from October 2019 publicly reported measure data on *Hospital Compare*).

In developing our proposal, as discussed in section a. Alternatives Considered, we also considered not stratifying the Readmission measure group and retaining the current measure group without stratification based on proportion of dual-eligible patients within the calculation of the Overall Star Rating. CMS' Overall Star Rating development contractor engaged stakeholders in discussion regarding the comparability of hospital star ratings for over 5 years throughout the development and reevaluation of the methodology. Throughout that engagement, some stakeholders expressed concerns regarding adjustment for social risk factors in general, adjustment for social risk factors within the Overall Star Rating methodology, or use of specific social risk factor variables that are currently available for adjustment.[281] Most stakeholders agreed that social risk factor adjustment is not appropriate for all measure types, such as measures capturing healthcare-associated infections, and therefore, not appropriate to be applied at aggregated levels, such as the Overall Star Rating.[282] [283] Some stakeholders, including patients and patient advocates, expressed concern that stratifying the Readmission measure group by the proportion of dual-eligible patients would result in a misrepresentation of quality of care at hospitals, particularly for dual-eligible patients, and would be confusing to patients as consumers of the Overall Star Rating.[284] [285] [286] Furthermore, the effect of stratifying the Overall Star Rating Readmission measure group score is negligible, as shown through a 0.967 correlation between unadjusted and adjusted Readmission measure group scores using January 2020 Overall Star Rating release data (from October 2019 publicly reported measure data on *Hospital Compare*).

CMS is also considering recommendations on risk-adjustment recently submitted to Congress. On behalf of the Secretary, ASPE recently submitted a HHS Report to Congress on *Social Risk Factors and Performance in Medicare's Value-Based Purchasing Programs* that includes recommendations on risk-adjustment for CMS programs and quality efforts, including the Overall Star Rating. For publicly reported quality measures, recommendations are that ''*Quality measures, resource use measures, and composite scores should not be adjusted for social risk factors for public reporting.*'' Instead, recommendations are for quality and resource use measures to be reported separately for dual-eligible beneficiaries and other beneficiaries in order to monitor disparities and improvements over time. The report indicates for public reporting, it is also important to hold providers accountable for outcomes, regardless of social risk. Overall, the report lays out a comprehensive approach for CMS programs to move towards incentivizing providers and initiatives to improve health outcomes by rewarding and supporting better outcomes for beneficiaries with social risk factors. The report indicates proposed solutions that address only the measures or programs, without considering the broader delivery system and policy context, are unlikely to mitigate the full implications of the relationship between social risk factors and outcomes.

However, we ultimately proposed to stratify the Readmission measure group based on the proportion of dual-eligible patients to align with HRRP and to be responsive to stakeholder feedback, particularly from healthcare providers. Considering inconsistent feedback received from stakeholders and HHS

[281] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[282] National Quality Forum. (2019, November 6). *National Quality Forum Hosptial Quality Star Ratings Summit.* Retrieved from *www.qualityforum.org: http://www.qualityforum.org/NQF_Hospital_Quality_Star_Rating_Summit.aspx.*

[283] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[284] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[285] Centers for Medicare & Medicaid Services. (2019, October 24) Patient and Patient Advocate Work Group Minutes—October 2019.

[286] National Quality Forum. (2019, November 6). *National Quality Forum Hosptial Quality Star Ratings Summit.* Retrieved from *www.qualityforum.org: http://www.qualityforum.org/NQF_Hospital_Quality_Star_Rating_Summit.aspx.*

recommendations for CMS programs, we also sought comment on an alternative to retain the Readmission measure group calculation without stratification based on the proportion of dual-eligible patients.

We invited public comment on our proposals to: (1) Stratify only the Readmission measure group score based on the proportion of dual-eligible patients by using peer groups annually designated by the HRRP, (2) assign hospitals that do not participate in the HRRP, but have their proportion of dual-eligible patients available, to HRRP designated peer groups, as they would not have already been assigned to a peer group through the HRRP, (3) not adjust a hospital's Readmission measure group score if that hospital has missing dual-eligible patient data, and (4) codify this policy at § 412.190(d)(4)(v). We refer readers to section a. Alternatives Considered of this final rule where we sought comment on the alternative to not stratify the Readmission measure group score based on the proportion of dual-eligible patients.

The following is a summary of the comments we received and our responses to those comments.

Comment: Many commenters opposed the proposal to stratify the Readmission measure group based on the proportion of dual-eligible patients, primarily noting concerns with the use of dual-eligibility for adjustment. Commenters expressed concern about Medicaid coverage varying by state and that Medicare Advantage might not be accurately captured in the adjustment. One commenter noted that the dual-eligible quintile used within HRRP are subjective and that hospitals with similar proportions of dual-eligible patients that are near a cut point of quintiles may end up in different peer groups.

Response: We acknowledge commenters' concerns with stratifying the Readmission measure group based on the proportion of dual-eligible patients, which are patients that are dually eligible for Medicare and full-benefit Medicaid among a hospital's total Medicare Fee-for-Service and Medicare Advantage patient discharges.[287] While we have heard from stakeholders that dual-eligibility doesn't fully address patient social risk factors at a hospital, few social risk variables are available and consistently captured.

Most of the measures included within CMS hospital quality programs and subsequently, the Overall Star Rating, include data from beneficiaries 65 years of age and older. The Affordable Care Act Medicaid coverage expansion, adopted by most states, did not directly impact coverage for seniors since the newly created optional eligibility pathway extended Medicaid eligibility for those under 65 years of age.[288] Thus, we disagree with concerns about variability in Medicaid by state.

However, we also acknowledge that stratifying the Readmission measure group based on the proportion of dual-eligible patients may be confusing and misleading to patients, especially dual-eligible patients. In addition, analyses reveal the stratification may not result in the intended effect, with a strong correlation of 0.967 between the unadjusted and adjusted measure group scores (see section E.4.d.(2) Proposal to Stratify Only the Readmission Measure Group Scores of this final rule) and significantly more hospitals losing a star rating than gaining a star rating as a result of stratification (see section 8. Effects of Requirements for the Overall Hospital Quality Star Ratings of the proposed rule (85 FR 49057 through 49077)).

Furthermore, we stated in the proposed rule that on behalf of the Secretary, ASPE recently submitted a HHS Report to Congress on *Social Risk Factors and Performance in Medicare's Value-Based Purchasing Programs* that includes recommendations not to adjust publicly reported quality measures and information, including composite scores such as the Overall Star Rating, for social risk.[289] Specifically, the report recommends that the stratification of hospitals by the proportion of dual-eligible patients be removed from HRRP, which served as the precedent and inspiration for the Overall Star Rating Readmission stratification proposal. The report indicates it is important to hold providers accountable for outcomes, regardless of social risk, indicates proposed solutions that address only the measures or programs, without consideration of the broader delivery system and policy context, are unlikely to mitigate the full implications of the relationship between social risk factors and outcomes, and outlines a comprehensive approach to incentivize providers and initiatives to improve health outcomes by rewarding and supporting better outcomes for beneficiaries with social risk factors.

As a result of analyses that indicate stratification of the Readmission measure group would not have the intended effect, ASPE's recent report to Congress, and continued stakeholder concerns with dual-eligibility as a variable and stratification potentially causing confusion for patients and caregivers, we are not finalizing our proposal to stratify the Readmission measure group score based on the proportion of dual-eligible patients. However, we will continue to evaluate approaches for increasing the comparability of hospital star ratings.

Comment: Many commenters recommended improved risk adjustment for or incorporation of sociodemographic factors, such as housing, food insecurity, social support, transportation, patient behavior, or functional status within the underlying individual measures or Overall Star Rating methodology. Some commenters recommended CMS utilize alternative forms of accounting for social risk factors, such as inclusion of health disparity reductions measures, reporting of patient social and behavioral risk data, and social risk factor variables, including zip code, Area Deprivation Index, U.S. Census, or American Community Survey data.

Response: We appreciate commenters' request for improved and alternative forms of social risk factor adjustment. The Overall Star Rating is a summary of certain existing quality measures reported as part of CMS quality programs, which undergo rigorous development and reevaluation processes, including but not limited extensive measure testing, stakeholder vetting, and evaluation by the NQF. When measure methodologies, including risk adjustment approaches, are updated within CMS quality programs, they are subsequently updated within the Overall Star Rating. Unfortunately, few patient social risk factors are available and consistently captured for use in quality measurement. As stated above, ASPE recently submitted a HHS Report to Congress on *Social Risk Factors and Performance in Medicare's Value-Based Purchasing Programs* that includes recommendations not to adjust publicly reported quality measures and

[287] Centers for Medicare & Medicaid Services. (2018, May). *Dual Eligible Beneficiaries Under Medicare and Medicaid.* Retrieved from *www.cms.gov: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Medicare_Beneficiaries_Dual_Eligibles_At_a_Glance.pdf.*

[288] Patient Protection and Affordable Care Act of 2010, Public Law 111–148, 124 Stat. 119 (2010). See: Section 2001.

[289] Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation (ASPE). (2020) Second Report to Congress: Social Risk Factors and Performance in Medicare's Value-based Purchasing Programs. Retrieved from: *https://aspe.hhs.gov/system/files/pdf/263676/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report.pdf.* Accessed July 2, 2020.

composite scores for social risk.[290] The report indicates it is important to hold providers accountable for outcomes, regardless of social risk, indicates proposed solutions that address only the individual measures or programs, without consideration of the broader delivery system and policy context, are unlikely to mitigate the full implications of the relationship between social risk factors and outcomes, and outlines a comprehensive approach to incentivize providers and initiatives to improve health outcomes by rewarding and supporting better outcomes for beneficiaries with social risk factors. As stated above, we are not finalizing our proposal to stratify the Readmission measure group score based on the proportion of dual-eligible patients. We are currently reviewing the report recommendations and considering how to incorporate these recommendations within our programs and initiatives. We will continue to evaluate approaches to increasing the comparability hospital star ratings.

Comment: One commenter specifically requested social risk factor adjustment for the Overall Star Rating measure groups, including Mortality.

Response: We acknowledge the commenter's request, but disagree that social risk factor adjustment should be applied to all of the Overall Star Rating measure groups, including the Mortality measure group. In general, stakeholders have agreed that social risk factor adjustment is not appropriate for all measure types, such as measures capturing healthcare-associated infections or surgical complications, including in-hospital death for example, where the outcome or adverse events occurs within the hospital setting without evidence-based rationale for differences in outcomes based on a patient's socioeconomic status. The proposal to stratify the Readmission measure group based on the proportion of dual-eligible patients would have only applied to the Readmission measure group, which measures returns to the hospital within 30 days of discharge and may be more likely to be influenced by factors outside of hospital control.

Comment: Many stakeholders commented on the proposal to stratify the Readmission measure group based on the proportion of dual-eligible patients, most of whom supported the proposal and appreciated the attempt to increase comparability of hospital star ratings and adjust for social risk factors that may influence readmissions and may be outside of hospital control. Some commenters noted that the proposal would allow for the Overall Star Rating to more accurately reflect the quality of care provided by safety-net, teaching, and hospitals receiving the highest DSH support. Several commenters also stated that the proposal would align with CMS programs and supported the use of the same dual-eligible groupings used within HRRP. Several commenters stated that the proposal would allow dual-eligible patients to make more informed decisions about where to seek care and provide a more accurate portrayal of a hospital's patient population.

Response: We acknowledge the support for our proposal to consider stratifying the Readmission measure group based on the proportion of dual-eligible patients. This proposal would not necessarily increase comparability as it would have improved alignment with the dual-eligible stratification within HRRP. However, this proposal would also reduce alignment, and, in turn, comparability, with public reporting of the individual measures on *Hospital Compare* or its successor website since the HRRP applies dual-eligible adjustment on the program-level, for payment purposes only, and the underlying readmission measure scores reported on *Hospital Compare* or its successor websites are not stratified (82 FR 38231 through 38237). Furthermore, ASPE's recent HHS Report to Congress specifically recommends that the stratification of hospitals by the proportion of dual-eligible patients be removed from HRRP. The Overall Star Rating is intended to summarize and reflect existing measures scores reported through CMS quality programs and reporting on *Hospital Compare* or its successor websites, which undergo rigorous development and reevaluation processes, and while analyses have indicated modest differences in star ratings based on hospital types, such as those receiving highest DSH support (see section 8. Effects of Requirements for the Overall Hospital Quality Star Ratings of the proposed rule (85 FR 49057 through 49077)), these analyses have not indicated that the summary of measure scores in the Overall Star Rating is an inaccurate representation of quality. We disagree that the proposal would have facilitated care decisions for dual-eligible patients. If implemented, the proposal may have obscured hospital quality results specifically for dual-eligible beneficiaries, as stated by the TEP[291] and work groups. As stated above, we are not finalizing our proposal to stratify the Readmission measure group score based on the proportion of dual-eligible patients. We will continue to evaluate approaches to increasing the comparability of hospital star ratings.

After consideration of the public comments received, we are not finalizing our proposals related to stratification of the readmission measure group scores.

5. Step 4: Calculation of Hospital Summary Scores as a Weighted Average of Group Scores

a. Calculation of Hospital Summary Scores Through a Weighted Average of Measure Group Scores

(1) Current Calculation of Hospital Summary Scores Through a Weighted Average of Measure Group Scores

In the past, we have calculated hospital summary scores as a weighted average of measure group scores. That is, each measure group score is multiplied by the assigned weight for that group, and then the weighted measure group scores are summed to calculate the hospital summary score. The measure group weights were based on CMS policy, stakeholder feedback, and similarities to that of the Hospital VBP Program[292] in that outcome measures are given more weight than process measures. Specifically, the Mortality, Safety of Care, Readmission, and Patient Experience measure groups are each weighted 22 percent and the Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging measure groups are each weighted 4 percent. In 2015, CMS' contracted development team engaged stakeholders for input on the measure group weights through the TEP,[293] the Patient & Advocate Work Group, and a public input period.[294] In general,

[290] Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation (ASPE). (2020) Second Report to Congress: Social Risk Factors and Performance in Medicare's Value-based Purchasing Programs. Retrieved from: *https://aspe.hhs.gov/system/files/pdf/263676/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report.pdf.* Accessed July 2, 2020.

[291] Centers for Medicare & Medicaid Services. (2019, November). Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare. Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[292] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 80 FR 49567 (Aug 17, 2015) (to be codified at 42 CFR part 412).

[293] Centers for Medicare & Medicaid Services. (2015, February). Summary *of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[294] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star*

Continued

stakeholders supported the current measure group weights and agreed that outcome measures should have more weight since they represent strong indicators of quality and are most important to patients in making healthcare decisions. The development contractor included this topic in several past public input periods,[295] [296] wherein some stakeholders suggested different measure group weightings; however, little consensus has been reached on an appropriate alternative weighting scheme.

(2) Continue Current Calculation of Hospital Summary Scores Through a Weighted Average of Measure Group Scores

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to continue to calculate hospital summary scores through a weighted average of measure group scores with a similar weighting scheme that continues to assign more weight to the outcome and patient experience measure groups and less weight to the process measure group. Specifically, for Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to weight each of the outcome and patient experience measure groups—Mortality, Safety of Care, Readmission, and Patient Experience—at 22 percent, and the proposed combined process measure group, Timely and Effective Care (we refer readers to section E.3.b. New Measure Group and Continuation of Certain Groups of this final rule), at 12 percent. We also proposed that hospital summary scores would then be calculated by multiplying the standardized measure group scores by the assigned measure group weight and then summed. We refer readers to an example equation and Table 68. We also proposed to codify the measure group weightings at § 412.190(d)(6)(i) and summary score calculations at § 412.190(d)(6).

Example of Weighted Average of Measure Group Scores To Calculate Summary Scores

$$\text{Summary score} = [(-0.70*0.22) + (0.23*0.22) + (-0.76*0.22) + (-1.13*0.22) + (-0.25*0.12)] = -0.55$$

TABLE 68: Example of Summary Score Calculation and Star Rating Assignment

Measure Groups	Example Group Scores*	Standardized Example Group Scores*	Measure Group Weights	Weighted Standardized Example Group Scores*	Summary Score Calculation*
Mortality	-0.45	-0.70	22 %	-0.15	-0.55
Safety of Care	0.16	0.23	22 %	0.05	
Readmission	-0.35	-0.76	22 %	-0.17	
Patient Experience	-0.93	-1.13	22 %	-0.25	
Timely and Effective Care	-0.07	-0.25	12 %	-0.03	

*Please note that measure group scores are continuous and rescaled. Negative and positive scores do not denote good or bad performance.

In developing our proposal, we also considered equal measure weights across all the measure groups, such that each measure group would be weighted 20 percent. We ultimately chose to propose to weight outcome measures more, because this was vetted and supported by stakeholders and is consistent with past and current stakeholder feedback that outcome measures capture important aspects of quality and are more important to patients.[297] [298]

We invited public comment on our proposals to: (1) Continue to calculate hospital summary scores by multiplying the standardized measure group scores by the assigned measure group weights and then summing the weighted measure group scores; (2) continue to weight outcome and patient experience measure groups, (that is, Mortality, Safety of Care, Readmission, and Patient Experience groups) at 22 percent; (3) weight the proposed Timely and Effective Care process measure group at 12 percent; and (4) codify these policies at § 412.190(d)(6) introductory text and (d)(6)(i). The following is a summary of the comments we received and our responses to those comments.

Comment: Many commenters supported the proposed measure group weights to calculate summary scores through a weighted average of measure group scores. Some commenters expressed specific support that the outcome and patient experience measure groups be weighted more than process measure groups, given the importance of patient outcomes. Many commenters supported measure group reweighting, in which the new process measure group, Timely and Effective Care, is weighted 12 percent.

Response: We appreciate the commenters' support for our proposals to calculate summary scores through a weighted average of measure group scores with Mortality, Safety of Care, Readmission, and Patient Experience each weighted 22 percent and Timely and Effective Care weighted 12 percent. We agree and have consistently heard

Rating on Hospital Compare Public Input Summary Report.

[295] Centers for Medicare & Medicaid Services. (2015, June). *Hospital Quality Star Ratings on Hospital Compare Public Comment Report #2: Methodology of Overall Hospital Quality Star Ratings.*

[296] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[297] Centers for Medicare & Medicaid Services. (2015, June). *Hospital Quality Star Ratings on Hospital Compare Public Comment Report #2: Methodology of Overall Hospital Quality Star Ratings.*

[298] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

from stakeholders[299] [300] that outcome and patient experience measures represent a strongly quality signal, are more important to patients, and therefore should be weighted more than process measures within the Overall Star Rating methodology.

Comment: Some commenters supported the notion of measure group weighting but recommended alternative weighting schemes with more weight on Mortality than Readmission, for example.

Response: We thank commenters for their support for weighting in general. As discussed in our proposal, the measure group weighting scheme was determined based on CMS policy, stakeholder feedback, and similarities to that of the Hospital VBP Program.[301] In 2015, CMS' development contractor engaged stakeholders for input on the measure group weights through the TEP,[302] the Patient & Advocate Work Group, and a public input period.[303] In general, stakeholders supported the current measure group weights and agreed that outcome measures should have more weight since they represent strong indicators of quality and are most important to patients in making healthcare decisions. The development contractor included this topic in several past public input periods,[304] [305] wherein some stakeholders suggested different measure group weightings; however, little consensus has been reached on an appropriate alternative weighting scheme. We will continue to evaluate weighting as CMS quality programs evolve and measures are added or removed.

After consideration of the public comments received, we are finalizing our proposals as proposed.

b. Reweighting Measure Group Scores To Calculate Summary Scores

(1) Current Reweighting Measure Group Scores To Calculate Summary Scores

In the past, if a hospital did not report or have sufficient measures for a given measure group under the Overall Star Rating methodology, the weights of those measure groups would be redistributed proportionally across the measure groups for which the hospital did report sufficient measures. Generally, the four outcome measure groups were weighted at 22 percent each, and the three process measure groups were weighted at 4 percent each. The approach to proportioning weights when a hospital did not report enough measures for one or more measure groups was similar to the Hospital VBP Program where the weighting of groups is redistributed where one or more groups are not reported,[306] and was vetted by stakeholders for the Overall Star Rating through TEP [307] engagement and a public input period.[308]

(2) Reweight Measure Group Scores To Calculate Summary Scores Beginning in CY 2021 and Subsequent Years

Moving forward, we proposed to continue to reweight measure group scores. Taking into consideration the new measure grouping (we refer readers to section 5 E.3.b. New Measure Group and Continuation of Certain Groups of this final rule) and the Timely and Effective Care process measure group weighting of 12 percent (we refer readers to section E.5.a. Calculation of Hospital Summary Scores Through a Weighted Average of Measure Group Scores of this final rule), for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to re-distribute measure group weights for measure groups which a hospital does not have sufficient measures within the Overall Star Rating methodology. Once a hospital meets the reporting threshold to receive a star rating, which is having at least three measure groups each with at least three measures, any additional measures and measure groups contribute to their star rating (we refer readers to section E.6.b. Minimum Reporting Thresholds for Receiving a Star Rating of this final rule). In other words, once the reporting thresholds are met, a hospital would need to report at least one measure in each group and the weight of any measure group that does not have at least one measure will be re-distributed amongst the other measure groups. Specifically, we proposed to re-distribute the weights for measure groups which are not reported proportionally across the remaining measure groups, to ensure the relative weight between groups is preserved. We would calculate this by subtracting the standard weight percentage of the group that does not meet the minimum threshold from 100 percent; the standard weight percentage of each of the remaining groups would then be divided by the resulting percentage giving new re-proportioned weights. If a hospital does not meet the threshold for two groups, then those two groups' standard weight percentages are added together before subtracting from 100 percent; the standard weight percentage of each of the remaining groups would then be divided by the resulting percentage giving new re-proportioned weights. We also proposed to codify this at § 412.190(d)(6)(ii). These calculations are illustrated in the three examples below.

For example, if a hospital does not report at least one measure within the Timely and Effective Care measure group, the group's 12 percent weight would be subtracted from the total of 100 (100 − 12 = 88) and then each of the measure group weights for that hospital would be determined using the new total of 88 (Mortality weight: 22/88 = 25 percent, Safety of Care weight: 22/88 = 25 percent, Readmission weight: 22/88 = 25 percent, and Patient Experience weight: 22/88 = 25 percent). This example is illustrated in Table 69.

[299] Centers for Medicare & Medicaid Services. (2015, June). *Hospital Quality Star Ratings on Hospital Compare Public Comment Report #2: Methodology of Overall Hospital Quality Star Ratings.*

[300] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[301] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 80 FR 49567 (Aug 17, 2015) (to be codified at 42 CFR part 412).

[302] Centers for Medicare & Medicaid Services. (2015, February). Summary *of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[303] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

[304] Centers for Medicare & Medicaid Services. (2015, June). *Hospital Quality Star Ratings on Hospital Compare Public Comment Report #2: Methodology of Overall Hospital Quality Star Ratings.*

[305] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[306] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 77 FR 53606 (August 31, 2012) (to be codified at 42 CFR parts 412, 413, 424, and 476).

[307] Centers for Medicare & Medicaid Services. (2015, February). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[308] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

TABLE 69: Example of Reweighting for a Hospital Which Does Not Report Timely and Effective Care Measure Group

Measure Group	Standard Weight	Re-Proportioned Weight
Mortality	22%	25%
Safety of Care	22%	25%
Readmission	22%	25%
Patient Experience	22%	25%
Timely and Effective Care	12%	--

As another example, if a hospital does not report at least one measure within the Readmission measure group, the group's 22 percent weight would be subtracted from the total of 100 (100 − 22 = 78) and then each of the measure group weights for that hospital would be determined using the new total of 78 (Mortality weight: 22/78 = 28.2 percent, Safety of Care weight: 22/78 = 28.2 percent, Patient Experience weight: 22/78 = 28.2 percent, and Timely and Effective Care weight: 12/78 = 15.4 percent). This example is illustrated in Table 70.

TABLE 70: Example of Reweighting for a Hospital Which Does Not Report Readmission Measure Group

Measure Group	Standard Weight	Re-Proportioned Weight
Mortality	22%	28.2%
Safety of Care	22%	28.2%
Readmission	22%	--
Patient Experience	22%	28.2%
Timely and Effective Care	12%	15.4%

This same principle would apply if a hospital did not have at least one measure reported in two measure groups. We proposed that a hospital must report at least three measure groups, each with at least three measures, one of which must be Mortality of Safety of Care, in order to receive a star rating; once both the minimum measure and measure group thresholds are met, any additional measures a hospital reports would be included in the Overall Star Rating calculation, including measures groups with as few as one measure (we refer readers to section E.6.b. Minimum Reporting Thresholds for Receiving a Star Rating of this final rule). If a hospital does not report at least one measure within both the Safety of Care and Timely and Effective Care measure groups, the groups' 22 and 12 percent weights would be subtracted from the total of 100 (100 − 22 − 12 = 66) and then each of the measure group weights would be determined using the new total of 66 (Mortality weight: 22/66 = 33.3 percent, Readmission weight: 22/66 = 33.3, and Patient Experience weight: 22/66 = 33.3 percent). This example is illustrated in Table 71.

TABLE 71: Example of Reweighting for a Hospital Which Does Not Report Safety of Care and Timely and Effective Care Measure Groups

Measure Group	Standard Weight	Re-Proportioned Weight
Mortality	22%	33.3%
Safety of Care	22%	--
Readmission	22%	33.3%
Patient Experience	22%	33.3%
Timely and Effective Care	12%	--

We invited public comment on our proposals to reweight measure group scores and codify at § 412.190(d)(6)(ii). The following is a summary of the comments we received and our responses to those comments.

Comment: Many commenters supported the proposal to continue to proportionally reweight measure group scores when hospitals have too few measures with one or more measure groups.

Response: We appreciate the commenters' support for our proposal to continue to proportionally reweight measure group scores when hospitals have too few measures within one or measure groups.

Comment: One commenter expressed concern with measure group reweighting if the remaining measure groups are calculating using less than three measures, in which case a measure group scores could be calculated using as few as one measure.

Response: In section E.6.b. Minimum Reporting Thresholds for Receiving a Star Rating of this final rule, we are finalizing that once the reporting thresholds are met, any additional measures or measure groups a hospital reports contribute to their star ratings. We acknowledge that this may result in occasional instances in which a hospital has only one or two measures in a group, and therefore the rare circumstance in which one measure contributes to a substantial portion of a hospital's summary score. However, incorporating all measures for which a hospital has scores aligns with one of the guiding principles of inclusivity of measure information (see section A.1.a. Purpose of this final rule). Using October 2020 public reporting data, of the 3,356 hospitals with an Overall Star Rating, 320 hospitals (10 percent) reported on a single measure in at least one measure group. Of these hospitals, the very rare circumstance in which a hospital reported a single measure in two measure groups only occurred for 10 hospitals (0.3 percent). The median contribution of a single measure score on hospitals' Overall Star Rating was below 5 percent for all measure groups. The maximum that a single measure score contributed to a hospital's Overall Star Rating was 28 percent for the Mortality, Safety or Care, or Readmission measure groups. This number was 5 percent for the Patient Experience group and 15 percent for the Timely and Effective Care group. For 76 percent of hospitals, no individual measure accounted for more than 10 percent of their Overall Star Rating. Thus, only in rare circumstances would a hospital meeting the reporting thresholds to receive a star rating have only one measure in a measure group contributing a high weight towards their star rating.

After consideration of the public comments received, we are finalizing our proposals as proposed.

6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating

a. Current Minimum Measure and Group Thresholds for Receiving a Star Rating

In the past, in order to receive a star rating, hospitals that provide acute inpatient and outpatient care had to publicly report sufficient measures to receive a star rating. Specifically, a minimum threshold was set to require at least three measure groups (one being an outcome group—that is, Mortality, Safety of Care, or Readmission), with at least three measures in each of the three groups. Additionally, in the past, once a hospital met the minimum measure and measure group thresholds, any additional measures and groups, including groups with as few as one measure, the hospital reported were included in the calculation of their star rating. These reporting thresholds were applied based on the guiding principle of information inclusivity, in that it allowed as many hospitals as possible to receive a star rating while also maintaining face validity [309] and reliability of the Overall Star Rating methodology, and were vetted through TEP and public comment stakeholder engagement.[310] [311]

In 2017, the CMS' Overall Star Rating development contractor vetted the minimum reporting thresholds through the TEP and public input.[312] In December 2017,[313] we updated the order of steps in the methodology for which minimum thresholds are applied; instead of applying minimum thresholds in step 6, after the assignment of hospitals to star ratings, we applied them in step 5, prior to the assignment of hospitals to star ratings so only hospitals meeting the threshold were included in the relative k-means

[309] Face validity refers to the notion that an instrument measures what it intends to measure at face value.

[310] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6*

[311] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov*: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[312] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

[313] Centers for Medicare & Medicaid Services. (2017, December 20). Quarterly Updates and Specifications Report (v2.3). Retrieved from qualitynet.org: *https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2.*

clustering algorithm.[314] K-means clustering [315] is the algorithm used to assign hospital summary scores to one of five star ratings. An overview of k-means clustering is provided in section E.8. Step 6: Application of Clustering Algorithm to Obtain a Star Rating of this final rule.

b. Minimum Reporting Thresholds for Receiving a Star Rating

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to continue a similar threshold as previously used, but with modification. We proposed that hospitals must report at least three measures for three measures groups, however, one of the groups must specifically be the Mortality or Safety of Care outcome groups. We believe this would increase the comparability of hospitals through the requirement of specific measure groups to receive a star rating. We also believe that this would ensure that, in order to receive a star rating, hospitals have information available on important indicators of acute inpatient and outpatient quality of care—mortality and safety of care—that reflect survival and preventable complications or infections following care and are, therefore, important to patients in making healthcare decisions, as indicated by the Patient & Patient Advocate Work Group. We also proposed to codify this minimum measure group threshold at § 412.190(d)(5).

However, we are aware that a requirement for at least three measures within the Mortality or Safety of Care groups would simultaneously limit the number of hospitals eligible to receive a star rating, particularly reducing the number of small, low volume hospitals with too few cases to report the individual measures. Furthermore, certain entities, such as CAHs, are not required to report safety measures (for example, healthcare-associated infections and PSI–90) as part of HAC Reduction Program (78 FR 50725 to 50728).[316] In January 2020, 125 hospitals did not report at least three measures in either the Mortality or Safety of Care groups. Of those 125 hospitals without at least three measures in either the Mortality or Safety of Care groups, 48 were safety-net hospitals, 68 were CAHs, and 16 were specialty hospitals. However, the TEP still recommended this change because Mortality and Safety of Care are aspects of quality that are most important to patients and reflective of performance under a hospital's control.[317] Once both the minimum measure and measure group thresholds are met, any additional measures a hospital reports would be included in the star rating calculation.

We invited public comment on our proposals to require that hospitals must report at least three measures groups, one of which must specifically be the Mortality or Safety of Care outcome group, each with at least three measures. Once this reported threshold is met, any additional measures and measure groups would contribute to hospital star ratings. We also proposed to codify these policies at § 412.190(d)(5).

We invited public comment on our proposals as discussed previously. The following is a summary of the comments we received and our responses to those comments.

Comment: Many commenters supported CMS' proposal to require that hospitals report at least three measures in at least three measure groups, one of which must be Mortality or Safety of Care, to receive a star rating. Multiple commenters acknowledged the importance that hospital star ratings reflect performance on the Mortality and Safety of Care measure groups.

Response: We appreciate the commenters' support for the proposal to require that hospitals report at least three measures in at least three measure groups, one of which must be Mortality or Safety of Care, to receive a star rating. We agree that requiring at least three measures in either Mortality or Safety of Care will ensure that hospital star ratings reflect important aspects of care for patients.

Comment: Some commenters opposed the proposed reporting threshold based on concerns that it would dramatically limit the number of hospitals eligible to receive a star rating. Such commenters specifically opposed the removal of the Readmission measure group as an option for meeting the reporting requirement for a Star Rating. They suggested CMS conduct further analyses to understand how no longer requiring the measure group would affect hospital reporting. One commenter supported the proposed reporting threshold based on their own analysis which confirmed that a very small proportion of hospitals in the January 2020 *Hospital Compare* dataset would not receive a rating due to the proposed threshold. One commenter did not support the proposal because select hospital characteristics may be disproportionally ineligible to receive star ratings, therefore questioning the value of the Overall Star Rating as a comparison tool.

Response: We disagree with commenters that this would dramatically limit the number of hospitals eligible to receive star ratings. As stated in the proposed rule, we simulated the proposed reported threshold in section 8. Effects of Requirements for the Overall Hospital Quality Star Ratings (85 FR 49057 through 49077). Using data from the January 2020 Overall Star Rating (October 2019 public reporting data), when requiring at least three measures in at least three measure groups, one of which must be Mortality or Safety of Care, and thus no longer specifying Readmission as a requirement option, only 125 fewer hospitals would receive a star rating, consisting of 48 safety-net hospitals, 68 CAHs, and 16 specialty hospitals. In addition, using data from January 2020 Overall Star Rating, the proposal to combine the three process measure groups into one measure group, Timely and Effective Care, resulted in 180 more hospitals, of which 157 were CAHs, receiving a star rating with the current reporting threshold of three measures in at least three measure groups, one of which must be an outcome measure group. As discussed in section 8. Effects of Requirements for the Overall Hospital Quality Star Ratings of this final rule using October 2020 public reporting data, the final methodology, combining both the effects of regrouping and updating the reporting thresholds, for CY 2021 and subsequent years actually results in slightly more hospitals receiving a star rating than the current methodology. While the proposed reporting threshold, when isolated, modestly limits the number of hospitals eligible to receive a star rating, the final combined methodology results in more hospitals receiving a star rating than previous. In addition, the proposed threshold increases the face validity of the Overall Star Rating as a representation of quality of care at a hospital since it is guaranteed to reflect mortality or safety outcomes, which are most meaningful to patients and consumers, as advised by

[314] Huang, Z. Extensions to the k-Means Algorithm for Clustering Large Data Sets with Categorical Values. *Data Mining and Knowledge Discovery* 2, 283–304 (1998) doi:10.1023/A:1009769707641.

[315] Ibid.

[316] Inpatient Prospective Payment System/Long-Term Care Hospital (IPPS/LTCH) Final Rule, 83 FR 50496 (Aug 19, 2013) (to be codified at 42 CFR parts 412, 413, 414, 419, 424, 482, 485, and 489).

[317] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

the TEP and Patient & Patient Advocate Work Group.

We also disagree that the proposed threshold will result in changes to hospital reporting levels since the Overall Star Rating uses measures as required for reporting under CMS quality programs and reported on *Hospital Compare* or its successor websites.

After consideration of the public comments received, we are finalizing our proposals as proposed.

7. Approach to Peer Grouping Hospitals

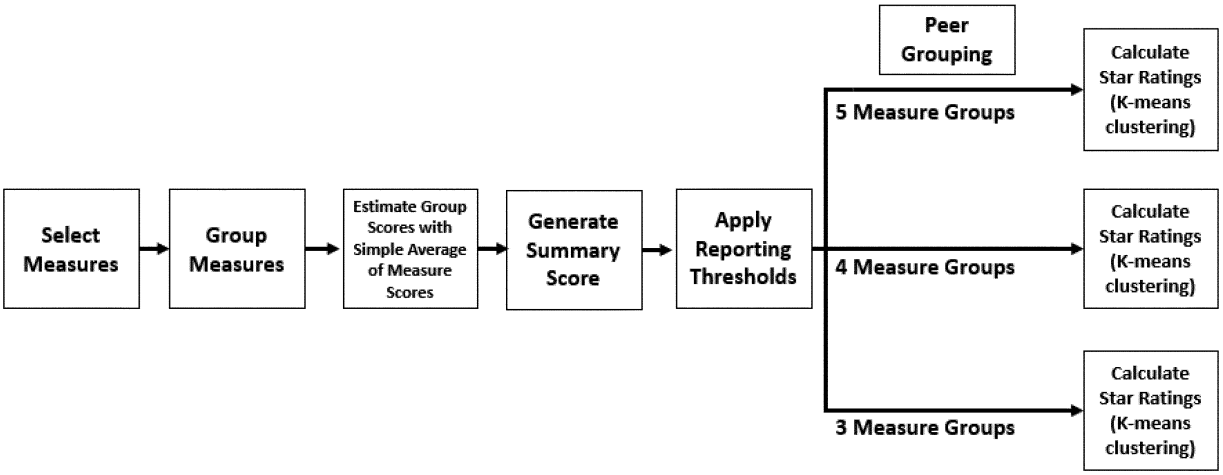
a. Background

We have not previously grouped hospitals by peers within the Overall Star Rating methodology. However, as part of our discussion with stakeholders about the comparability of the Overall Star Rating, peer grouping and potential peer grouping variables were discussed in two TEP meetings (March 2018 [318] and November 2019 [319]), two Provider Leadership Work Group meetings (February and November 2019), two Patient & Advocate Work Group meetings (December 2017 and October 2019), and presented during two public comment periods (August 2017 [320] and March 2019 [321]). Through stakeholder engagement activities, we presented data on peer grouping variables including number of measures or measure groups a hospital reports, teaching designation, specialty designation, critical access designation, and number of beds at a hospital, among others. While there was no consensus among stakeholders regarding which hospital characteristic variable would be most appropriate for peer grouping,[322] CMS focused on the number of measure groups reported as a peer grouping variable based on analyses for many possible variables that assessed similarities among hospitals within peer groups and predictability of hospitals assignments to peer groups over time. Larger hospitals, for example, generally submit the most measures and smaller hospitals submit the fewest. Peer grouping by number of measure groups provides alignment with hospital size.

b. Peer Grouping

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for Overall Star Rating beginning with CY 2021 and subsequent years, we proposed to group hospitals that provide acute inpatient and outpatient care by the number of measure groups for which they have at least three measures as shown in Figure 2. Specifically, after the minimum reporting thresholds are applied, hospitals would be grouped into one of three peer groups based on the number of measure groups for which they report at least three measures—three measure groups, four measure groups, and five measure groups. Once grouped, k-means clustering would be applied within each peer group to assign hospital summary scores to star ratings. We also proposed to codify this policy at § 412.190(d)(7).

Figure 2. Approach to Peer Grouping



Peer grouping hospitals based on the number of measure groups for which they report at least three measures is responsive to stakeholder concerns about the comparability of hospital star ratings and allows hospitals to be assigned to star ratings relative only to other similar hospitals in the same peer group.

We proposed to group hospitals by measure group reporting to capture key differences that are important to stakeholders, such as differences in size, patient volume, case mix,[323] and services provided (service mix [324]). For example, larger hospitals with more diverse case mix and service mix, such as large urban teaching hospitals, report a greater number of measures, and therefore measure groups, and would be grouped separately from smaller

[318] Centers for Medicare & Medicaid Services. (2018, June). *Summary of Technical Expert Panel (TEP): Hospital Quality Star Rating on Hospital Compare.*

[319] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[320] Centers for Medicare & Medicaid Services. (2018, June). *Summary of Technical Expert Panel (TEP): Hospital Quality Star Rating on Hospital Compare.*

[321] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[322] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[323] Centers for Medicare & Medicaid Services. (2019). *Frequently Asked Questions for the Risk-Standardized Outcome and Payment Measures.* Retrieved from *qualitynet.org: https://www.qualitynet.org/files/5d0d374c764be766b010136d?filename=2019_IQR_CBMsrs_FAQs.pdf.*

[324] Ibid.

hospitals with less diverse patient cases and service mix, which tend to report fewer measures and measure groups.

Hospital summary scores would be placed into three peer groups after calculation of the weighted average of measure group scores and before the assignment of hospitals to star ratings using k-means clustering.[325] This proposal is dependent on a sufficient number of hospitals that provide acute inpatient and outpatient care reporting three, four, and five measure groups to form the three peer groups. We simulated effects of this policy based on January 2020 Overall Star Rating release data (from October 2019 publicly reported measure data on *Hospital Compare*): 348 (10 percent) hospitals reported at least 3 measures in 3 groups, 583 (17 percent) reported 4 groups, and 2,509 (73 percent) reported all 5 groups. These group sizes were vetted with the TEP [326] and work groups and considered adequately sized for clustering into peer grouped star ratings.

Of note, this proposal was contingent on the participation of CAHs, as outlined in section B.2. Inclusion of Critical Access Hospitals in the Overall Star Rating of this final rule, since CAHs make up approximately half of the hospitals in the three measure group peer group and their exclusion from the Overall Star Rating would not produce peer groups with a sufficient amount of hospitals for comparison. Because many CAHs currently report the minimum three measure groups required by the reporting threshold, as discussed in section E.6. Step 5: Application of Minimum Thresholds for Receiving a Star Rating of this final rule, and make up approximately half of the hospitals within the three measure group peer group, there would likely be an insufficient number of hospitals in the three measure group peer group to produce adequate variation through k-means clustering [327] if CAHs were not included in the calculation. If CAHs were not included, the difference in summary score between a two-star and three-star hospital may be modest and not truly reflective of differences in hospital quality.

After peer grouping, we would then assign star ratings using k-means clustering [328] (discussed in section E.8. Step 6: Application of Clustering Algorithm to Obtain a Star Rating of this final rule) among hospitals within a single group, that is, relative only to hospitals in the same group. Specifically, hospitals would be grouped based on whether they have at least three measures for three measure groups, four measure groups, or five measure groups. The approach to peer grouping would retain the method used for assigning star ratings. Currently, the Overall Star Rating methodology uses a k-means clustering algorithm to assign hospitals to one of five star rating categories based on the distribution of hospital summary scores. This method aims to make hospital summary scores more similar within one star rating category and more different than hospital summary scores in other star rating categories. The proposed approach to peer grouping would be to also apply k-means clustering [329] to assign hospitals to one of five star ratings based only on hospitals in that peer group. For example, hospitals with three measure groups would be assigned to star ratings based on their summary score relative to other hospital summary scores with three measures groups, but not with respect to hospital summary scores among hospitals with four or five measure groups. Since hospitals in a peer group are being compared only to each other and k-means clustering is a comparative approach to assigning star ratings,[330] hospitals with the same summary score but different peer groups could receive different star ratings. In other words, a hospital with three measure groups could have the same summary score as a hospital with four measure groups; however, that summary score could fall within the four-star cluster for the three measure group peer group and the five-star cluster for the four measure group peer group. In addition, peer grouping hospitals would increase the comparability of star ratings within peer groups but decrease the comparability of star ratings across peer groups for patients. For example, once summary scores are calculated through the weighted average of measure group scores, a hospital within the three measure group peer group would not be assigned to a star rating relative to hospitals within the four or five measure group peer groups in the same geography or service line to whom that hospital is being compared by patients and consumers.

Applying peer grouping after the calculation of summary scores and before the assignment of hospitals to star ratings, allows: (1) Hospital summary scores to be equivalent and comparable among all hospitals, regardless of peer grouping; (2) transparency and the ability for stakeholders to review measure group and summary score results comparable to all other hospitals in the nation for quality improvement efforts within their confidential hospital-specific reports during the 30-day confidential preview period or the *Hospital Compare* or its successor websites' downloadable database upon public release; (3) minimal sensitivity of measure-level differences between peer groups on star ratings; and (4) hospitals' final star ratings to only be in comparison to ''like'' hospitals that have a similar number of measure groups.

We have conducted several analyses to inform decision making regarding peer grouping. To determine whether peer grouping not only supports CMS efforts to improve the comparability of star ratings, but also the predictability of hospital assignments to peer groups, we simulated potential effects of this proposal and assessed the stability of peer groups over time. Hospitals tend to report the same number of measure groups over time and therefore are often assigned to the same peer group each reporting period. Using historical data over five previous years, hospitals would have been assigned to the same peer groups of three, four, or five measure groups 96 to 98 percent of the time, indicating a high level of consistency over time. Furthermore, peer grouping hospitals based on the number of measure groups for which they report at least three measures creates similar within peer group hospital reporting profiles. Using January 2020 reporting data (from October 2019 publicly reported measure data on *Hospital Compare*), hospitals with three measure groups tend to almost always report at least three measures in the Mortality (86 percent), Readmission (86 percent), and Timely and Effective Care (96 percent) measure groups but tend to seldom report at least three measures in the Safety of Care (15 percent) and Patient Experience (17 percent) measures groups. Hospitals with four measure groups tend to always report at least three measures in the Readmission (100 percent) measure

[325] Huang, Z. Extensions to the k-Means Algorithm for Clustering Large Data Sets with Categorical Values. *Data Mining and Knowledge Discovery* 2, 283–304 (1998) doi:10.1023/A:1009769707641.

[326] Centers for Medicare & Medicaid Services. (2019, November). *Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare.* Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[327] Huang, Z. Extensions to the k-Means Algorithm for Clustering Large Data Sets with Categorical Values. *Data Mining and Knowledge Discovery* 2, 283–304 (1998) doi:10.1023/A:1009769707641.

[328] Ibid.

[329] Huang, Z. Extensions to the k-Means Algorithm for Clustering Large Data Sets with Categorical Values. *Data Mining and Knowledge Discovery* 2, 283–304 (1998) doi:10.1023/A:1009769707641.

[330] Ibid.

group, tend to almost always report at least three measures in the Mortality (92 percent), Patient Experience (98 percent), and Timely and Effective Care (99 percent) measure groups, and tend to seldom report at least three measures in the Safety of Care (11 percent) measure group. Hospitals with five measure groups report at least three measures in all five measure groups. Hospitals with three and four measure groups are more likely to be critical access hospitals (58 percent in the peer group with three measure groups and 52 percent in the peer group with four measure groups) while hospitals in the peer group with five measure groups tend to be safety-net (19 percent of the peer group) and teaching (56 percent of the peer group) hospitals. These results confirm that peer grouping results in the grouping of hospitals with similar reporting profiles and characteristics and may address stakeholder concerns about the comparability of hospital star ratings.

Peer grouping hospitals by the number of measure groups for which they report at least three measures for the assignment of hospital summary scores to star ratings addresses stakeholder concerns about the comparability of hospitals with fundamental differences, such as measure reporting, hospital size or volume, patient case mix, and service mix. However, we note that peer grouping hospitals would decrease the comparability of all hospitals for patients and change the historical, conceptual comparative nature of the Overall Star Rating.

In developing our proposal, we also considered not peer grouping and continuing to apply k-means clustering amongst all hospitals meeting the minimum reporting thresholds to assign hospitals to star ratings. However, we ultimately decided to propose to peer group hospitals based on the number of measure groups to be responsive to stakeholder feedback and increase comparability of hospital star ratings. Should we not finalize our proposal to include CAHs, we will not peer group the Overall Star Rating by number of measure groups.

We invited public comment on our proposal to peer group hospitals by number of measure groups and to codify this policy at § 412.190(d)(7). The following is a summary of the comments we received and our responses to those comments.

Comment: Many stakeholders commented on peer grouping, most of whom supported CMS' proposal to peer group hospitals by the number of measure groups reported because it provides more equitable comparisons among hospitals. They agreed that number of measure groups serves as a proxy for hospital size, patient volume, case mix, and services, especially considering the analyses that demonstrate hospitals tend to report the same number of measure groups over time. One commenter recommended that CMS finalize the proposal to peer group hospitals, regardless of the inclusion of CAHs.

Response: We appreciate support for our proposal to peer group hospitals by the number of measure groups for which they have at least three measures. We refer readers to section B.2. Inclusion of Critical Access Hospitals in the Overall Star Rating of this final rule where we are finalizing our proposal to include CAHs resulting in a sufficient amount of hospitals in each peer group.

Comment: Some commenters did not support the proposal to peer group hospitals by the number of measure groups, with many of the commenters expressing concerns that peer grouping, as proposed, does not address stakeholder concerns about comparing hospitals with different characteristics, such as safety-net, specialty, hospital size, and patient case mix, and encouraged CMS to continue to evaluate approaches of more direct adjustment within the Overall Star Rating methodology. Many commenters recommended that CMS continue to evaluate other approaches to and options for peer grouping hospitals. They suggested alternative peer grouping variables, including CAH designation, teaching status, hospital size, services provided, and other hospital characteristics.

Response: One of the guiding principles of the Overall Star Rating is responsiveness to stakeholders, from whom we heard concerns that the Overall Star Rating attempts to compare all hospitals that are fundamentally different in terms of services provided, patients treated, and other characteristics. We have evaluated many variables, including but not limited to CAH designation, teaching status, bed size, and other hospital characteristics, and our development contractor solicited input from a TEP, Provider Leadership Work Group, Patient and Patient Advocate Work Group, and the general public through multiple public input periods. Stakeholder engagement consistently results in no consensus, particularly among providers, regarding which variable is most suitable for peer grouping hospitals within the Overall Star Rating methodology. In addition, few variables are available and consistently captured for all hospitals in the nation. While peer grouping hospitals by the number of measure groups may not directly address differences in hospital characteristics, we believe it does distribute hospitals in a way that indirectly accounts for differences in hospital size, case mix, and services provided, as demonstrated through the number and type of measures they report. For example, as stated in section E.7. Approach to Peer Grouping Hospitals of this final rule, hospitals with three or four measure groups report fewer measures and tend to be CAHs while hospitals with all five measure groups tend to be safety-net and teaching hospitals. The recent TEP and work groups supported peer grouping hospitals by the number of measure groups, acknowledging the availability and usability of other characteristics.

We acknowledge that for many commenters this approach did not fully address interest in creating comparable groups of hospitals. However, we believe that peer grouping by the number of measure groups reported would distribute hospitals in a way that indirectly accounts for differences in hospital size, case mix, and services provided, as demonstrated through the number and type of measures they report. As stakeholder input evolves and data becomes available, we will continue to examine alternative approaches to peer grouping both for the calculation as well as display of the Overall Star Rating.

Comment: Some commenters raised concerns that peer grouping would limit meaningfulness and usefulness to patients, such as the ability to compare hospitals based on their needs, result in inconsistent peer group assignments from year to year, create different star rating category cutoffs thereby preventing comparable scores and star ratings between peer groups, and prevent some measure groups important to patients, such as Safety of Care and Patient Experience, and rural and CAHs from being included within the Overall Star Rating.

Response: The Overall Star Rating is intended to summarize and complement individual measure scores reported through CMS quality programs and on *Hospital Compare* or its successor website. The Overall Star Rating and individual measure scores can be viewed together for patients and stakeholders seeking hospital quality information specific to their clinical needs, values, or interests and peer grouping hospitals within the Overall Star Rating would not impede access to that information. Peer grouping hospitals based on the number of

measure groups for which they report at least three measures is intended to improve comparability of hospital star ratings by accounting for differences in measure information. Peer grouping is applied independent of the measure and measure group reporting threshold and would therefore not result in any reduction in the number or type of hospitals receiving star ratings or the number or type of measures or measure groups contributing to hospital scores.

While peer grouping will result in slightly different summary score cutoffs for star rating assignments between groups, reevaluation analyses presented to the TEP [331] and work groups reveal those differences are modest. As outlined in section E.7. Approach to Peer Grouping Hospitals of this final rule, analyses using historical data have confirmed that hospitals tend to report a similar number and type of measures over time, resulting in hospitals assigned to the same peer group 96 to 98 percent of the time over 5 years of data. We plan to make public the summary score cutoffs for each peer group along with each publication of the Overall Star Ratings.

To clarify, peer grouping itself would not prevent measures or measure groups from being included within hospital star ratings nor prevent any specific hospitals from receiving a star rating. In section E.6. of this final rule, we are finalizing a policy about the minimum reporting thresholds for receiving a star rating which details that to receive a star rating, hospitals must report at least three measures within at least three measure groups, one of which must be Mortality of Safety of Care. Once that reporting threshold is met, any additional measures and measure groups a hospital reports contribute to their star rating. Therefore, all measures for which a hospital meets the specified measure threshold will be included within their star rating. We do note that, using data from January 2020 Overall Star Ratings, the proposed reporting threshold does result in 125 fewer hospitals receiving a star rating, consisting of 48 safety-net hospitals, 68 CAHs, and 16 specialty hospitals. These hospitals did not meet the minimum reporting threshold of at least three measures within at least three measure groups, one of which must be Mortality or Safety of Care.

Comment: One commenter stated that the peer grouping proposal does not account for geographic characteristics, especially in light of variations in COVID–19 hospitalizations in certain regions.

Response: The Overall Star Rating summarizes certain existing measure scores reported within CMS quality programs and on *Hospital Compare* or its successor website, which do not make geographical distinction within specifications. The impact of variation in COVID–19 hospitalizations, and healthcare broadly, is under active surveillance by CMS and any updates to the individual measures as a result of COVID–19 will subsequently be incorporated within the Overall Star Rating. We also refer readers to section G. Overall Star Rating Suppressions of this final rule where we are finalizing suppression of star ratings under certain circumstances, including when a Public Health Emergency substantially affects the underlying measure data.

Comment: Regardless of support, several commenters recommended that CMS make transparent on *Hospital Compare* or its successor websites the details of and information regarding peer grouping, including the hospital characteristics within each peer group, to educate stakeholders, including patients.

Response: Historically, we have publicly posted the Overall Star Rating comprehensive methodology report, input file, and SAS pack at the time of the Overall Star Rating publication so that stakeholders may review and replicate the methodology. Using the input file and SAS pack, coupled with hospital characteristic data, stakeholders would have the ability to review the types of hospitals assigned to each peer group. We plan to continue to publicly post, for each publication of the Overall Star Rating, the Overall Star Rating input file and SAS pack on QualityNet and Overall Star Rating results on *data.cms.gov,* which will include all specifications and results of the Overall Star Rating, including peer grouping.

Comment: One commenter suggested that peer grouping be applied earlier in the methodology so that measure group scores and summary scores are also only calculated relative to hospital peers.

Response: In early evaluation of peer grouping, application of peer grouping hospitals as early as measure group score calculation and as late as prior to clustering within the Overall Star Rating methodology were considered. Empirical analyses and stakeholder engagement efforts consistently favored the proposed approach of peer grouping hospitals after summary score calculation and before clustering, because it ensures the most valid comparisons of hospital measure and measure group scores prior to peer grouping. Also, given that peer grouping is based on an aggregate variable of measure group reporting, application of peer grouping at an earlier stage would be less impractical and transparent to stakeholders, potentially confusing stakeholders and patients.

After consideration of the public comments we received, we are finalizing our proposals as proposed.

8. Step 6: Application of Clustering Algorithm To Assign Star Rating

a. K-Means Clustering

(1) Current Application of K-Means Clustering

In the past, in order to assign hospitals to star ratings, we used an approach called k-means clustering to categorize hospitals' summary scores. K-means clustering is a clustering algorithm that groups entities, in this case hospitals, into a specified number of categories,[332] in this case five star rating categories in which one star is the lowest and five stars is the highest, by grouping values, in this case hospital summary scores, so that they are more similar within groups and more different between groups. In other words, for each publication of the Overall Star Rating, k-means clustering establishes cutoffs, or a range of summary scores, for each of the star rating categories so that summary scores in one star rating category would be more similar to each other and less similar to summary scores in other star rating categories.

We considered multiple approaches to assigning hospitals to star ratings, including percentiles, statistically significant cutoffs, and clustering algorithms. Each option was presented to the TEP[333] [334] and during a public input period [335] by the Overall Star Rating development contractor. While any approach to assigning hospitals to star ratings will result in some hospitals with summary scores near the cutoffs of two star rating categories, at that time, we chose to use k-means clustering

[331] Centers for Medicare & Medicaid Services. (2019, November). Summary of Technical Expert Panel (TEP): Overall Hospital Quality Star Rating on Hospital Compare. Retrieved from: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TEP-Current-Panel#p6.*

[332] Ibid.

[333] Centers for Medicare & Medicaid Services. (2015, February). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[334] Centers for Medicare & Medicaid Services. (2017, June). *Hospital Quality Star Ratings on Hospital Compare Technical Expert Panel.*

[335] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

because it applied a data-driven approach to specification of five categories, minimized the within-category differences and maximized the between-category differences in summary scores, and was similar to the clustering algorithm used to calculate the HCAHPS Star Rating.[336] Stakeholders have generally supported the use of k-means clustering to assign star ratings over arbitrary percentiles and statistically significant cutoffs.[337] [338] [339]

In December 2017, we applied a minor update to the application of k-means clustering by running the summary scores through the clustering algorithm multiple times, a statistical method called complete convergence,[340] to provide more reliable and stable star rating assignments. Prior to December 2017, we performed Winsorization [341] of hospital summary scores to limit the influence of extreme outliers. Winsorization is a common strategy used to set extreme outliers to a specified percentile of the data.[342] While k-means clustering has been used within the methodology since implementation in July 2016, the update to run k-means clustering to complete convergence results in a broader distribution of star ratings and negates the need for Winsorization of hospital summary scores.[343]

(2) Continuation of K-Means Clustering

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to continue to use k-means clustering with complete convergence without Winsorization of hospital summary scores, to group hospitals into five clusters to assign star ratings so that one star is the lowest and five stars is the highest. We also proposed to codify this policy at § 412.190(d)(8). We believe use of k-means clustering is most appropriate because it aligns with the clustering algorithm used for the HCAHPS Star Rating [344] and maximizes the within star rating category similarities and between star rating category differences.

We invited public comment on our proposal to continue to use k-means clustering to complete convergence to assign hospitals to star ratings, where one star is the lowest and five stars is the highest, and to codify this policy at § 412.190(d)(8). The following is a summary of the comments we received and our responses to those comments.

Comment: Many commenters supported CMS' proposal to continue use of k-means clustering to assign hospitals to star ratings. Some commenters supported alignment with the clustering algorithm used within the HCAHPS Star Ratings.

Response: We appreciate the commenters' support for our proposal to continue use of k-means clustering to assign hospitals to star ratings and agree that it aligns with the clustering algorithm used within the HCAHPS Star Ratings.[345]

Comment: Some commenters opposed CMS' approach to continue use of k-means clustering because it may not be transparent for or reproducible by stakeholders. Commenters specifically noted that the relative methodology of k-means clustering makes it difficult for hospitals on the border of star rating categories to evaluate and predict their performance from one publication to the next. Some commenters recommended that CMS assign hospital star ratings through fixed cutoffs, which could be initially determined by k-means clustering but remain static over time, in order to increase predictability of star rating assignments and help inform quality improvement efforts.

Response: The use of k-means clustering was originally implemented as a result of testing and stakeholder engagement through a TEP and public input. While k-means clustering may not be as predictable as fixed cutoffs, it clusters hospitals so that summary scores in one star rating category are more similar to each other and more different than summary scores in other star rating categories, effectively minimizing within-category and maximizing between-category differences in summary scores. Historically, we have publicly posted the Overall Star Rating comprehensive methodology report, input file, and SAS pack at the time of the Overall Star Rating publication so that stakeholders may review and replicate the methodology. With any approach to assigning hospitals to star ratings, there will be some hospitals with summary scores at the border of star rating categories that have the potential to increase or decrease star ratings between publications. In addition, k-means clustering aligns with the clustering approach used for the HCAHPS Star Ratings [346] and, at the time of development, resulted in a broader distribution of star rating that alternative approaches. Furthermore, the primary goal of the Overall Star Rating is to summarize existing hospital quality information for patients. For targeted quality improvement efforts, we refer hospitals to their detailed measure rates under each individual CMS hospital quality program.

After consideration of the public comments received, we are finalizing our proposals as proposed.

F. Preview Period

1. Background

In the past, similar to the process in place for multiple CMS quality programs prior to public reporting of measure scores, hospitals providing acute inpatient and outpatient care that are included in the Overall Star Rating had the opportunity to confidentially review their star rating as well as the measures and measure group scores that contribute to their star rating during the confidential preview period a few months prior to the public release of the Overall Star Rating. We provided hospitals with a confidential report and at least 30 days to preview their results prior to releasing the Overall Star Rating. During the confidential preview period, hospitals received a confidential

[336] Centers for Medicare and Medicaid Services (2019, April). *Technical Notes for HCAHPS Star Ratings.* Retrieved from *www.hcahpsonline.org: https://www.hcahpsonline.org/globalassets/hcahps/star-ratings/tech-notes/april_2019_star-ratings_tech-notes.pdf.*

[337] Centers for Medicare & Medicaid Services. (2015, February). *Summary of Technical Expert Panel (TEP) Evaluation of Hospital Quality Star Ratings on Hospital Compare.*

[338] Centers for Medicare & Medicaid Services. (2017, October). *Overall Hospital Quality Star Rating on Hospital Compare Public Input Summary Report.*

[339] Centers for Medicare & Medicaid Services. (2017, June). *Hospital Quality Star Ratings on Hospital Compare Technical Expert Panel.*

[340] Hsu, P.L., & Robbins, H. (1947). Complete Convergence and the Law of Large Numbers. *Proceedings of the National Academy of Sciences of the United States of America, 33*(2), 25–31. doi:10.1073/pnas.33.2.25.

[341] Kwak, S.K., & Kim, J.H. (2017, July 27). ''Statistical data preparation: management of missing values and outliers.'' Korean journal of anesthesiology 70.4: 407.

[342] Ibid.

[343] Centers for Medicare & Medicaid Services. (2017, December). Overall Hospital Quality Star Rating on Hospital Compare Methodology Report (v3.0). Retrieved from *www.qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab1.*

[344] Centers for Medicare and Medicaid Services (2019, April). *Technical Notes for HCAHPS Star Ratings.* Retrieved from *www.hcahpsonline.org: https://www.hcahpsonline.org/globalassets/hcahps/star-ratings/tech-notes/april_2019_star-ratings_tech-notes.pdf.*

[345] Centers for Medicare and Medicaid Services (2019, April). *Technical Notes for HCAHPS Star Ratings.* Retrieved from *www.hcahpsonline.org: https://www.hcahpsonline.org/globalassets/hcahps/star-ratings/tech-notes/april_2019_star-ratings_tech-notes.pdf.*

[346] Centers for Medicare and Medicaid Services (2019, April). *Technical Notes for HCAHPS Star Ratings.* Retrieved from *www.hcahpsonline.org: https://www.hcahpsonline.org/globalassets/hcahps/star-ratings/tech-notes/april_2019_star-ratings_tech-notes.pdf.*

hospital-specific report (HSR), which detailed their measure performance and measure group scores with comparisons to the national average, as well as their summary score and star rating. The HSRs also provided information about how the measures' scores contribute to measure group scores, how measure group scores are weighted to calculate summary scores, and the range of summary scores for each star rating category. The Overall Star Rating preview period allowed hospitals to review, understand, and ask CMS questions about how the star rating was calculated.

2. Preview Period

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for Overall Star Rating beginning with the CY 2021 and subsequent years, we proposed to continue our current process regarding the preview period. Specifically, a few months prior to public release of the Overall Star Rating, we would issue a confidential HSR, which would detail measure and measure group scores as well as their summary score and star rating. The HSRs would also provide information about how the measures' scores contribute to measure group scores, how measure group scores are weighted to calculate summary scores, and the range of summary scores for each star rating category. During this preview period, hospitals would have at least 30 days to preview their results, and if necessary, reach out to CMS via the QualityNet Question and Answer tool, or additional contact information provided within preview period resources with questions about the methodology and their star ratings results. We also proposed to codify this policy at § 412.190(e). This proposal as well as the proposal to report Overall Star Rating annually using data publicly reported on *Hospital Compare* or its successor websites from a quarter within the prior year would allow hospitals more time to review and understand the methodology and their results, as well as reach out with questions.

We invited public comment on our proposals to: (1) Establish a 30-day confidential preview period, and (2) codify the confidential preview period at § 412.190(e). The following is a summary of the comments we received and our responses to those comments.

Comment: Commenters supported the Overall Star Rating preview period and CMS' provision of Hospital-Specific Reports. One commenter suggested that the confidential preview period be 60 days, rather than 30 days.

Response: We appreciate the commenters' support for our proposal to continue providing a preview period during which providers have the opportunity to confidentially review their measure, measure group, summary score, and star rating results prior to publication. We believe a 30-day preview period is sufficient because it allows hospitals to preview their Overall Star Rating results while maintaining timely publication on *Hospital Compare* or its successor website. In addition, a 30-day preview period is consistent with the standard amount of time provided for hospitals to review their results for the individual measures reported on *Hospital Compare* or its successor website under various CMS hospital quality programs.[347]

After consideration of the public comments received, we are finalizing our proposals as proposed.

G. Overall Star Rating Suppressions

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for the Overall Star Rating beginning in CY 2021 and subsequent years, we proposed separate suppression policies for subsection (d) hospitals and CAHs given that subsection (d) hospitals are subject to CMS quality programs and CAHs voluntarily submit measure data.

1. Subsection (d) Hospitals

a. Background

In the past, we would have only suppressed Overall Star Rating for subsection (d) hospitals when there were errors within the Overall Star Rating calculation or the calculation for individual measures, which would first need to be addressed through CMS programs prior to recalculating star ratings. Furthermore, there is currently no specific corrections process for the Overall Star Rating.

b. Suppression

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), we proposed to continue to allow for suppression, but only in limited circumstances. Specifically, for the Overall Star Rating beginning with the CY 2021 and subsequent years, we proposed to consider suppressing Overall Star Rating only under extenuating circumstances that affect numerous hospitals (as in, not an individualized or localized issue) as determined by CMS or when CMS is at fault, including but not limited to when:

- There is an Overall Star Rating calculation error by CMS;
- There is a systemic error at the CMS quality program level that substantively affects the Overall Star Rating calculation. For example, there is a CMS quality program level error for one or more measures included within the Overall Star Rating due to incorrect data processing or measure calculations that affects a substantial number of hospitals reporting those measures. We note that we would strive to first correct systemic errors at the program level per program policies and then recalculate the Overall Star Rating, if possible; or
- A Public Health Emergency substantially affects the underlying measure data. We also proposed to codify this policy at § 412.190(f)(1).

As mentioned above, consistent with past practices, we proposed that we would not suppress an individual hospital's Overall Star Rating because the hospital or one of its agents (for example, authorized vendors, representatives, or contractors) submitted inaccurate data to CMS, including inaccurate underlying measure data and claims records. We note that the Overall Star Rating is calculated using individual measures publicly reported on *Hospital Compare* or its successor site via CMS quality programs. Hospitals can utilize established processes under each program in order to review and correct individual measure scores. As policies are specific to each program, we refer readers to the respective hospital program's policies. We also refer readers to the QualityNet website: *https://qualitynet.org/* for additional program-related information.

We invited public comment on our proposals as discussed previously. The following is a summary of the comments we received and our responses to those comments.

Comment: Commenters supported CMS' suppression policy for subsection (d) hospital star ratings but requested that CMS add clear criteria for suppression in the event of data submission error on the part of the provider or calculation error on the part of CMS.

Response: We appreciate the commenters' support for our proposal to

[347] As one example, Section 1886(b)(3)(B)(viii)(VII) of the Act, as amended by section 3001(a)(2) of the Affordable Care Act, requires that the Secretary establish procedures for making information regarding measures submitted available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50776 through 50778), we finalized our proposal, for the FY 2014 Hospital IQR Program and subsequent years, to continue our current policy of reporting data from the Hospital IQR Program as soon as it is feasible on CMS websites such as the Hospital Compare website, *http://www.hospitalcompare.medicare.gov,* and/or the interactive *https://data.medicare.gov* website, after a 30- day preview period.

suppress star ratings for subsection (d) hospitals only under extenuating circumstances that affect numerous hospitals as determined by CMS or when CMS is at fault. These extenuating circumstances include: (1) A calculation error on the Overall Star Rating, (2) a systemic error at the CMS quality program level that substantively affects the Overall Star Rating calculation, or (3) a public health emergency that substantially affects the underlying measure data. We would not suppress an individual hospital's star rating because the hospital or one of its agents submitted inaccurate claims and underlying measure data to CMS.

Comment: Several commenters expressed concern about the impact of COVID–19 on the Overall Star Rating and recommended CMS provide the option to suppress data and ratings possibly affected by COVID–19.

Response: On March 27, 2020, we granted exceptions under certain Medicare quality reporting and value-based purchasing programs.[348] [349] In addition, the 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 Interim Final Rule (IFC) (85 FR 54820) updated the extraordinary circumstances exceptions granted for the Hospital Acquired Condition (HAC) Reduction Program, Hospital Readmissions Reduction Program (HRRP), and Hospital VBP Program for the PHE for COVID–19 as a result of the PHE for COVID–19. This IFC also announced that with respect to the Hospital VBP Program, HRRP, and HAC Reduction Program, if, as a result of a decision to grant a new nationwide ECE without request or a decision to grant a substantial number of individual ECE requests, we do not have enough data to reliably compare national performance on measures, we may propose to not score facilities, hospitals based on such limited data or make the associated payment adjustments for the affected program year.

We are currently analyzing how our exemptions granted and the COVID–19 pandemic impact the measures within various CMS quality programs. We note that the Overall Star Rating is calculated using individual measures publicly reported through CMS quality programs and on *Hospital Compare* or its successor website. The Overall Star Rating uses data publicly reported through CMS quality programs and thus, data excluded from those CMS quality programs, will be subsequently excluded from the Overall Star Rating. Hospitals can also utilize established processes under each program in order to review and correct individual measure scores. We refer readers to the QualityNet website: *https://qualitynet.org/* for additional program-related information. We may also consider suppression of the Overall Star Rating if we determine that due to a public health emergency underlying measure data were substantially affected.

After consideration of the public comments received, we are finalizing our proposals as proposed.

(1) CAHs

(a) Background

As discussed in section B. Critical Access Hospitals in the Overall Star Rating of this final rule, CAHs voluntarily submit measure data consistent with certain CMS programs. These measure results are then publicly reported on *Hospital Compare* or its successor websites. In the past, since the Overall Star Rating summarizes available measure information on *Hospital Compare* or its successor websites, CAHs with publicly reported measures results on *Hospital Compare* that also met the reporting thresholds to receive a star rating were assigned a star rating.

CAHs that did not want their voluntarily submitted measure data publicly reported on *Hospital Compare* could submit a form (''Request Form for Withholding/Footnoting Data for Public Reporting'' available on QualityNet) per the forms' instructions during the CMS quality program-level 30-day confidential preview period for the *Hospital Compare* refresh used to calculate the Overall Star Rating. We note that this preview period is distinct from the Overall Star Rating preview period. If the measure data itself was withheld on *Hospital Compare,* it subsequently could not be included in the Overall Star Rating. Generally, upon public release of the Overall Star Rating, we also provide a public input file containing aggregate hospital measure scores, measure group scores, and summary scores along with the Overall Star Rating SAS pack for transparency and to allow stakeholders the opportunity to replicate the calculation of star ratings. If a CAH withheld its data from *Hospital Compare* at this stage, that data was excluded from both the Overall Star Rating calculation and the public input file.

Furthermore, because CAHs voluntarily reported measures, CAHs that would otherwise receive an Overall Star Rating could request to withhold their star rating during the Overall Star Rating preview period. However, at this stage, individual measure scores were still included in the public input file due to time and process constraints.

(b) Withholding

In the CY 2021 OPPS/ASC proposed rule (85 FR 48996 through 49027), for Overall Star Rating beginning in CY 2021 and subsequent years, we proposed to (1) continue to allow CAHs to withhold their Overall Star Rating; and (2) to codify this at § 412.190(f)(2). These proposals, discussed in more detail below, align with the guiding principles of transparency and inclusivity of hospitals, as outlined within section A. Background of this final rule, while allowing CAHs to voluntarily withhold their Overall Star Rating.

i. Withholding Star Ratings

Beginning with CY 2021 and for subsequent years, we proposed that CAHs may request to withhold their Overall Star Rating from public release on *Hospital Compare* or its successor websites as long as the request for withholding is made, at the latest, during the Overall Star Rating preview period as finalized in section F.2. Proposed Preview Period of this final rule. We also proposed to codify this policy at § 412.190(f)(2)(i). CAHs may make this request by submitting the ''Request Form for Withholding/Footnoting Data for Public Reporting'' form [350] available on QualityNet by midnight of the last day of the Overall Star Rating preview period. This is the same form used for withholding data from CMS programs. If CAHs request withholding of any of the measures included within the Overall Star Rating from public reporting on *Hospital*

[348] CMS Press Release, dated March 22, 2020, CMS Announces Relief for Clinicians, Providers, Hospitals and Facilities Participating in Quality Reporting Programs in Response to COVID–19. Located at *https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting.*

[349] CMS Guidance Memo, dated March 27, 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. Located at *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

[350] The ''Request Form for Withholding/Footnoting Data for Public Reporting'' form is in the process of being updated for use in CY21.

Compare or its successor websites through completion of this form, all of their measure scores will be withheld from the Overall Star Rating calculation. However, individual measure scores would still be included in the public input file. By the time the Overall Star Rating preview period begins, there would not be sufficient time for CMS to remove a CAH's data from the public input file and then recalculate the Overall Star Rating for all affected hospitals. As an example, for a January 2021 Overall Star Rating publication based on data publicly reported on *Hospital Compare* or its successor websites using October 2020 data, CAHs would need to submit their withholding request during the Overall Star Rating preview period, which would occur a few months prior to the January 2021 publication, in order to withhold their Overall Star Rating (but their data would still remain in the public input file).

ii. Withholding Star Ratings and Public Input File Data

We proposed that CAHs may request to have their Overall Star Rating withheld from public release on *Hospital Compare* or its successor website, as well as their data from the public input file, which is posted upon the public release of the Overall Star Rating and used by stakeholders to replicate the calculation of star ratings, so long as the request is made during the CMS quality program-level 30-day confidential preview period for the *Hospital Compare* refresh used to calculate the Overall Star Rating. We also proposed to codify this policy at § 412.190(f)(2)(ii). As an example, we refer readers to our discussion in the Hospital IQR Program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51608) for more information about this preview period in one of CMS' quality programs. CAHs may request that CMS withhold their measure and star rating results from public posting on *Hospital Compare* or its successor websites and the Overall Star Rating public input file by submitting a form (''Request Form for Withholding/Footnoting Data for Public Reporting'' [351] available on QualityNet) per the forms' instructions. This is the same form used for withholding from CMS programs. If CAHs request withholding of any of the measures included within the Overall Star Rating from public reporting on *Hospital Compare* or its successor websites through completion of this form during this stated timeframe, all of their measures scores would be withheld from the Overall Star Rating calculation and public input file.

As an example, for a January 2021 Overall Star Rating publication based on data publicly reported on *Hospital Compare* or its successor websites using October 2020 data, CAHs would need to submit their withholding request during the CMS quality program-level 30-day confidential preview period, which would generally occur a few months prior to the October 2020 *Hospital Compare* refresh in order to withhold both their Overall Star Rating and data from the public input file.

We invited public comment on our proposals as discussed previously. The following is a summary of the comments we received and our responses to those comments.

Comment: Some commenters supported the ability for CAHs to choose to withhold their Overall Star Rating from publication.

Response: We thank commenters for their support. We believe this proposal is consistent with the ability for CAHs to voluntarily report measures within CMS quality programs.[352]

Comment: Some commenters did not support CAHs having the option to withhold their rating. These commenters expressed concerns that allowing CAHs to withhold their Overall Star Rating from publication after they have an opportunity to preview their data decreases transparency and allows CAHs to choose to share positive ratings and withhold negative ratings.

Response: We disagree that this policy would actually decrease transparency. As discussed in section B. Critical Access Hospitals in the Overall Star Rating above in this final rule, many CAHs are located in remote areas that face unique challenges in resources and are often one of the only options for patients to seek care.[353] We believe it is important to include CAH data when available because it aligns with CMS goals of healthcare transparency, consumer choice, and the guiding principle of the Overall Star Rating, which is to be inclusive of measure and hospital information. The inclusion of CAHs in the Overall Star Rating has been supported by the Health Resources and Services Administration (HRSA) through their ongoing work with rural hospitals and facilities that provide acute inpatient and outpatient care, including CAHs. HRSA encourages CAHs to report quality measure data as part of quality improvement and public reporting and supports the inclusion of publicly reported measure scores for CAHs within the Overall Star Rating. Additionally, as part of ongoing stakeholder engagement activities, we have heard from some CAHs that they are interested in receiving a star rating and that voluntary measure reporting places no additional burden on CAHs. Furthermore, CMS historical data shows that as few as zero and as many as two CAHs actually exercise the ability to request withholding of their measure data and star rating for a given publication. Many CAHs voluntarily submit measure data for certain CMS quality programs, which are then subsequently displayed on *Hospital Compare* or its successor websites selecting Optional Public Reporting Notice of Participation through their QualityNet account. If CAHs elect to voluntarily submit measure data and report their measure scores on *Hospital Compare* or its successor website, they are subsequently eligible to receive a star rating, should they meet the Overall Star Rating reporting thresholds. The inclusion of CAHs within the Overall Star Rating provides patients with transparency on the hospital performance for hospitals that may be providing acute inpatient and outpatient care in their area.

After consideration of the public comments received, we are finalizing our proposals as proposed.

XVII. Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process

A. Background

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Social Security Act (the Act), which allows the Secretary to develop ''a method for controlling unnecessary increases in the volume of covered OPD services'' (84 FR 61142, November 12, 2019).[354] The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

[351] The ''Request Form for Withholding/Footnoting Data for Public Reporting'' form is in the process of being updated for use in CY21.

[352] Centers for Medicare & Medicaid Services. (2020, November 15). Participation. Retrieved from *www.qualitynet.org*: *https://www.qualitynet.org/inpatient/public-reporting/public-reporting/participation.*

[353] Centers for Medicare & Medicaid Services. (2013, April 9). *Critical Access Hospitals.* Retrieved from *www.cms.gov*: *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/CAHs.*

[354] See also Correction notification issued January 3, 2020 (85 FR 224).

In addition to codifying the basis and scope of subpart I, Prior Authorization for Outpatient Department Services, the regulations include definitions associated with the prior authorization process, provide that prior authorization must be obtained as a condition of payment for the listed service categories, and include the process by which hospitals must obtain prior authorization. Paragraph (a)(1) of § 419.83 lists the specific service categories for which prior authorization must be obtained, which are: (i) Blepharoplasty, (ii) Botulinum toxin injections, (iii) Panniculectomy, (iv) Rhinoplasty, and (v) Vein ablation. Paragraph (b) states that CMS will update this list through formal notice-and-comment rulemaking, paragraph (c) describes the circumstances under which CMS may elect to exempt a provider from the prior authorization process, and paragraph (d) states that CMS may suspend the prior authorization process requirements generally or for a particular service at any time by issuing a notification on the CMS website.

B. Controlling Unnecessary Increases in the Volume of Covered OPD Services

1. Proposed Addition of Two New Service Categories

In accordance with § 419.83(b), we proposed to require prior authorization for two new service categories: Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators. We also proposed to add those service categories to § 419.83(a). We proposed that the prior authorization process for these two additional service categories will be effective for dates of services on or after July 1, 2021. As explained more fully below, the proposed addition of these service categories is consistent with our authority under section 1833(t)(2)(F) and is based upon our determination that there has been an unnecessary increase in the volume of these services. Based on the different implementation dates for the original five service categories and the two proposed service categories, we proposed to add a reference to the July 1, 2020 implementation date to the end of paragraph (a)(1) to reflect the implementation date for the original five service categories. Specifically, we proposed that paragraph (a)(1) would read, ''[t]he following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2020.'' We also proposed to add a new paragraph (a)(2), which would read: ''[t]he following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2021.'' We proposed that the two proposed service categories would be added as new paragraphs (a)(2)(i) through (ii) to new paragraph (a)(2) as follows: (i) Cervical Fusion with Disc Removal and (ii) Implanted Spinal Neurostimulators. We also proposed that existing paragraph (a)(2) would be renumbered as paragraph (a)(3).

We proposed that the list of covered OPD services that would require prior authorization are those identified by the CPT codes in Table 72. For ease of review, we only included in Table 72 the CPT codes that fell into the two proposed service categories in proposed new § 419.83(a)(2)(i) and (ii). Note that this is the same approach we took in establishing the initial five service categories in § 419.83(a)(1). For ease of reference, we also included the Final List of Outpatient Services that Require Prior Authorization for the five initial service categories in Table 73.[355]

2. Basis for Adding Two New Service Categories

As part of our responsibility to protect the Medicare Trust Funds, we are continuing our routine analysis of data associated with all facets of the Medicare program. This responsibility includes monitoring the total amount or types of claims submitted by providers and suppliers; analyzing the claims data to assess the growth in the number of claims submitted over time (for example, monthly and annually, among other intervals); and conducting comparisons of the data with other relevant data, such as the total number of Medicare beneficiaries served by providers, to help ensure the continued appropriateness of payment for services furnished in the hospital OPD setting.

As we noted in the CY 2020 OPPS/ASC proposed rule,[356] we recognize the need to establish baseline measures for comparison purposes, including, but not limited to, the yearly rate-of-increase in the number of OPD claims submitted and the average annual rate-of-increase in the Medicare allowed amounts. For the CY 2021 OPPS/ASC proposed rule, we updated the analyses undertaken for the CY 2020 OPPS/ASC proposed rule.[357] In proposing the addition of these two service categories, we reviewed over 1.2 billion claims related to OPD services during the 12-year period from 2007 through 2018.[358] We determined that the overall rate of OPD claims submitted for payment to the Medicare program increased each year by an average rate of 2.8 percent. This equated to an increase from approximately 90 million OPD claims submitted for payment in 2007 to approximately 117 million claims submitted for payment in 2018. The 2.8 percent rate reflects a slight decrease when compared to the 3.2 percent rate identified in the CY 2020 OPPS proposed rule. Our analysis also showed an average annual rate-of-increase in the Medicare allowed amount (the amount that Medicare would pay for services regardless of external variables, such as beneficiary plan differences, deductibles, and appeals) of 7.8 percent. Again, this is a slight decrease when compared to the 8.2 percent rate identified in the CY 2020 OPPS/ASC proposed rule. We found that the total Medicare allowed amount for the OPD services claims processed in 2007 was approximately $31 billion and increased to $68 billion in 2018, while during this same 12-year period, the average annual increase in the number of Medicare beneficiaries per year was only 0.9 percent.

In the proposed rule, we described what we believe are the unnecessary increases in volume for each of the categories of services for which we proposed to require prior authorization, which we have also included below.

- *Implanted Spinal Neurostimulators:* Our analysis of Integrated Data Repository (IDR) data showed that, with regard to Implanted Spinal Neurostimulators, claims volume for insertion or replacement of spinal neurostimulator pulse generator or receiver, CPT® [359] code 63685, increased by 174.6 percent between 2007 and 2018, reflecting a 10.2 percent average annual increase, a significantly greater annual increase than the 2.8 percent average annual increase for all OPD services. From 2016 through 2018,

[355] The table appears on pages 61456 and 61457 of the final rule but contains certain technical errors. The table printed here is consistent with our January 3, 2020 correction notification. See 85 FR at 225.

[356] *See* Hospital Outpatient Prospective System/Ambulatory Surgical Center Payment System Proposed Rule, 84 FR 39398 at 39603 (August 9, 2019).

[357] 84 FR 39604.

[358] The data reviewed are maintained in the CMS Integrated Data Repository (IDR). The IDR is a high volume data warehouse integrating Medicare Parts A, B, C, and D, and DME claims, beneficiary and provider data sources, along with ancillary data such as contract information and risk scores. Additional information is available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/IDR/index.html.*

[359] The Current Procedural Technology (CPT) coding system is a registered trademark of the American Medical Association.

the average annual increase in volume was 17 percent. For CPT code 63688, revision or removal of implanted spinal neurostimulator pulse generator or receiver, we observed an increase of 149.7 percent between 2007 and 2018, reflecting a 8.8 percent average annual increase, and for CPT code 63650, implantation of spinal neurostimulator electrodes, accessed through the skin, we observed an increase in volume of 77.9 percent between 2007 and 2018, which was an average annual increase of 6.5 percent; these average annual increases for both codes are higher than the 2.8 percent average annual increase for all OPD services over the same period. When analyzing these data, we fully accounted for changes that occurred in 2014 related to electrodes being incorporated into the CPT code 63650, which did not show a corresponding claims volume change that would explain the large increases noted over time when compared to the rates of change for all OPD services.

• *Cervical Fusion with Disc Removal:* When reviewing CMS data available through the IDR, we determined that claims volume for the initial level of spinal fusion of the cervical spine with removal of the corresponding intervertebral disc, CPT code 22551, had increased by 1,538.9 percent between 2012 and 2018, reflecting a 124.9 percent average annual increase, a substantially greater increase than the 2.8 percent average annual increase for all OPD services over the same period and the 2.1 percent average annual increase for all OPD services from 2007 through 2018. In fact, the increase between 2016 and 2018 for this code was 736 percent. The add-on code, CPT code 22552 (for additional levels), reflected claims volume increases of 3,779.6 percent between 2012 and 2018, reflecting a 174.9 percent average annual increase, again, far eclipsing the 2.8 percent average annual increase for all OPD services. Between 2016 and 2018 alone, the claims volume for this code increased 1,020 percent. These codes were first used in 2011 to better reflect the combination of the cervical fusion and the disc removal procedures. Accordingly, we used data from 2012 forward to allow for the start-up statistics to normalize. Nonetheless, the dramatic increases in volume that we identified persisted well after the initial use of these codes.

A rate of increase higher than the expected rate is not always improper; however, when we considered the data, we believed the increases in the utilization rate for this service were unnecessary. CPT code 22551 began being used in 2011. The use of the code almost tripled in 2012 and significantly increased each year thereafter. The increases became even more dramatic beginning in 2016, when the ambulatory payment classification (APC) for CPT code 22551 was changed to a higher level. Effective January 1, 2016, the CY 2016 OPPS/ASC final rule [360] moved the APC for CPT code 22551 from APC 0208 (Laminectomies and Laminotomies) to APC 0425 (Level II Arthroplasty or Implantation with Prosthesis). APC 0425 has a higher payment than APC 0280, the group to which the codes were originally assigned. APC 0208 had a geometric mean cost of $4,267, but APC 0425 had a geometric mean cost of $10,606. This represents a 149 percent increase in allowed amount as a result of the move to APC 0425, which may have contributed to the unnecessary increase in volume. Again, this represents a 736 percent increase in claims volume between 2016 and 2018 when all outpatient department services demonstrated an 0.4 percent increase overall for the same time period. We stated our belief that the change in the payment rate likely prompted the unnecessary volume increases and may have created a financial motivation to utilize these codes more than may be considered medically necessary. We also noted our belief that prior authorization is an appropriate control method for the unnecessary increase in volume for this service.

Our conclusion that the increases in volume for both Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators are unnecessary was based not only on the data specific to each service category, but also on a comparison of the rate of increase for the service categories to the overall trends for all OPD services. We noted our belief that comparing the utilization rate to the baseline growth rate is an appropriate method for identifying unnecessary increases in volume, particularly where there are no legitimate clinical or coding reasons for the changes. For both services categories, we researched possible causes for the increases in volume that would indicate the services are increasingly necessary, but we did not find any explanations that would cause us to believe the increases were necessary. Moreover, other than the recent changes in the CPT code and APC assignments described above, CMS has not taken any action that would explain the significant increases identified. We also conducted reviews of clinical and industry-related literature and found no indication of changes that would justify the increases observed. After reviewing all available data, we found no evidence suggesting other plausible reasons for the increases, which we believe means financial motivation is the most likely cause. We stated our belief that utilizing codes because of financial motivations, as opposed to medical necessity reasons, has resulted in an unnecessary increase in volume. Therefore, comparing the utilization rate to the baseline growth rate is an appropriate method for identifying unnecessary increases in volume, and prior authorization is an appropriate method to control these volume increases.

We stated in the proposed rule that we continue to believe prior authorization is an effective mechanism to ensure Medicare beneficiaries receive medically necessary care while protecting the Medicare Trust Funds from unnecessary increases in volume by virtue of improper payments, without adding onerous new documentation requirements. A broad program integrity strategy must use a variety of tools to best account for potential fraud, waste and abuse, including unnecessary increases in volume. We stated that we believe prior authorization for these services will be an effective method for controlling unnecessary increases in the volume of these services and noted our expectation that it will reduce the instances in which Medicare pays for services that are determined not to be medically necessary. We requested comments on the addition of these two service categories.

[360] 79 FR 66769 and 80 FR 70297.

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TABLE 72: 2021 Proposed List of Additional Outpatient Department Services That Would Require Prior Authorization

	Beginning for service dates on or after July 1, 2021
Code	(i) Cervical Fusion with Disc Removal
22551	Fusion of spine bones with removal of disc at upper spinal column, anterior approach, complex, initial
22552	Fusion of spine bones with removal of disc in upper spinal column below second vertebra of neck , anterior approach, each additional interspace
Code	(ii) Implanted Spinal Neurostimulators
63650	Implantation of spinal neurostimulator electrodes, accessed through the skin
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver

TABLE 73: 2020 Final List of Outpatient Department Services That Require Prior Authorization

	Beginning for service dates on or after July 1, 2020
Code	(i) Blepharoplasty, Eyelid Surgery, Brow Lift, and related services
15820	Removal of excessive skin of lower eyelid
15821	Removal of excessive skin of lower eyelid and fat around eye
15822	Removal of excessive skin of upper eyelid
15823	Removal of excessive skin and fat of upper eyelid
67900	Repair of brow paralysis
67901	Repair of upper eyelid muscle to correct drooping or paralysis
67902	Repair of upper eyelid muscle to correct drooping or paralysis
67903	Shortening or advancement of upper eyelid muscle to correct drooping or paralysis
67904	Repair of tendon of upper eyelid
67906	Suspension of upper eyelid muscle to correct drooping or paralysis
67908	Removal of tissue, muscle, and membrane to correct eyelid drooping or paralysis
67911	Correction of widely-opened upper eyelid
Code	(ii) Botulinum Toxin Injection
64612	Injection of chemical for destruction of nerve muscles on one side of face
64615	Injection of chemical for destruction of facial and neck nerve muscles on both sides of face
J0585	Injection, onabotulinumtoxina, 1 unit
J0586	Injection, abobotulinumtoxina
J0587	Injection, rimabotulinumtoxinb, 100 units
J0588	Injection, incobotulinumtoxin a
Code	(iii) Panniculectomy, Excision of Excess Skin and Subcutaneous Tissue (Including Lipectomy), and related services

15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (e.g., abdominoplasty) (includes umbilical transposition and fascial plication) (list separately in addition to code for primary procedure)
15877	Suction assisted removal of fat from trunk
Code	(iv) Rhinoplasty, and related services[361]
20912	Nasal cartilage graft
21210	Repair of nasal or cheek bone with bone graft
30400	Reshaping of tip of nose
30410	Reshaping of bone, cartilage, or tip of nose
30420	Reshaping of bony cartilage dividing nasal passages
30430	Revision to reshape nose or tip of nose after previous repair
30435	Revision to reshape nasal bones after previous repair
30450	Revision to reshape nasal bones and tip of nose after previous repair
30460	Repair of congenital nasal defect to lengthen tip of nose
30462	Repair of congenital nasal defect with lengthening of tip of nose
30465	Widening of nasal passage
30520	Reshaping of nasal cartilage
Code	(v) Vein Ablation, and related services
36473	Mechanochemical destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36474	Mechanochemical destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36475	Destruction of insufficient vein of arm or leg, accessed through the skin
36476	Radiofrequency destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36478	Laser destruction of incompetent vein of arm or leg using imaging guidance, accessed through the skin
36479	Laser destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36482	Chemical destruction of incompetent vein of arm or leg, accessed through the skin using imaging guidance
36483	Chemical destruction of incompetent vein of arm or leg, accessed through the skin using imaging guidance

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1. Summary of the Public Comments and Responses to Comments on the Proposed Rule

We received over 100 comments on this proposal, including comments from healthcare providers, professional and trade organizations, and device manufacturers. The following is a summary of the comments we received and our responses.

Comment: Several commenters reiterated concerns that we addressed in the CY 2020 OPPS/ASC final rule with comment period that prior authorization processes add burden and costs, can result in unnecessary delays in care, and interfere with the physician-patient care decision or otherwise negatively affect patient care. Other commenters

[361] Code 21235, ''Obtaining ear cartilage for grafting'' was removed on June 10, 2020 in accordance with § 419.83(d). See CMS *http://go.cms.gov/OPD_PA.*

similarly expressed concerns with the prior authorization processes within Medicare Advantage Plans. Some commenters stated that prior authorization is contrary to CMS' Patients Over Paperwork initiative and referenced CMS Administrator Seema Verma's comments related to prior authorization. Other commenters stated that CMS has limited experience with prior authorization in Medicare Fee-For-Service and that there is a lack of administrative structure for implementing the proposed changes and a lack of guidelines about the process by which providers would obtain prior authorization. Commenters also noted that time is needed to develop and maintain the communication logistics between physicians and hospitals. Still other commenters requested information regarding how prior authorization will impact advance beneficiary notices (ABNs) and continued to express concern regarding the inability to appeal the outcome of prior authorization requests.

Response: As we stated in the CY 2020 OPPS/ASC final rule with comment period, the process we are establishing specifically relates to Medicare Fee-For-Service, not Medicare Advantage, and we believe that we have structured the Medicare Fee-For-Service prior authorization processes to effectively account for concerns associated with processing timeframes, patient care, and other administrative concerns. We have implemented prior authorization processes while still preserving access to care and are building upon our already established prior authorization program for certain durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) under 42 CFR 414.234. Similarly, we recently announced the nationwide expansion of the Medicare Prior Authorization Model for Repetitive, Scheduled Non-Emergent Ambulance Transport (RSNAT) in light of its success in reducing spending while maintaining quality of care. We remain fully committed to the agency's ''Patients over Paperwork'' initiative to reduce unnecessary burden, and, as explained below, our proposals are not inconsistent with this initiative. Moreover, while we agree that Administrator Verma noted concerns about potential burden related to prior authorization, she also recognized that prior authorization ''is an important utilization management tool.'' [362] More recently in discussing the resounding success of the RSNAT model, Administrator Verma stated that ''[w]hen deployed appropriately, prior authorization can help ensure Medicare requirements are met before a service is provided and the claim is paid, without creating any new documentation requirements for providers.'' [363] We recognize apprehension resulting from problems with prior authorization in other settings related to burden, cost, and patient access, but as with our other Medicare Fee-For-Service prior authorization processes, we believe that the Hospital OPD prior authorization process will not have these problems. We have established timeframes for contractors to render decisions on prior authorization requests, as well as an expedited review process when the regular review timeframe could seriously jeopardize the beneficiary's health, that we believe will enable hospitals to receive timely provisional affirmations. Additionally, we note that our prior authorization policy does not create any new documentation or administrative requirements. Instead, it just requires the same documents that are currently required to be submitted earlier in the process. Hospital OPDs should not need to divert resources from patient care. We note that prior authorization has the added benefit of giving hospitals some assurance of payment for services for which they received a provisional affirmation. In addition, beneficiaries will have information regarding coverage prior to receiving the service and will benefit by knowing in advance of receiving a service if they will incur financial liability for non-covered services.

We also believe that some assurance of payment and some protection from future audits will ultimately reduce burdens associated with denied claims and appeals. We note that because the prior authorization process is not a final determination and a provider has the ability to resubmit a prior authorization request multiple times, it is not necessary to provide appeal rights. Appeal rights still exist once a claim is actually denied.

We note that the prior authorization process does not change a provider's obligation with regard to ABNs. An ABN is used to advise a beneficiary in advance that the provider expects Medicare payment to be denied.

Comment: We received comments in support of prior authorization and our goal of ensuring the appropriateness of payment for Medicare services.

Response: We thank the commenters for their comments. We appreciate the positive responses to our proposed prior authorization process.

Comment: Some commenters continue to question whether section 1833(t)(2)(F) of the Act grants CMS the authority to establish a prior authorization process and again questioned the inclusion of botulinum toxin injections. Still other commenters suggested adding new procedures is arbitrary and capricious because the commenters believed that CMS has not demonstrated that increases in the volume of services for which we proposed to require prior authorization are unnecessary and that we did not demonstrate there are not other clinical reasons for the increases.

Response: As we conveyed in the CY 2020 OPPS/ASC final rule with comment period, we believe section 1833(t)(2)(F) of the Act gives us discretion to determine the appropriate methods to control unnecessary increases in the volume of covered OPD services. We carefully considered all available options in choosing to propose the prior authorization process, which has already been shown to be an effective tool in Medicare Fee-for-Service, and which we believe will be effective at controlling unnecessary increases for both cervical fusion with disk removal and implanted spinal neurostimulators. Our decision to include botulinum toxin injections in the CY 2020 OPPS/ASC final rule is beyond the scope of this CY 2021 rule, but our reasoning is discussed in detail in last year's proposed and final rules. Our extensive data analysis included in this year's proposed rule demonstrates that there have been unnecessary increases for each of the two proposed service categories and that we did not identify other, legitimate reasons for the sustained increases.

Comment: Several commenters again questioned why ambulatory surgical centers (ASCs) and physicians are exempt from this prior authorization process and believe the prior authorization process should cover ASCs and physicians. Commenters also stated that services may shift to ASCs, physicians' offices, or even inpatient hospitals to avoid the OPD prior authorization process.

Response: This prior authorization process is being adopted under section 1833(t)(2)(F) of the Act, which is specific to the OPPS, which provides payment only to hospital outpatient

[362] See Administrator Seema Verma's speech at the American Medical Association National Advocacy Conference at *https://www.cms.gov/newsroom/press-releases/speech-remarks-cms-administrator-seema-verma-american-medical-association-national-advocacy.*

[363] See CMS Press Release, dated September 22, 2020, CMS to Expand Successful Ambulance Program Integrity Payment Model Nationwide located at *https://www.cms.gov/newsroom/press-releases/cms-expand-successful-ambulance-program-integrity-payment-model-nationwide.*

departments. As such, we cannot extend the process to ASCs or other healthcare provider types, including physicians outside of the hospital outpatient department setting. These other entities, such as ASCs, are paid under other payment systems. We thank the commenters for reminding us of the potential for these services to shift to other care settings. We will monitor the data and may consider additional program integrity oversight if such shifts are realized.

Comment: Several commenters stated that CMS is not providing adequate time for training and education that providers will require in learning the new process in relation to the additional procedures. Some commenters suggested that CMS must evaluate the current process and assess the administrative burden, costs, impact on patient care, and effectiveness with regard to program integrity and managing inappropriate utilization prior to expanding the process to include cervical fusion with disk removal and implanted spinal neurostimulators. Other commenters stated that in light of the continuing public health emergency (PHE) resulting from the 2019 Novel Coronavirus (COVID–19) and the resulting serious financial impact, CMS should have delayed the implementation of the process and also delay the implementation date for the current proposal.

Response: No new documentation requirements are created as a result of this process. Instead, currently required documents are submitted earlier in the process. We recognize the impact of the COVID–19 PHE, but because we initially focused this process on elective cosmetic procedures, we believed that the impact of the PHE would be minimal. Further, given the importance of prior authorization activities to CMS' program integrity efforts, we did not believe a delay of the implementation date was warranted. The proposed date for the expansion of the prior authorization process to include the two new service categories is July 1, 2021. We believe this provides CMS and the Medicare Administrative Contractors (MACs) more than adequate lead time to educate and train providers on the addition of the new service categories. While these service categories are not cosmetic procedures, they are still elective and non-emergent, thus we do not believe delaying the expansion beyond July 1, 2021 due to the impact of the COVID–19 PHE is warranted.

Comment: Several commenters suggested that prior authorization is unnecessary and that CMS should focus on using already existing tools, such as National Coverage Decisions (NCDs) and Local Coverage Determinations (LCDs), prepayment and postpayment reviews, and provider outreach and education, since these are more effective methods to control unnecessary increases in volume. One commenter suggested CMS should use the Beneficiary and Family Centered Care Quality Improvement Organization contractor to retrospectively educate providers whose use of these procedures is statistically greater than their peers when adjusted for patient population characteristics. Other commenters referenced the trial period that must be completed with regard to spinal cord stimulation and asserted that this trial period served to prevent overutilization of the device. Still other commenters suggested that CMS should clarify already existing LCDs and NCDs to remedy the overutilization instead of using prior authorization.

Response: We have a variety of tools that can be used in making reasonable and necessary determinations, including NCDs and LCDs. For procedures that do not have specific LCDs or NCDs, contractors may make individual claim determinations to assess whether or not the services are reasonable and necessary under section 1862(a)(1)(A) of the Act. This prior authorization process does not make any changes to current documentation or medical necessity requirements. While we recognize the utility of NCDs and LCDs, the existence of an NCD or an LCD does not, in and of itself, guarantee compliance with the policy. Thus, the need for medical record review. We also believe that a broad program integrity strategy must use a variety of tools to best account for potential fraud, waste and abuse, including unnecessary increases in volume, so we use prior authorization, prepayment review, and postpayment reviews to review medical records and ensure compliance with these policies. Prior authorization entails the review of the same documentation provided when submitting a claim to ensure compliance with coverage policy, for example, NCDs or LCDs. Prior authorization has already proven to be an effective method for controlling improper payments and decreasing the volume of potentially improperly billed services for certain DMEPOS items. Thus, we believe that the use of prior authorization in the OPD context will be an effective tool in controlling unnecessary increases in the volume of covered OPD services by ensuring that the correct payments are made for medically necessary OPD services, while also being consistent with our overall strategy of protecting the Medicare Trust Fund from improper payments, reducing the number of Medicare appeals, and improving provider compliance with Medicare program requirements. Merely clarifying existing NCDs and/or LCDs, if warranted, does not equate to a comprehensive strategy. We will continue to work toward enhancing our overall program integrity strategy in meaningful ways.

Comment: Some commenters again suggested that MACs must have the clinical review capabilities to sufficiently handle prior authorization requests and suggested that CMS require specific credentials of the MAC medical reviewers to ensure the accuracy of MAC decisions. One commenter requested that we follow the principles noted in the *2018 Consensus Statement on Improving the Prior Authorization Process*[364] developed in consensus with various national provider associations and insurer trade organizations, including application of prior authorization to only outliers; adjustment of prior authorization lists to remove low-value services; transparency of requirements; protections of patient continuity of care; and automation to improve process efficiency.

Response: In all Medicare Fee-for-Service medical review programs, we require that MACs utilize clinicians, specifically, registered nurses, when reviewing medical documentation. We also require the oversight of a Medical Director and additional clinician engagement if necessary. We are confident that MACs have the requisite expertise to effectively administer the prior authorization process, and we maintain a robust oversight process to ensure the accuracy and consistency of their review decisions. Further, we believe the prior authorization process we have adopted aligns with the principles outlined by the commenters. We have established review timeframes for both initial and resubmitted prior authorization requests, as well as an expedited process when the regular timeframe could impact the health of the beneficiary. Having established turnaround times allows providers and patients to plan accordingly and reduces provider burden. We have also established an exemption process with specific requirements for providers to demonstrate compliance with Medicare requirements for these services and be exempt from the prior authorization

[364] See *https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf.*

process. We are also committed to incorporating automation into our prior authorization processes and recognize the value of automation in shortening the receipt of prior authorization requests and our response time frames. We recognize that not all providers have the same level of technology. With regard to the Hospital OPD prior authorization process, the majority of providers so far continue to submit requests and medical information to the MACs via facsimile. Other providers submit the requests through the United States (U.S.) postal service. We also support a variety of electronic mechanisms used by providers in submitting prior authorization requests. These providers use either the MAC-specific web portals, CMS's electronic submission of medical documentation (esMD) system, and may also send prior authorization requests using the X12 278 standard, though currently, relatively few providers submit prior authorization requests electronically. We continue to monitor other federal and industry initiatives in order to improve the efficiency of our prior authorization processes, increase provider willingness to submit requests electronically, reduce provider burden, decrease delays in patient care and promote high quality, affordable health care.

Comment: We received comments that the growth in utilization of a procedure/product class exceeding the baseline growth rates in the Medicare population is not a sufficient basis for inferring that utilization is inappropriate or that utilization growth is unwarranted. Some commenters suggested that CMS must be more transparent in the analyses undertaken while other commenters suggested that the reduction of inappropriate or unnecessary care does not outweigh the increased burden on providers and the impact on patient care. Still other comments agreed that the rates had increased but suggested that CMS analyze readily available clinical information to explain the changes in utilization before the agency adopts broad-based interventions such as imposing prior authorization on outpatient hospitals. Some commenters stated that the increase in cervical fusion with disc removal can be attributed to its removal from the Inpatient Only List (IPO) list as of January 1, 2012. Some of these commenters questioned whether CMS analyzed only the volume of outpatient claims or if the total number of claims that involved cervical fusions were analyzed, specifically to determine if there was a decline in the volume of inpatient claims. Others suggested that we did not consider efforts to combat the opioid public health emergency as a reason for the increased utilization of implanted spinal neurostimulators, as an alternative to treat chronic pain, along with the comorbidity of the patient population. Several commenters suggested that the proposal to include implanted spinal neurostimulators is not in alignment with the Department of Health and Human Services (HHS) Pain Management Best Practices Inter-Agency Task Force Report, which encourages CMS and other payers to provide timely insurance coverage of such procedures in efforts to reduce opioid dependency for pain management. Some commenters stated that CMS changed its methodology because the initial process focused upon items that were cosmetic, while the new items are being added as a result of overutilization. One commenter indicated that in contrast to our findings, they had experienced a decrease in cervical fusion with disk removal procedures in their area of the country.

Response: We thank the commenters for their input. We continue to believe that comparing the utilization rate to the baseline growth rate is an appropriate method for identifying potentially unnecessary increases in volume. Moreover, we clearly conveyed in the CY 2021 OPPS/ASC proposed rule the precise data and time frames used in our analyses and our efforts to identify potential clinical reasons that would explain the increase. As we have noted, we have endeavored to minimize the burden associated with this prior authorization process and this burden is more than outweighed by the need to control unnecessary increases in the volume of these services. We believe that the 10-day timeframe for obtaining a decision on a prior authorization request is not significant considering that these are non-emergency procedures that require the beneficiary to undergo conservative treatment prior to the procedure. While we are aware that the cervical fusion codes were removed from the Inpatient Only List in 2012, the more significant increases in volume occurred years later, when the reimbursement changed for the procedure. This supports our conclusion that financial reasons may have factored into the utilization increases. In confirming our conclusion, we looked at data across both inpatient and outpatient settings for the total volume of cervical fusions, and considered the change in inpatient procedure coding from ICD–9 to ICD–10. The conversion from ICD–9 to ICD–10 makes an exact comparison difficult, but based on our assessment, we do not believe that the 1,538.9 percent increase between 2012 and 2018 for cervical fusion with disc removal is due to its removal from the IPO as of January 1, 2012.

Similarly, we do not agree that the 174.6 percent increase between 2007 and 2018 for implanted spinal neurostimulators is due solely to efforts to avoid opioids. As we noted in the proposed rule, the claims volume that formed the basis of our conclusions regarding implanted neural stimulators was based on data from the time period 2007 through 2018. The opioid crisis affecting our Nation was not declared a PHE until October, 26, 2017. While the crisis certainly existed prior to the declaration of a PHE, most of the data forming the basis of our conclusion that implanted spinal neurostimulators demonstrated unnecessary increases in volume pre-dates the PHE and any federally coordinated efforts to reduce the use of opioids. Thus, most of the data forming the basis of our conclusion pre-dates that PHE and any substantial or coordinated efforts to reduce the use of opioids. We also believe the proposal is in alignment with the Department of Health and Human Services (HHS) Pain Management Best Practices Inter-Agency Task Force Report that encourage CMS and other payers to provide timely insurance coverage of such procedures. We believe that the 10-day timeframe for obtaining a decision on a prior authorization request is not significant considering that these are non-emergency procedures that require the beneficiary to undergo conservative treatment prior to the procedure. Additionally, providers may request an expedited review, and ultimately providers can be exempt from the prior authorization process should a provider demonstrate compliance with Medicare coverage, coding, and payment rules. With regard to our methodology, we again compared the utilization rate to the baseline growth rate and believe that this is an appropriate method for identifying potentially unnecessary increases in volume. We also looked at the overall rates from a national perspective and believe that this approach is warranted, despite the commenter's observation about its area of the country.

Comment: One commenter disagreed with the average hourly rate used by CMS in calculating the average practice labor costs and noted that rather than using clerical employees, clinical staff, from nurses up to and including

physicians, are often involved in completing the documentation required for prior authorization. This same commenter also stated that there is a time burden associated with determining which services require prior authorization and the documentation required associated with a particular procedure code.

Response: We thank the commenter for the comment. We typically use a clerical staff rate because the documentation being submitted is the same documentation that should be regularly maintained in support of claims submitted for payment. The prior authorization process does not require anything new with regard to documentation. The prior authorization process merely requires the documentation be provided earlier in the process. With regard to the time burden, we include 3 hours of training in our burden estimate for each provider. During this time, the staff can be educated on the services that require prior authorization under this program and what documentation is needed as part of the prior authorization request. Moreover, we include the 3 hours each year so that new staff can be trained and current staff can have a refresher course. Given that this process does not create any new documentation requirements and merely necessitates the submission of the documentation earlier in the claims process, we believe the amount estimated is more than sufficient.

Comment: Some commenters indicated that implanted spinal neurostimulators are nothing like the devices CMS originally considered when drafting the NCD in light of advancements in technology. Commenters noted that the process should treat rechargeable and non-rechargeable neurostimulators differently and only include non-rechargeable neurostimulators in the prior authorization process because of the reduced product life of the non-rechargeable neurostimulators.

Response: We thank the commenters for the information. While we recognize that there have been advancements in technology, the NCD does not distinguish the coverage between different types of implanted spinal neurostimulators. Additionally, although our initial review of the data looked solely at unnecessary increases in procedure codes and did not distinguish between the type of product, we have since reviewed our data for any distinctions based on the type of implanted spinal neurostimulators. Both types showed unnecessary increases in volume. As such, we have determined that segmenting the implanted spinal neurostimulators and only including the non-rechargeable neurostimulators in the prior authorization process is not warranted.

Comment: We received several comments that the MACs have not demonstrated the ability to handle the volume of prior authorization requests since the OPD process begin July 1, 2020. These commenters stated that MACs have taken longer than the 10 days specified for communicating the results of prior authorization requests.

Response: We thank the commenters for sharing this concern. While we require prior authorization decisions to be made within 10 days of the request, we acknowledge that there have been occasions when a few of the MACs were not able to issue decisions within this timeframe, as they adjusted to this new workload. When concerns with missed timeframes were brought to CMS' and the MAC's attention, we worked diligently to ensure that outstanding requests were resolved as soon as possible. As this prior authorization process as finalized in last years' rule has only recently been implemented for services furnished beginning July 1, 2020, we have minimal data to track this issue. However, experience with our other prior authorization programs has shown that the MACs are able to meet their established timeframes the vast majority of the time. In the prior authorization process for certain DMEPOS items, the MACs exceeded their required review timeframe only 16 times out of over 62,000 initial prior authorization requests submitted in FY 2020 (less than 0.01 percent). Response times for our Prior Authorization Model for Repetitive, Scheduled Non-emergent Ambulance Transports are similar. As this program continues, we will continue tracking MAC timeliness metrics and are confident that the MACs will be able to meet the required review and decisions timeframes so as not to cause additional burden for OPD providers or delay medically necessary services.

In sum, we continue to believe prior authorization is an effective mechanism to ensure Medicare beneficiaries receive medically necessary care while protecting the Medicare Trust Funds from unnecessary increases in volume by virtue of improper payments, without adding onerous new documentation requirements. A broad program integrity strategy must use a variety of tools to best account for potential fraud, waste and abuse, including unnecessary increases in volume. We believe prior authorization for these services will be an effective method for controlling unnecessary increases in the volume of these services and expect that it will reduce the instances in which Medicare pays for services that are determined not to be medically necessary. We will continue to monitor and report on the effect of this policy on beneficiary access to services.

We are finalizing our proposal without modification to add these two new service categories to the list of hospital outpatient department services requiring prior authorization and finalizing the proposed changes to the regulation text at 42 CFR 419.83(a)(2)(i) and (ii) to add these categories. Table 74 includes the overall list of services with the effective dates for each.

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TABLE 74: 2021 Final List of Outpatient Department Services That Require Prior Authorization

The following is the list of codes associated with the list of hospital outpatient department services contained in 42 CFR 419.83(a)(1) and (2).	
The following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after *July 1, 2020*: (i) Blepharoplasty. (ii) Botulinum toxin injections. (iii) Panniculectomy. (iv) Rhinoplasty. (v) Vein ablation.	
Code	(i) Blepharoplasty, Eyelid Surgery, Brow Lift, and related services
15820	Removal of excessive skin of lower eyelid
15821	Removal of excessive skin of lower eyelid and fat around eye
15822	Removal of excessive skin of upper eyelid
15823	Removal of excessive skin and fat of upper eyelid
67900	Repair of brow paralysis
67901	Repair of upper eyelid muscle to correct drooping or paralysis
67902	Repair of upper eyelid muscle to correct drooping or paralysis
67903	Shortening or advancement of upper eyelid muscle to correct drooping or paralysis
67904	Repair of tendon of upper eyelid
67906	Suspension of upper eyelid muscle to correct drooping or paralysis
67908	Removal of tissue, muscle, and membrane to correct eyelid drooping or paralysis

67911	Correction of widely-opened upper eyelid
Code	(ii) Botulinum Toxin Injection
64612	Injection of chemical for destruction of nerve muscles on one side of face
64615	Injection of chemical for destruction of facial and neck nerve muscles on both sides of face
J0585	Injection, onabotulinumtoxina, 1 unit
J0586	Injection, abobotulinumtoxina
J0587	Injection, rimabotulinumtoxinb, 100 units
J0588	Injection, incobotulinumtoxin a
Code	(iii) Panniculectomy, Excision of Excess Skin and Subcutaneous Tissue (Including Lipectomy), and related services
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (e.g., abdominoplasty) (includes umbilical transposition and fascial plication) (list separately in addition to code for primary procedure)
15877	Suction assisted removal of fat from trunk
Code	(iv) Rhinoplasty, and related services
20912	Nasal cartilage graft
21210	Repair of nasal or cheek bone with bone graft
30400	Reshaping of tip of nose
30410	Reshaping of bone, cartilage, or tip of nose
30420	Reshaping of bony cartilage dividing nasal passages
30430	Revision to reshape nose or tip of nose after previous repair
30435	Revision to reshape nasal bones after previous repair
30450	Revision to reshape nasal bones and tip of nose after previous repair
30460	Repair of congenital nasal defect to lengthen tip of nose
30462	Repair of congenital nasal defect with lengthening of tip of nose
30465	Widening of nasal passage
30520	Reshaping of nasal cartilage
Code	(v) Vein Ablation, and related services
36473	Mechanochemical destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36474	Mechanochemical destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36475	Destruction of insufficient vein of arm or leg, accessed through the skin
36476	Radiofrequency destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36478	Laser destruction of incompetent vein of arm or leg using imaging guidance, accessed through the skin

36479	Laser destruction of insufficient vein of arm or leg, accessed through the skin using imaging guidance
36482	Chemical destruction of incompetent vein of arm or leg, accessed through the skin using imaging guidance
36483	Chemical destruction of incompetent vein of arm or leg, accessed through the skin using imaging guidance
The following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2021: (i) Cervical Fusion with Disc Removal. (ii) Implanted Spinal Neurostimulators.	
Code	(i) Cervical Fusion with Disc Removal
22551	Fusion of spine bones with removal of disc at upper spinal column, anterior approach, complex, initial
22552	Fusion of spine bones with removal of disc in upper spinal column below second vertebra of neck , anterior approach, each additional interspace
Code	(ii) Implanted Spinal Neurostimulators
63650	Implantation of spinal neurostimulator electrodes, accessed through the skin
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver

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XVIII. Clinical Laboratory Fee Schedule: Revisions to the Laboratory Date of Service Policy

A. Background on the Medicare Part B Laboratory Date of Service Policy

The date of service (DOS) is a required data field on all Medicare claims for laboratory services. However, a laboratory service may take place over a period of time—the date the laboratory test is ordered, the date the specimen is collected from the patient, the date the laboratory accesses the specimen, the date the laboratory performs the test, and the date results are produced may occur on different dates. In the final rule on coverage and administrative policies for clinical diagnostic laboratory services published in the **Federal Register** on November 23, 2001 (66 FR 58791 through 58792), we adopted a policy under which the DOS for clinical diagnostic laboratory services generally is the date the specimen is collected. In that final rule, we also established a policy that the DOS for laboratory tests that use an archived specimen is the date the specimen was obtained from storage (66 FR 58792).

In 2002, we issued Program Memorandum AB–02–134, which permitted contractors discretion in making determinations regarding the length of time a specimen must be stored to be considered ''archived.'' In response to comments requesting that we issue a national standard to clarify when a stored specimen can be considered ''archived,'' in the Procedures for Maintaining Code Lists in the Negotiated National Coverage Determinations for Clinical Diagnostic Laboratory Services final notice, published in the **Federal Register** on February 25, 2005 (70 FR 9357), we defined an ''archived'' specimen as a specimen that is stored for more than 30 calendar days before testing. Specimens stored for 30 days or less continued to have a DOS of the date the specimen was collected.

B. Medicare DOS Policy and the ''14-Day Rule''

In the final rule with comment period entitled, in relevant part, ''Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B'' published in the **Federal Register** on December 1, 2006 (December 1, 2006 MPFS final rule) (71 FR 69705 through 69706), we added a new § 414.510 in title 42 of the CFR regarding the clinical laboratory DOS requirements and revised our DOS policy for stored specimens. We explained in that MPFS final rule that the DOS of a test may affect payment for the test, especially in situations in which a specimen that is collected while the patient is being treated in a hospital setting (for example, during a surgical procedure) is later used for testing after the patient has been discharged from the hospital. We noted that payment for the test is usually bundled with payment for the hospital service, even when the results of the test did not guide treatment during the hospital stay. To address concerns raised for tests related to cancer recurrence and therapeutic interventions, we finalized modifications to the DOS policy in § 414.510(b)(2)(i) for a test performed on a specimen stored less than or equal to 30 calendar days from the date it was collected (a non-archived specimen), so that the DOS is the date the test was

performed (instead of the date of collection) if the following conditions are met:

- The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;
- The specimen was collected while the patient was undergoing a hospital surgical procedure;
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test do not guide treatment provided during the hospital stay; and
- The test was reasonable and medically necessary for the treatment of an illness.

As we stated in the December 1, 2006 MPFS final rule, we established these five criteria, which we refer to as the ''14-day rule,'' to distinguish laboratory tests performed as part of posthospital care from the care a beneficiary receives in the hospital. When the 14-day rule applies, laboratory tests are not bundled into the hospital stay, but are instead paid separately under Medicare Part B (as explained in more detail below).

We also revised the DOS requirements for a chemotherapy sensitivity test performed on live tissue. As discussed in the December 1, 2006 MPFS final rule (71 FR 69706), we agreed with commenters that these tests, which are primarily used to determine posthospital chemotherapy care for patients who also require hospital treatment for tumor removal or resection, appear to be unrelated to the hospital treatment in cases where it would be medically inappropriate to collect a test specimen other than at the time of surgery, especially when the specific drugs to be tested are ordered at least 14 days following hospital discharge. As a result, we revised the DOS policy for chemotherapy sensitivity tests, based on our understanding that the results of these tests, even if they were available immediately, would not typically affect the treatment regimen at the hospital. Specifically, we modified the DOS for chemotherapy sensitivity tests performed on live tissue in § 414.510(b)(3) so that the DOS is the date the test was performed if the following conditions are met:

- The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;
- The specimen was collected while the patient was undergoing a hospital surgical procedure;
- It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
- The results of the test do not guide treatment provided during the hospital stay; and
- The test was reasonable and medically necessary for the treatment of an illness.

We explained in the December 1, 2006 MPFS final rule that, for chemotherapy sensitivity tests that meet this DOS policy, Medicare would allow separate payment under Medicare Part B; that is, separate from the payment for hospital services.

C. Billing and Payment for Laboratory Services Under the OPPS

As noted previously, the DOS requirements at 42 CFR 414.510 are used to determine whether a hospital bills Medicare for a clinical diagnostic laboratory test (CDLT) or whether the laboratory performing the test bills Medicare directly. Separate regulations at 42 CFR 410.42(a) and 411.15(m) generally provide that Medicare will not pay for a service furnished to a hospital patient during an encounter by an entity other than the hospital unless the hospital has an arrangement (as defined in 42 CFR 409.3) with that entity to furnish that particular service to its patients, with certain exceptions and exclusions. These regulations, which we refer to as the ''under arrangements'' provisions in this discussion, require that if the DOS falls during an inpatient or outpatient stay, payment for the laboratory test is usually bundled with the hospital service.

Under our current rules, if a test meets all DOS requirements in § 414.510(b)(2)(i) or (b)(3) or (5), the DOS is the date the test was performed. In this situation, the laboratory would bill Medicare directly for the test and would be paid under the Clinical Laboratory Fee Schedule (CLFS) directly by Medicare. However, if the test does not meet the DOS requirements in § 414.510(b)(2)(i) or (b)(3) or (5), the DOS would be the date the specimen was collected from the patient. In that case, the hospital would bill Medicare for the test and then would pay the laboratory that performed the test, if the laboratory provided the test under arrangement.

In previous rulemakings, we have reviewed appropriate payment under the OPPS for certain diagnostic tests that are not commonly performed by hospitals. In CY 2014, we finalized a policy to package certain CDLTs under the OPPS (78 FR 74939 through 74942 and 42 CFR 419.2(b)(17) and 419.22(l)). In CYs 2016 and 2017, we made some modifications to this policy (80 FR 70348 through 70350 and 81 FR 79592 through 79594). Under our current policy, certain CDLTs that are listed on the CLFS are packaged as integral, ancillary, supportive, dependent, or adjunctive to the primary service or services provided in the hospital outpatient setting during the same outpatient encounter and billed on the same claim. Specifically, we package most CDLTs under the OPPS. However, when a CDLT is listed on the CLFS and meets one of the following four criteria, we do not pay for the test under the OPPS, but rather, we pay for it under the CLFS when it is: (1) The only service provided to a beneficiary on a claim; (2) considered a preventive service; (3) a molecular pathology test; or (4) an advanced diagnostic laboratory test (ADLT) that meets the criteria of section 1834A(d)(5)(A) of the Act (78 FR 74939 through 74942; 80 FR 70348 through 70350; and 81 FR 79592 through 79594). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70348 through 70350), we excluded all molecular pathology laboratory tests from packaging because we believed these relatively new tests may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged.

For similar reasons, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79592 through 79594), we extended the exclusion to also apply to all ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act. We stated that we will assign status indicator ''A'' (Separate payment under the CLFS) to ADLTs once a laboratory test is designated an ADLT under the CLFS. Laboratory tests that meet one of the four criteria above and that are listed on the CLFS are paid under the CLFS, rather than being packaged and paid for under the OPPS.

D. ADLTs Under the New Private Payor Rate-Based CLFS

Section 1834A of the Act, as established by section 216(a) of Public Law 113–93, the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for CDLTs under the CLFS. Section 216(a) of PAMA also established a new subcategory of CDLTs known as ADLTs, with separate reporting and payment requirements under section 1834A of the Act. In the CLFS final rule published in the **Federal Register** on June 23, 2016, entitled ''Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System Final

Rule'' (81 FR 41036), we implemented the requirements of section 1834A of the Act.

As defined in § 414.502, an ADLT is a CDLT covered under Medicare Part B that is offered and furnished only by a single laboratory, and cannot be sold for use by a laboratory other than the single laboratory that designed the test or a successor owner. Also, an ADLT must meet either Criterion (A), which implements section 1834A(d)(5)(A) of the Act, or Criterion (B), which implements section 1834A(d)(5)(B) of the Act, as follows:

- *Criterion (A):* The test is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins; when combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy(ies); provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and may include other assays.

Or:

- *Criterion (B):* The test is cleared or approved by the FDA.

Generally, under the revised CLFS, ADLTs are paid using the same methodology based on the weighted median of private payor rates as other CDLTs. However, updates to ADLT payment rates occur annually instead of every 3 years. The payment methodology for ADLTs is detailed in the June 23, 2016 CLFS final rule (81 FR 41076 through 41083). For additional information regarding ADLTs, we refer readers to the CMS website: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.html*.

E. Additional Laboratory DOS Policy Exception for the Hospital Outpatient Setting

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59393 through 59400), we established an additional exception at § 414.510(b)(5) so that the DOS for molecular pathology tests and certain ADLTs that are excluded from the OPPS packaging policy is the date the test was performed (instead of the date of specimen collection) if certain conditions are met. Under the exception that we finalized at § 414.510(b)(5), in the case of a molecular pathology test or a test designated by CMS as an ADLT under paragraph (1) of the definition of an ADLT in § 414.502, the DOS of the test must be the date the test was performed only if:

- The test was performed following a hospital outpatient's discharge from the hospital outpatient department;
- The specimen was collected from a hospital outpatient during an encounter (as both are defined in 42 CFR 410.2);
- It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;
- The results of the test do not guide treatment provided during the hospital outpatient encounter; and
- The test was reasonable and medically necessary for the treatment of an illness.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59397), we explained that we believed the laboratory DOS policy in effect prior to CY 2018 created administrative complexities for hospitals and laboratories with regard to molecular pathology tests and laboratory tests expected to be designated by CMS as ADLTs that meet the criteria of section 1834A(d)(5)(A) of the Act. We noted that under the laboratory DOS policy in effect prior to CY 2018, if the tests were ordered less than 14 days following a hospital outpatient's discharge from the hospital outpatient department, laboratories generally could not bill Medicare directly for the molecular pathology test or ADLT. In those circumstances, the hospital had to bill Medicare for the test, and the laboratory had to seek payment from the hospital. We noted that commenters informed us that because ADLTs are performed by only a single laboratory and molecular pathology tests are often performed by only a few laboratories, and because hospitals may not have the technical ability to perform these complex tests, the hospital may be reluctant to bill Medicare for a test it would not typically (or never) perform. The commenters also stated that as a result, the hospital might delay ordering the test until at least 14 days after the patient is discharged from the hospital outpatient department, or even cancel the order to avoid the DOS policy, which may restrict a patient's timely access to these tests. In addition, we noted that we had heard from commenters that the laboratory DOS policy in effect prior to CY 2018 may have disproportionately limited access for Medicare beneficiaries under Medicare Parts A and B, because Medicare Advantage plans under Medicare Part C and other private payors allow laboratories to bill directly for tests they perform.

We also recognized that greater consistency between the laboratory DOS rules and the current OPPS packaging policy would be beneficial and would address some of the administrative and billing issues created by the DOS policy in effect prior to CY 2018. We noted that we exclude all molecular pathology tests and ADLTs under section 1834A(d)(5)(A) of the Act from the OPPS packaging policy because we believe these tests may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged, and we had already established exceptions to the DOS policy that permit the DOS to be the date of performance for certain tests that we believe are not related to the hospital treatment and are used to determine posthospital care. We stated that we believed a similar exception is justified for the molecular pathology tests and ADLTs excluded from the OPPS packaging policy, which we understood are used to guide and manage the patient's care after the patient is discharged from the hospital outpatient department. We noted that we believed that, like the other tests currently subject to DOS exceptions, these tests can legitimately be distinguished from the care the patient receives in the hospital, and thus we would not be unbundling services that are appropriately associated with hospital treatment. Moreover, we reiterated that these tests are already paid separately outside of the OPPS at CLFS payment rates. Therefore, we agreed with the commenters that the laboratory performing the test should be permitted to bill Medicare directly for these tests, instead of relying on the hospital to bill Medicare on behalf of the laboratory under arrangements.

Following publication of the CY 2018 OPPS/ASC final rule with comment period, we issued Change Request (CR) 10419, Transmittal 4000, the claims processing instruction implementing the laboratory DOS exception at § 414.510(b)(5), with an effective date of January 1, 2018 and an implementation date of July 2, 2018. After issuing CR 10419, we heard from stakeholders that many hospitals and laboratories were having administrative difficulties implementing the DOS exception set forth at § 414.510(b)(5). On July 3, 2018, we announced that, for a 6-month period, we would exercise enforcement discretion with respect to the laboratory DOS exception at § 414.510(b)(5). We explained that stakeholder feedback suggested many providers and suppliers would not be able to implement the laboratory DOS exception by the July 2, 2018 implementation date established

by CR 10419, and that such entities required additional time to develop the systems changes necessary to enable the performing laboratory to bill for tests subject to the exception. We noted that this enforcement discretion would apply to all providers and suppliers with regard to ADLTs and molecular pathology tests subject to the laboratory DOS exception policy, and that during the enforcement discretion period, hospitals may continue to bill for these tests that would otherwise be subject to the laboratory DOS exception.

We then extended the enforcement discretion period for two additional, consecutive 6-month periods, after learning that there were still many entities needing additional time to come into compliance. The final enforcement discretion announcement as well as CR 10419, Transmittal 4000 is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy.html*. The enforcement discretion period ended on January 2, 2020.

During the period of enforcement discretion, we continued to gage the industry's readiness to implement the laboratory DOS exception at § 414.510(b)(5). In particular, we heard from stakeholders that some entities performing molecular pathology testing subject to the laboratory DOS exception, such as blood banks and blood centers, may not be enrolled in the Medicare program and may not have established a mechanism to bill Medicare directly. In the CY 2020 OPPS/ASC proposed rule (84 FR 39603), we sought comments on excluding blood banks and blood centers from the laboratory DOS exception at § 414.510(b)(5). Based on concerns raised by stakeholders, we stated that we believe blood banks and centers perform molecular pathology testing for patients to enable hospitals to prevent adverse conditions associated with blood transfusions, rather than perform molecular pathology testing for diagnostic purposes. Given the different purpose of molecular pathology testing performed by the blood banks and centers, that is, blood compatibility testing, we questioned whether the molecular pathology testing performed by blood banks and centers is appropriately separable from the hospital stay, given that it typically informs the same patient's treatment during a future hospital stay. We stated that we were concerned that our current policy may unbundle molecular testing performed by a blood bank or center for a hospital patient.

For these reasons, and based on the support received from commenters, in the CY 2020 OPPS/ASC final rule (84 FR 61444), we finalized a revision to the laboratory DOS policy to exclude molecular pathology tests when performed by laboratories that are blood banks or centers from the laboratory DOS exception at 42 CFR 414.510(b)(5). We also finalized a definition for ''blood bank or center'' at § 414.502 as an entity whose primary function is the performance or responsibility for the performance of, the collection, processing, testing, storage and/or distribution of blood or blood components intended for transfusion and transplantation.

A list of the specific laboratory tests currently subject to the laboratory DOS exception at § 414.510(b)(5) is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy.html*.

F. Revisions to the Laboratory DOS Policy for Cancer-Related Protein-Based MAAAs

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61438 through 61439), we explained that protein-based Multianalyte Assays with Algorithmic Analyses tests (MAAAs) that are not considered molecular pathology tests and are not designated as ADLTs under paragraph (1) of the definition of ADLT in § 414.502, were packaged under the OPPS at that time. Though they did not qualify for the DOS exception at § 414.510(b)(5) solely because they were MAAAs, we noted that several stakeholders had suggested that the pattern of clinical use of some of these protein-based MAAAs make them relatively unconnected to the primary hospital outpatient service.

In particular, stakeholders suggested that certain protein-based MAAAs, specifically, those described by CPT codes 81490, 81503, 81535, 81536, 81538, and 81539, are generally not performed in the HOPD setting and have similar clinical patterns of use as other tests that are not paid under the OPPS and are paid separately under the CLFS, and so should be treated similarly (82 FR 59299). Consequently, the stakeholders believed that protein-based MAAAs should be excluded from OPPS packaging and paid separately under the CLFS. Notably, with one exception (CPT code 81490), each of those tests described by the CPT codes identified by stakeholders was a cancer-related protein-based MAAA. We did not establish an exception to the laboratory DOS policy for protein-based MAAAs in the CY 2020 OPPS/ASC final rule with comment period, but we did note that a protein-based MAAA that is designated by CMS as an ADLT under paragraph (1) of the definition of an ADLT in § 414.502 would be eligible for the DOS exception at § 414.510(b)(5). We indicated in that rule that we intended to consider policies regarding the application of the DOS policy to MAAAs for future rulemaking (84 FR 61439).

In the CY 2021 OPPS/ASC proposed rule (85 FR 49032 through 49036), we stated that after further consideration of this issue, we now believe certain MAAAs, specifically, cancer-related protein-based MAAAs, which stakeholders identified, as discussed above, have a pattern of clinical use that make them relatively unconnected to the primary hospital outpatient service during which the specimen was collected because the results of these tests are typically used to determine posthospital care. We stated that these tests are distinguishable from the care the patient receives in the hospital, similar to molecular pathology tests and tests designated as ADLTs under paragraph (1) of the definition of ADLT in § 414.502, which are currently excluded from the OPPS packaging policy and subject to the laboratory DOS exception at § 414.510(b)(5). Therefore, we proposed to exclude cancer-related protein-based MAAAs from the OPPS packaging policy, as discussed in section II.a.3. of the CY 2021 OPPS/ASC proposed rule, and create an exception to the laboratory DOS rule for them. We noted that these proposals, if finalized, would mean that Medicare would pay for cancer-related protein-based MAAAs under the CLFS instead of the OPPS and the performing laboratory would bill Medicare directly for the test if the test meets all the laboratory DOS requirements specified in § 414.510(b)(5).

We further explained in the CY 2021 OPPS/ASC proposed rule (85 FR 49036) that we understand that, similar to molecular pathology tests and ADLTs under paragraph (1) of the definition of an ADLT in § 414.502, cancer-related protein-based MAAAs are typically used to guide and manage the patient's care after the patient is discharged from the hospital outpatient department because the test results are used to determine potential future oncologic surgical and chemotherapeutic interventions; they would almost never affect the treatment regimen during the same hospital outpatient service in which the specimen was collected, even if the results were available immediately. In other words, decisions as to particular therapies and/or surgical procedures, as guided by the results of

the test, are not made during the same hospital outpatient encounter during which the specimen was collected.

For these reasons, we proposed to add cancer-related protein-based MAAAs to our current laboratory DOS exception rule at § 414.510(b)(5). Under this proposed revision, the DOS for a cancer-related protein-based MAAA would be the date the test was performed if: (1) The test was performed following a hospital outpatient's discharge from the hospital outpatient department; (2) the specimen was collected from a hospital outpatient during an encounter (as both are defined in § 410.2); (3) it was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter; (4) the results of the test do not guide treatment provided during the hospital outpatient encounter; and (5) the test was reasonable and medically necessary for the treatment of an illness.

We noted that this proposed revision to our laboratory DOS policy would require laboratories performing cancer-related protein-based MAAAs, that are excluded from the OPPS packaging policy and meet the DOS requirements at § 414.510(b)(5), to bill Medicare directly for those tests instead of seeking payment from the hospital. We stated that, similar to molecular pathology tests and ADLTs under paragraph (1) of the definition of ADLT in § 414.502, we believe that cancer-related protein-based MAAAs are distinguishable from the care the patient receives during the primary hospital outpatient encounter because, as noted above, the results of the test would almost never affect the treatment regimen during the same hospital outpatient encounter in which the specimen was collected. Therefore, we noted, if we were to finalize our proposal, we believe we would not be unbundling laboratory tests that are appropriately associated with the primary hospital outpatient service.

As discussed in section II.a.3. of the CY 2021 OPPS/ASC proposed rule, the AMA CPT 2020 manual describes a MAAA, in part, as ''procedures that utilize multiple results derived from panels of analyses of various types, including molecular pathology assays, fluorescent in situ hybridization assays, and non-nucleic acid based assays (for example, proteins, polypeptides, lipids, carbohydrates).'' Additionally, the AMA CPT 2020 manual provides a MAAA code descriptor format that includes several specific characteristics, including but not limited to disease type (for example, oncology, autoimmune, tissue rejection), and material(s) analyzed (for example, DNA, RNA, protein, antibody). We noted in the proposed rule that, because the AMA CPT 2020 manual describes a MAAA, and the code descriptor of each MAAA distinguishes MAAAs that are cancer-related assays from those that test for other disease types, the AMA CPT manual is a potentially instructive tool to identify cancer-related MAAA tests that are ''protein-based''. Accordingly, we stated that using the AMA CPT 2020 manual criteria to identify MAAA tests that are cancer-related, and, of those tests, identifying the ones whose test analytes are proteins, we have determined there are currently six cancer-related protein-based MAAAs: CPT codes 81500, 81503, 81535, 81536, 81538 and 81539. We also noted that CPT code 81538 has been designated as an ADLT under section 1834A(d)(5)(A) of the Act as of December 21, 2018, and therefore, is currently already subject to the laboratory DOS exception in § 414.510(b)(5). Therefore, the cancer-related protein-based MAAAs that we proposed to exclude from the OPPS packaging policy and subject to an exception from the laboratory DOS policy under our proposals are CPT codes 81500, 81503, 81535, 81536 and 81539. We stated that these tests have not been designated by CMS as ADLTs under paragraph (1) of the definition of ADLT in § 414.502 and so were not currently subject to the laboratory DOS exception in § 414.510(b)(5). We proposed to apply this policy to cancer-related protein-based MAAAs that do not currently exist, but that are developed in the future.

We received approximately 40 public comments on the proposed modification to the laboratory DOS policy for cancer-related protein-based MAAAs. The following is a summary of the comments we received and our responses.

Comment: Generally, most commenters supported the proposed revisions to the laboratory DOS policy, expressing that changes to this policy will lead to improved beneficiary access to precision diagnostic tests and targeted treatment by removing barriers that once led to delayed and canceled laboratory test orders while also reducing hospital administrative burden. Commenters noted that excepting cancer-related protein-based MAAAs from the DOS policy and allowing laboratories to bill Medicare for them directly, will minimize delays in testing and enable patient diagnosis, treatment decision-making, and initiation of care to proceed without interruption or unnecessary delay.

Additionally, some commenters stated that cancer-related protein-based MAAA test codes almost never impact the treatment regimen during the same hospital outpatient service in which the specimen is collected, and the commenters therefore believe it is appropriate to exclude these services from the OPPS packaging policy, as discussed in section II.A. of this final rule, and include these test codes on the list of codes subject to the laboratory DOS exception.

Response: We appreciate the support from commenters for our proposed revisions to the laboratory DOS policy for cancer-related protein-based MAAAs. We agree that the expansion of the laboratory DOS policy exception at § 414.510(b)(5) to include cancer-related protein-based MAAAs is beneficial and appropriate, as these tests have a pattern of clinical use that make them relatively unconnected to the primary hospital outpatient service during which the specimen was collected and the results of these tests are typically used to determine post-hospital care and generally reduces delay with respect to access to these tests and subsequent results.

Comment: Some commenters suggested that CMS consider expanding the list of codes excluded from OPPS packaging and adding to the list of tests included in the laboratory DOS exception at § 414.510(b)(5). Specifically, commenters recommended adding all AMA CPT Proprietary Laboratory Analysis (PLA) test codes that may have similar characteristics to AMA CPT MAAA test codes but are not currently categorized as AMA CPT MAAA test codes. Some commenters asserted that the AMA CPT Committee has clearly stated that MAAAs can be assigned PLA codes, and therefore the assignment of a PLA code by the AMA CPT, as opposed to a Category 1 CPT code under the MAAA section of the CPT Manual, should not dictate whether the code is included under the laboratory DOS exception at § 414.510(b)(5). Additionally, commenters suggested that CMS identify the protein-based MAAAs in the PLA section of the AMA CPT manual by determining which codes' descriptors include both multiple proteins and reference to an algorithm.

Commenters also noted that while PLA test codes are not automatically included under § 414.510(b)(5) and the outpatient laboratory packaging exclusion, some tests described by PLA codes are often included under these policies if they qualify as a molecular pathology test or Criterion A ADLT. Therefore, the commenters stated that CMS should continue its historical practice in applying the laboratory DOS policy and OPPS laboratory packaging exclusion to PLA test codes as occurs

with molecular pathology tests and ADLTs that have been assigned PLA codes.

One commenter also requested that CMS include in the laboratory DOS exception under § 414.510(b)(5) MAAA cancer tests of proteins or metabolites. The commenter stated that metabolite biomarkers such as increased levels of metanephrines in the blood or urine are used to diagnose adrenal cancers, such aspheochromocytoma, and represent new and ''under development'' diagnostic MAAA tests. Another commenter requested that CMS evaluate tests for diseases other than cancer to determine if the tests have a distinct pattern of clinical use that make them relatively unconnected to a patient's hospital encounter and therefore should be considered for policy modifications in future rulemaking. Another commenter suggested that CMS modify the regulatory language for the laboratory DOS to include both cancer-related protein-based or metabolite-based MAAA tests, stating that there is a continuum between proteins, amino acids, amino acid modifications or dimers, and metabolites, and drawing fine lines between these biochemical classes is not relevant for this policy.

Response: We appreciate the commenters' suggestions about other test codes that CMS should consider including under the laboratory DOS exception policy at § 414.510(b)(5). We note that our proposal in the CY 2021 OPPS/ASC proposed rule focused on certain protein-based MAAA tests identified by stakeholders. As we discuss previously, we started with the 6 MAAA tests brought to our attention and concluded that the subset of cancer-related protein-based MAAA tests are distinguishable from the care the patient receives during the primary hospital outpatient encounter because the results of the test would almost never affect the treatment regimen during the same hospital outpatient encounter in which the specimen was collected. Further, we explained that the AMA CPT manual easily identifies these tests, which made it straightforward to ensure we captured all cancer-related protein-based MAAA tests currently available.

With regard to PLA tests, according to the AMA CPT Committee, PLA codes ''are alpha-numeric CPT codes with a corresponding descriptor for labs or manufacturers that want to more specifically identify their test. Tests with PLA codes must be performed on human specimens and must be requested by the clinical laboratory or the manufacturer that offers the test.'' [365] We understand PLA codes were created by the AMA CPT Committee so laboratories and manufacturers could have corresponding descriptors to more specifically identify their test as required by PAMA. The PLA category as a whole does not address the clinical use of the test. Therefore, in order for CMS to consider certain PLA tests as potential additions to the DOS exception policy, CMS would need to establish that, like the molecular pathology tests and ADLTs currently excepted from the DOS policy under § 414.510(b)(5), the nature and function of all PLA tests are such that they are appropriately separable from the hospital outpatient encounter and therefore laboratory services for which the performing laboratory must bill Medicare. At this time, CMS cannot establish that every PLA test, MAAA test, or ''MAAA-like'' PLA test, including those that are protein-based, are generally used to guide treatment outside of the outpatient clinical encounter and have a distinct pattern of clinical use that make them relatively unconnected to a patient's hospital encounter. For example, there are currently over 240 codes in the PLA category. In contrast to non-PLA codes which are categorized into groups such as immunoassays, chemistry, molecular pathology tests, MAAAs, etc., PLAs are not separated in separate categories like Category 1 CPT codes. Additions to the PLA code list are frequent and the array of tests included in the PLA category is varied. As such, inclusion in the category of PLA codes alone does not provide sufficient basis for payment policy decisions categorically. However, we note that a protein-based MAAA test that is designated by CMS as an ADLT under paragraph (1) of the definition of an ADLT in § 414.502 would be eligible for the laboratory DOS exception at § 414.510(b)(5).

Therefore, CMS does not believe that all PLA tests, MAAA tests, or ''MAAA-like'' PLA test codes, as a group, should be considered for the laboratory DOS exception at § 414.510(b)(5) at this time. However, we plan to continue to evaluate the laboratory DOS policy and consider whether any additional changes may be merited, and may consider proposing future changes to the laboratory DOS policy through notice-and-comment rulemaking.

Nevertheless, we continue to believe that cancer-related protein-based MAAA tests have a pattern of clinical use that make them relatively unconnected to the primary hospital outpatient service during which the specimen was collected because the results of these tests are typically used to determine post-hospital care. In previous rulemakings, commenters have identified certain protein-based MAAAs and informed us that the cancer-related tests are typically used to guide and manage the patient's care after the patient is discharged from the hospital outpatient department and the test results generally are used to determine potential future oncologic surgical and chemotherapeutic interventions. We understand the results would almost never affect the treatment regimen during the same hospital outpatient service in which the specimen was collected, even if the results were available immediately. Consequently, decisions as to particular therapies and/or surgical procedures, as guided by the results of the test, generally are not made during the same hospital outpatient encounter during which the specimen was collected.

Consequently, we believe that cancer-related protein-based MAAA tests should be excluded from OPPS packaging and paid separately under the CLFS and included under the laboratory DOS exception policy at § 414.510(b)(5).

Comment: Commenters requested that we add several specific PLA codes to the laboratory DOS policy exception at § 414.510(b)(5) because they believe these tests meet the AMA CPT description of MAAA tests, analyze proteins, and/or are cancer-related, while also meeting the DOS standard of having a pattern of clinical use that is unrelated to the primary outpatient service when the specimen is collected at an outpatient encounter. Specifically, commenters recommended adding the OVERA test from Aspira Labs (CPT 0003U), EPI assay by Bio-Techne (CPT 0005U), TissueCypher assay from Cernostics (CPT 0108U), and KidneyIntelX (0105U).

Commenters asserted that the results of these tests are used to determine a longer-term care treatment for the patient, and the results are typically discussed at a follow up appointment with the ordering physician. Additionally, the commenters noted that the clinical use of these tests is similar to the clinical use of the cancer-related protein-based MAAA tests. Commenters stated that it would be inconsistent for CMS to require hospitals to bill Medicare for the PLA tests that commenters believe meet the AMA CPT description of MAAA tests, analyze proteins, and/or are cancer-related, and also demonstrate a pattern of clinical use that is unrelated to the

[365] *https://www.ama-assn.org/practice-management/cpt/cpt-pla-codes.*

primary outpatient service when the specimen is collected at an outpatient encounter, while requiring the performing laboratory to bill Medicare for the non-PLA cancer-related protein based MAAAs.

Response: We appreciate the commenters' suggestion that we consider adding the OVERA test from Aspira Labs (CPT 0003U), TissueCypher assay from Cernostics (CPT 0108U), EPI assay by Bio-Techne (CPT 0005U), and KidneyIntelX (CPT 0105U), to the laboratory DOS exception at § 414.510(b)(5). These PLA tests are relatively new, with none to minimal Medicare utilization, and at this time we do not have a sufficient understanding regarding how these tests may be used to guide treatment outside of the outpatient encounter and whether they should be unpackaged under OPPS. The tests would need to demonstrate a pattern of clinical use that make them relatively unconnected to the primary hospital outpatient service during which the specimen was collected and the results of these tests are typically used to determine post-hospital care. At this time, we cannot establish that these tests would generally be utilized for guiding treatment outside of the hospital encounter. Nevertheless, we intend to continue to study the laboratory DOS policy and determine whether any additional changes are warranted and may consider proposing changes to the laboratory DOS policy through notice-and-comment rulemaking in the future.

Comment: Commenters also recommended the inclusion of a particular protein-based MAAA test, CPT code 81490, in the laboratory DOS exception at § 414.510(b)(5). Commenters asserted that the use of this rheumatoid arthritis (RA) test is unconnected to the hospital outpatient encounter during which the specimen is collected and is instead used to determine potential future interventions outside of the hospital outpatient encounter; it is used by the rheumatologist to make longer-term changes in RA treatment. The commenters stated that this RA test appears to be generally less tied to a primary service in the hospital outpatient setting and does not appear to be a common or routine laboratory test that would otherwise be packaged into OPPS payment.

Response: In the CY 2021 OPPS/ASC proposed rule (85 FR 48799), we stated that we believed the results for the test described by CPT code 81490 are used to determine disease activity in rheumatoid arthritis patients, guide current therapy to reduce further joint damage, and may be tied to the primary hospital outpatient service, that is, the hospital outpatient encounter during which the specimen was collected. Therefore, we stated that we believed that payment for CPT code 81490 remains appropriately packaged under the OPPS.

However, given commenter feedback, we are convinced that the pattern of clinical use for CPT code 81490 is generally unconnected to the hospital outpatient encounter during which the specimen is collected, as it is typically used to determine potential interventions outside of the hospital outpatient encounter and is generally used by the rheumatologist to make longer-term changes in RA treatment. Commenters informed us that physicians and patients utilize the objective information provided by the results of the test to make longer-term modifications in treatment, to monitor disease activity, and to prevent joint damage progression, and the results would generally not be utilized for the purposes of the hospital outpatient encounter. The commenters further stated that the output of the test is used to assess disease activity, including evaluating response to therapy, directing choice of second-line treatment in patients with inadequate response to the current first line therapy, and identifying patients in stable remission for therapy reduction. The test results appear to guide longer-term therapies and treatments; therefore, we believe that this test, identified by CPT code 81490, is generally less tied to the primary service the patient receives in the hospital outpatient setting and does not appear to be a common or routine laboratory test that would otherwise be packaged into OPPS payment. Given the similarity in clinical pattern of use, we believe that we have sufficient information to add CPT code 81490 to the list of tests included in the laboratory DOS exception at § 414.510(b)(5) at this time. In conclusion, for the reasons discussed previously in this section, we believe that cancer-related protein-based MAAAs, such as CPT codes 81500, 81503, 81535, 81536 and 81539, appear to have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that are packaged. Given the similarity in clinical pattern of use, we believe that CPT code 81490 should also be added to the list of tests in the laboratory DOS exception at § 414.510(b)(5). We believe these tests should therefore be excluded from OPPS packaging policy and subject to the laboratory DOS exception at § 414.510(b)(5) as described in section II.A. of this final rule. We intend to continue to study the list of laboratory tests included the laboratory DOS exception policy and to determine whether any additional changes are warranted and may consider proposing future changes to this policy through notice-and-comment rulemaking.

For these reasons and in light of the commenters' suggestions, we are revising the current laboratory DOS exception at 42 CFR 414.510(b)(5) to include cancer-related protein-based MAAAs, such as CPT codes 81500, 81503, 81535, 81536, 81539, as well as the test described by CPT code 81490. We are also finalizing that we will exclude cancer-related protein-based MAAAs that do not currently exist, but that are developed in the future, from the laboratory DOS policy.

XIX. Physician-Owned Hospitals

A. Background

Section 1877 of the Social Security Act (the Act), also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless all requirements of an applicable exception are satisfied; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for any improperly referred designated health services. A financial relationship may be an ownership or investment interest in the entity or a compensation arrangement with the entity. The statute establishes a number of specific exceptions and grants the Secretary of the Department of Health and Human Services (the Secretary) the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. Section 1903(s) of the Act extends aspects of the physician self-referral prohibitions to Medicaid.

Section 1877(d) of the Act sets forth exceptions related to ownership or investment interests held by a physician (or an immediate family member of a physician) in an entity that furnishes designated health services. Section 1877(d)(2) of the Act provides an exception for ownership or investment interests in rural providers (the ''rural provider exception''). In order to qualify for the rural provider exception, the designated health services must be

furnished in a rural area (as defined in section 1886(d)(2) of the Act), substantially all of the designated health services furnished by the entity must be furnished to individuals residing in a rural area, and, in the case where the entity is a hospital, the hospital meets the requirements of section 1877(i)(1) of the Act no later than September 23, 2011. Section 1877(d)(3) of the Act provides an exception for ownership or investment interests in a hospital located outside of Puerto Rico (the ''whole hospital exception''). In order to qualify for the whole hospital exception, the referring physician must be authorized to perform services at the hospital, the ownership or investment interest must be in the hospital itself (and not merely in a subdivision of the hospital), and the hospital meets the requirements of section 1877(i)(1) of the Act no later than September 23, 2011.

B. Prohibition on Facility Expansion

Section 6001(a)(3) of the Affordable Care Act amended the rural provider and whole hospital exceptions to provide that a hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but did have a provider agreement in effect on December 31, 2010, the effective date of such provider agreement). Section 6001(a)(3) of the Affordable Care Act added new section 1877(i)(3)(A)(i) of the Act, which required the Secretary to establish and implement an exception process to the prohibition on expansion of facility capacity for hospitals that qualify as an ''applicable hospital.'' Section 1106 of the Health Care and Education Reconciliation Act of 2010 (HCERA) amended section 1877(i)(3)(A)(i) of the Act to require the Secretary to establish and implement an exception process to the prohibition on expansion of facility capacity for hospitals that qualify as either an ''applicable hospital'' or a ''high Medicaid facility.'' These terms are defined at sections 1877(i)(3)(E) and 1877(i)(3)(F) of the Act.

The requirements for qualifying as an applicable hospital are set forth at § 411.362(c)(2) and the requirements for qualifying as a high Medicaid facility are set forth at § 411.362(c)(3). An applicable hospital means a hospital: (1) That is located in a county in which the percentage increase in the population during the most recent 5-year period (as of the date that the hospital submits its request for an exception to the prohibition on expansion of facility capacity) is at least 150 percent of the percentage increase in the population growth of the State in which the hospital is located during that period, as estimated by the Bureau of the Census; (2) whose annual percent of total inpatient admissions under Medicaid is equal to or greater than the average percent with respect to such admissions for all hospitals in the county in hospital is located during the most recent 12-month period for which data are available (as of the date that the hospital submits its request for an exception to the prohibition on expansion of facility capacity); (3) that does not discriminate against beneficiaries of federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries; (4) that is located in a state in which the average bed capacity in the state is less than the national average bed capacity; and (5) that has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located. The regulations at § 411.362(c)(2)(ii), (iv), and (v) specify acceptable data sources for determining whether a hospital qualifies as an applicable hospital. A ''high Medicaid facility'' means a hospital that: (1) Is not the sole hospital in a county; (2) with respect to each of the three most recent 12-month periods for which data are available, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located; and (3) does not discriminate against beneficiaries of federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries. Section 411.362(c)(3)(ii) specifies the acceptable data sources for determining whether a hospital qualifies as a high Medicaid facility. In the CY 2012 OPPS/ASC final rule, we issued regulations setting forth the process for a hospital to request an exception from the prohibition on facility expansion (the exception process) at § 411.362(c) and related definitions at § 411.362(a) (76 FR 74122).

Section 1877(i)(3)(B) of the Act provides that the exception process shall permit an applicable hospital to apply for an exception to the prohibition on expansion of facility capacity up to once every 2 years. In the CY 2012 OPPS/ASC final rule, we extended this provision to high Medicaid facilities using our authority under sections 1871 and 1877(i)(3)(A)(1) of the Act (76 FR 74525). There, we stated that, although the statute provides that an applicable hospital may request an exception up to once every 2 years, we believe that providing a high Medicaid facility the opportunity to request an exception once every 2 years (while also limiting its total growth) balances the Congress' intent to prohibit expansion of physician-owned hospitals with the purpose of the exception to the prohibition on expansion of facility capacity (76 FR 74524). We did not receive any public comments regarding the frequency of exception requests. Under current § 411.362(c)(1), both applicable hospitals and high Medicaid facilities may request an exception to the prohibition on expansion of facility capacity up to once every 2 years from the date of a CMS decision on the hospital's most recent request.

Section 1877(i)(3)(C)(ii) of the Act provides that the Secretary shall not permit an increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed to the extent such increase would result in the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed exceeding 200 percent of the baseline number of operating rooms, procedure rooms, and beds of the applicable hospital. In the CY 2012 OPPS/ASC final rule, using our rulemaking authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we adopted a parallel limit in the increase in the number of operating rooms, procedure rooms, and beds for which a high Medicaid facility may request an exception to the prohibition on expansion of facility capacity (76 FR 74524). There, we noted that, in response to our request for comment on whether the 200 percent limit would be sufficient to balance the intent of the general prohibition on facility expansion with the purpose of the exception process, which is to provide the opportunity to expand in areas where a sufficient need for access to high Medicaid facilities is demonstrated, commenters supported our proposal regarding the amount of permitted increase and at least one commenter specifically supported the parallel treatment of high Medicaid facilities (76 FR 74524). Under current § 411.362(c)(6)(i), a 200 percent limitation applies to both applicable hospitals and high Medicaid facilities.

Section 1877(i)(3)(D) of the Act provides that any increase in the number of operating rooms, procedure rooms, and beds for which an applicable

hospital is licensed may occur only in facilities on the main campus of the applicable hospital. In the CY 2012 OPPS/ASC final rule, using our rulemaking authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we extended this limitation on the location of expanded facility capacity to high Medicaid facilities, explaining that we believe that applying the same limitation to applicable hospitals and high Medicaid facilities will result in an efficient and consistent process (76 FR 74524). We did not receive any public comments regarding the location of the permitted increase. Under current § 411.362(c)(6)(ii), expanded facility capacity may occur only in facilities on the hospital's main campus.

In 2017, CMS launched the Patients over Paperwork initiative, a crosscutting, collaborative process that evaluates and streamlines regulations with a goal to reduce unnecessary burden, increase efficiencies, and improve the beneficiary experience. This effort emphasizes a commitment to removing regulatory obstacles to providers spending time with patients. As part of this initiative, we reviewed the regulations at § 411.362(c) as they apply to high Medicaid facilities. Certain of the statutory provisions regarding expansion of facility capacity apply only to applicable hospitals and their extension to high Medicaid facilities was effectuated using the Secretary's authority under sections 1871 and 1877(i)(3)(A)(i) of the Act. We continue to believe that our current regulations, for which the Secretary appropriately used his authority and which treat high Medicaid facilities the same as applicable hospitals, are consistent with the Congress' intent to prohibit expansion of physician-owned hospitals generally. Nevertheless, the Congress did not mandate this treatment of high Medicaid facilities and, in light of the Patients over Paperwork initiative, we reconsidered our policies. As we stated in the proposed rule, we believe that our current regulations impose unnecessary burden on high Medicaid facilities, which, by definition, serve significant numbers of Medicaid patients relative to other hospitals in the counties in which they are located (85 FR 49038). Because the statute does not apply to high Medicaid facilities those requirements related to the frequency of permitted requests for exceptions to the prohibition on expansion of facility capacity, the total amount of permitted expansion of facility capacity, or the location of permitted expanded facility capacity, using the Secretary's authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we proposed to remove certain regulatory requirements for high Medicaid facilities that are not included in the statute. Specifically, we proposed to revise § 411.362(c)(1) to permit a high Medicaid facility to request an exception to the prohibition on expansion of facility capacity more frequently than once every 2 years. To preserve CMS resources and to continue to maintain an orderly and efficient exception process, we proposed that a high Medicaid facility may submit only one exception request at a time. Under proposed § 411.362(c)(1), a high Medicaid facility could request an exception to the prohibition on expansion of facility capacity at any time, provided that it has not submitted another request for an exception to the prohibition on facility expansion for which CMS has not issued a decision. We also proposed to revise § 411.362(c)(6), with respect to high Medicaid facilities only, to remove the restriction that permitted expansion of facility capacity may not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed exceeding 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds, as well as the restriction that permitted expanded facility capacity must occur only in facilities on the hospital's main campus. Under proposed § 411.362(c)(6), these restrictions would apply only to applicable hospitals.

Section 1877(i)(3)(A)(ii) requires CMS to provide an opportunity for community input when an applicable hospital applies for an exception to the prohibition on expansion of facility capacity. Through regulation, we made the community input opportunity applicable to facility expansion requests submitted by high Medicaid facilities (76 FR 74523). However, the statute does not expressly require CMS to furnish an opportunity for community input when a high Medicaid facility has applied for such an exception. In the proposed rule, we stated that we are considering whether we should eliminate the opportunity for community input in the review process with respect to high Medicaid facilities (85 FR 49038). We noted specific interest in comments regarding the importance of community input, which allows for confirmation of (or disagreement with) the data provided by a high Medicaid facility seeking an exception to the prohibition on expansion of facility capacity, and how CMS could obtain independent confirmation of the data provided by a high Medicaid facility in the absence of the community input opportunity (see 76 FR 74523). We also noted that obtaining independent confirmation of the data furnished by a high Medicaid facility could delay or add complexity to the review process. We solicited comments regarding whether the additional delay and complexity caused by the elimination of the community input opportunity for requests by high Medicaid facilities would result in greater burden or cause greater harm to high Medicaid facilities than continuing to permit community input on the expansion exception requests submitted by these hospitals.

We are finalizing without modification our proposals to remove the limitations on high Medicaid facilities with respect to the frequency of exception requests, permitted amount of facility expansion, and location of expansion capacity. We are not revising our regulations regarding community input on the expansion requests submitted by hospitals that qualify as high Medicaid facilities.

We received the following comments regarding our proposals and our responses follow:

Comment: Many commenters supported our proposals to eliminate from regulation any limitations on the expansion of facility capacity for high Medicaid facilities not mandated in section 1877 of the Act. Some of the commenters stated that removing existing regulatory limitations would allow physician-owned hospitals to serve greater numbers of Medicaid patients. One commenter suggested that expanded capacity of physician-owned hospitals could increase competition and choice, as well as patient access to high-quality care. Another commenter stated that, if finalized, the removal of the restrictions on high Medicaid facilities that receive an exception to the prohibition on expansion of facility capacity would help increase access to vital health care services for the most vulnerable patients.

In contrast, numerous commenters opposed our proposals to remove limitations on expansion of facility capacity imposed on high Medicaid facilities by regulation. Some commenters noted that certain physician-owned hospitals that qualify as high Medicaid facilities have Medicaid discharge percentages that are extremely low and potentially significantly lower than that of hospitals in surrounding counties where they could locate the large facility expansion capacity permitted under our proposals. Another commenter stated that, if we finalize our proposals, physician-owned

hospitals could expand and move into markets without large Medicaid patient populations, creating additional campuses far away from the patients the expansion is intended by statute to serve. This commenter also asserted that removing the restrictions on high Medicaid facilities could incentivize physician-owned hospitals to ''game the limited exception'' by working to temporarily meet the high Medicaid facility threshold, then, once an exception from the prohibition on expansion of facility capacity is obtained, return to rejecting Medicaid patients because there is no requirement for a physician-owned hospital to maintain its status as a high Medicaid facility following the approval of an exception request.

Response: The plain language of the statute does not impose the same limitations on the expansion of high Medicaid facilities as it does the expansion of applicable hospitals. Therefore, the Secretary is not required under section 1877(b)(4) of the Act to retain the limitations imposed on high Medicaid facilities by regulation. As we explained in the proposed rule, we believe that the existing regulations impose unnecessary burden on high Medicaid facilities. In alignment with our Patients over Paperwork initiative, we are finalizing our proposals to remove this unnecessary burden.

To determine whether a hospital qualifies as a high Medicaid facility, the statute requires a relativity analysis based on the location of the existing hospital; that is, a hospital that has the highest Medicaid discharge percentage relative to the hospitals in the same county will qualify as a high Medicaid facility even if the overall number of Medicaid discharges in the county is low. Although we understand the commenters' concerns regarding actions that a hospital may take after the Secretary grants an exception to the prohibition on facility expansion, as one of the commenters noted, neither the statute nor our regulations require that a hospital maintain its qualification as a high Medicaid facility for any minimum period of time after it requests or receives an exception to the prohibition on expansion of facility capacity. Similarly, the statute does not require the Secretary to compare a high Medicaid facility to the hospitals in the county where it plans to locate the expansion capacity (if approved). However, we emphasize that any expansion of facility capacity must be part of the hospital for which the exception is approved. Medicare rules and regulations regarding the location of hospital facilities, including the expansion capacity, such as distance limitations related to the location of off campus facilities and provider-based departments remain applicable. (See section 1833(t)(B)(i) of the Act and § 413.65(e)(3)(v)(F).) With respect to the concern that a hospital granted an exception would ''return to rejecting Medicaid patients,'' we note that a hospital that rejects (or otherwise discriminates against Medicaid beneficiaries) does not qualify as an applicable hospital or a high Medicaid facility and, thus, would not qualify for an exception to the prohibition on expansion of facility capacity. Under § 411.362(c)(2)(iii) and (c)(3)(iii), to qualify as an applicable hospital or a high Medicaid facility, respectively, which is the prerequisite to the approval of an exception to the prohibition on the expansion of facility capacity, a hospital may not discriminate against beneficiaries of federal health care programs and may not permit physicians practicing at the hospital to discriminate against such beneficiaries. Further, other federal and state laws and regulations, such as the Emergency Medical Treatment and Labor Act (EMTALA) and State Medicaid program rules and regulations, prohibit a hospital from refusing to care for or otherwise discriminate against Medicaid patients.

Comment: Several commenters cited studies that they asserted indicate that physician-owned hospitals present a risk of program or patient abuse. Other commenters cited studies that they asserted show the benefits of physician ownership of hospitals. The commenters that opposed our proposals highlighted various studies, including studies by the Congressional Budget Office, Medicare Payment Advisory Commission.[366] The aforementioned studies concluded that physician self-referral to facilities in which they have an ownership stake leads to greater *per capita* utilization of services and higher costs for the Medicare program. Two of these commenters also shared data from a 2017 study that found physician-owned hospitals cherry-pick patients by avoiding Medicaid and uninsured patients, treat fewer medically complex patients and have margins nearly three times those of nonphysician-owned hospitals.[367] The commenters stated that finalizing the proposals could lead to these abuses of the Medicare program and its beneficiaries. Some of the commenters who supported our proposals cited to a British Medical Journal study that concluded that physician-owned hospitals have similar quality and costs of care when compared to nonphysician-owned hospitals [368] and a study published by the Journal of the American College of Surgeons that concluded that physician-owned surgical hospitals outperform other hospitals in the Medicare value-based purchasing program.[369] One of these commenters quoted the December 2018 HHS report titled ''Reforming America's Healthcare System Through Choice and Competition'' in support of finalizing our proposals, noting HHS' statement that concerns about self-referral and cherry-picking ''may have been overstated, considering that many studies suggest physician-owned hospitals provide higher quality care and that patients benefit when traditional hospitals have greater competition.'' [370]

Response: As we understand the research into the risks and benefits of physician ownership in hospitals that was cited by the commenters, the studies' authors have differed in their conclusions regarding whether physician ownership in hospitals poses a risk of program or patient abuse and, thus, whether further or less regulation of physician-owned hospitals is warranted. Although we appreciate the concerns discussed in the studies cited by the commenters in opposition to our proposals, as discussed in the response to the previous comment, the plain language of the statute does not impose the same limitations on the expansion of high Medicaid facilities as it does the expansion of applicable hospitals, and we believe that the existing regulations impose unnecessary burden on high Medicaid facilities. In alignment with our Patients over Paperwork initiative, we are finalizing our proposals to remove this unnecessary burden.

Comment: Many commenters, including some that supported the proposals to eliminate other restrictions

[366] *https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/kylltrsec651ofhr3162.pdf* and *http://www.medpac.gov/docs/default-source/reports/Mar05_SpecHospitals.pdf?sfvrsn=0.*

[367] *https://www.fah.org/blog/analysis-highlights-need-to-maintain-law-banning-self-referral-to-physician.*

[368] Blumenthal, D., et al., ''Access, quality, and costs of care at physician owned hospitals in the United States: observational study'', British Medical Journal, 2015;351:h4466 (September 2, 2015); available at *http://www.bmj.com/content/bmj/351/bmj.h4466.full.pdf.*

[369] Ramirez AG, Tracci MC, Stukenborg GJ, Turrentine FE, Kozower BD, Jones RS. Physician-owned surgical hospitals outperform other hospitals in Medicare value-based purchasing program. J Am Coll Surg. 2016 Oct; 223(4):559–567; available at *https://www.journalacs.org/article/S1072-7515(16)30720-7/fulltext.*

[370] *https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf.*

on high Medicaid facilities, recommended that CMS maintain the requirement for community input related to the request of a high Medicaid facility for an exception to the prohibition on expansion of facility capacity. The comments stated that community input is a valuable part of the expansion exception process. One commenter supported eliminating the community input requirement for high Medicaid facilities, noting that, according to a study entitled ''Specialty Versus Community Hospitals: Referrals, Quality, And Community Benefits,'' physician-owned specialty hospitals exhibit higher levels of net community benefits.[371] Neither this commenter, nor any other commenter, shared an alternative method for CMS to obtain independent confirmation of data provided by a high Medicaid facility in the absence of community input.

Response: We agree with the commenters that community input is vital to the expansion exception process and that it was the Congress' intent to include it. Moreover, we believe that it would significantly lengthen the expansion exception process to eliminate community input, as CMS would need to engage in additional independent verification activities, which is not in line with our burden reduction efforts and our Patients over Paperwork initiative. Therefore, we are not revising our regulations to eliminate the requirement for community input related to the request of a high Medicaid facility for an exception to the prohibition on expansion of facility capacity.

C. Deference to State Law for Purposes of Determining the Number of Beds for Which a Hospital Is Licensed

In order to qualify for the rural provider or whole hospital exception to the physician self-referral law, a hospital may not increase the aggregate number of operating rooms, procedure rooms, and beds above that for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of March 23, 2010, but did have a provider agreement in effect on December 31, 2010, the effective date of such agreement), unless the Secretary has granted an exception to the prohibition on expansion of facility capacity under section 1877(i)(3) of the Act and § 411.362(c). The statute and our regulations refer to this number as the hospital's ''baseline number of operating rooms, procedure rooms, and beds.'' Thus, at the time a hospital wishes to qualify for the rural provider or whole hospital exception, it may not have an aggregate number of operating rooms, procedure rooms, and beds that exceeds its baseline number of operating rooms, procedure rooms, and beds (unless the Secretary has granted an exception).

Because the availability of the rural provider and whole hospital exceptions turns on whether a hospital has exceeded its baseline number of operating rooms, procedure rooms, and beds at the time of a physician's referral, a clear understanding of how to calculate the hospital's baseline number of operating rooms, procedure rooms, and beds is critical. Stakeholders have asked what CMS would consider the number of operating rooms, procedure rooms, and beds for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but does have a provider agreement in effect on December 31, 2010, the effective date of such agreement) under various state licensure schemes. We responded to formal advisory opinion requests in August 2019 (*https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-AO-2019-01-Redacted.pdf*) and March 2020 (*https://www.cms.gov/files/document/cms-ao-2020-01.pdf*) regarding the inclusion of certain operating rooms, procedure rooms, and beds in a hospital's baseline number of operating rooms, procedure rooms, and beds. In March 2020, we also published a Frequently Asked Question addressing stakeholder inquiries regarding the determination of the number of beds for which a hospital was licensed on March 23, 2010 (*https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/FAQs-Physician-Self-Referral-Law.pdf*).

The March 2020 Frequently Asked Question states:

Q: If a state's hospital licensure laws and regulations provide that a hospital may increase its licensed bed complement by a certain amount without prior approval of the state's licensing agency, what would CMS consider the number of beds for which the hospital was licensed on March 23, 2010 for purposes of section 1877(i)(1)(B) of the Social Security Act (the Act'') and 42 CFR 411.362(b)(2)?

A: As a general matter, neither section 1877 of the Act nor the physician self-referral regulations (42 CFR 411.350 through 411.389) preempt state licensure laws and regulations. In interpreting and applying the physician self-referral law, CMS defers to state law with respect to the determination of whether a bed is licensed as of a certain date. If the state would consider a bed to be ''licensed'' or within a hospital's ''bed complement'' on March 23, 2010, CMS would also consider the bed to be ''licensed'' or within a hospital's ''bed complement'' as of that date, regardless of the exact number printed on the hospital's physical license. To illustrate, assume that a state does not require prior approval from its licensing agency for a hospital to increase its bed complement by not more than ten beds or 10 percent of the total bed capacity, whichever is less, during a period of a license. However, the state requires notification of the change and that the hospital must at all times meet the physical plant, staffing, and all other requirements set forth in state law and regulations if additional beds are added. The license issued to the hospital on January 1, 2009 indicated that the hospital's bed complement was 100 beds. If the hospital increased its bed complement by 9 beds (to 109 beds) on January 1, 2010 and made no further changes to its bed complement prior to March 23, 2010, its baseline number of licensed beds on March 23, 2010 would be 109 for purposes of section 1877(i)(1)(B) of the Act and 42 CFR 411.362(b)(2), provided that the hospital made the appropriate notification to the state and the hospital at all times met the physical plant, staffing, and all other requirements set forth in state law and regulations after increasing its bed complement. The same would apply to any beds that a state considered to be licensed under its specific licensure scheme on March 23, 2010. Section 1877(i)(1)(B) of the Act limits the expansion of facility capacity of a hospital that wishes to qualify for the rural provider or hospital exceptions to the law's ownership or investment prohibition. (See section 1877(d)(2) and (3); 42 CFR 411.356(c)(1) and (3).) Specifically, section 1877(i)(1)(B) of the Act states that, among other things, to qualify for the rural provider or hospital exceptions, the number of operating rooms, procedure rooms, and beds for which the hospital is licensed at any time on or after March 23, 2010 is no greater than the number of operating rooms, procedure rooms, and beds for which the hospital was licensed on March 23, 2010. For purposes of applying this provision of the physician self-referral law, we refer to the number of operating rooms, procedure rooms, and beds for which the hospital was licensed on March 23, 2010 as the hospital's ''baseline.'' As stated

[371] *https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.25.1.106.*

previously, we defer to state law with respect to the determination of whether a bed is licensed as of a certain date. However, in extraordinary circumstances, we may include additional beds when determining a hospital's ''baseline'' for purposes of section 1877 of the Act. See, for example, CMS–AO–2020–01 (*https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions*).

In order to ensure stakeholders' awareness of our interpretation regarding the determination of the number of beds for which a hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but does have a provider agreement in effect on December 31, 2010, the effective date of such agreement), we proposed to revise the definition of ''baseline number of operating rooms, procedure rooms, and beds'' at § 411.362(a) to include a statement that, for purposes of determining the number of beds in a hospital's baseline number of operating rooms, procedure rooms, and beds, a bed is included if the bed is considered licensed for purposes of state licensure, regardless of the specific number of beds identified on the physical license issued to the hospital by the state. We sought comments on our proposal to include this language in regulation text at § 411.362(a) generally, and specifically whether the inclusion of this language is necessary or could be perceived as inadvertently limiting the definition of ''baseline number of operating rooms, procedure rooms, and beds.'' We are finalizing our proposal to revise the definition of ''baseline number of operating rooms, procedure rooms, and beds.'' We received the following comment and our response follows.

Comment: A few commenters supported our proposal to codify the policy articulated in our existing Frequently Asked Question into regulation at § 411.362(a). We received no comments in opposition.

Response: Based on the comments and to facilitate stakeholder awareness of our policy that, for purposes of determining the number of beds in a hospital's baseline number of operating rooms, procedure rooms, and beds, a bed is included if the bed is considered licensed for purposes of state licensure, regardless of the specific number of beds identified on the physical license issued to the hospital by the state, we are finalizing our proposal. Under revised § 411.362(a), the definition of ''baseline number of operating rooms, procedure rooms, and beds'' states: baseline number of operating rooms, procedure rooms, and beds means the number of operating rooms, procedure rooms, and beds for which the applicable hospital or high Medicaid facility is licensed as of March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of such date, but does have a provider agreement in effect on December 31, 2010, the date of effect of such agreement). For purposes of determining the number of beds in a hospital's baseline number of operating rooms, procedure rooms, and beds, a bed is included if the bed is considered licensed for purposes of state licensure, regardless of the specific number of beds identified on the physical license issued to the hospital by the state.

XX. Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots

A. Background Section

Section 5506 of the Affordable Care Act (Pub. L. 111–148) added subsection (vi) to section 1886(h)(4)(H) of the Social Security Act (the Act) and modified language at section 1886(d)(5)(B)(v) of the Act, to instruct the Secretary of the Department of Health and Human Services (the Secretary) to establish a process to redistribute residency slots after a hospital that trained residents in an approved medical residency program closes. Specifically, the Secretary is instructed to increase the full-time equivalent (FTE) resident caps for teaching hospitals based upon the FTE resident caps in teaching hospitals that closed ''on or after a date that is 2 years before the date of enactment'' (that is, March 23, 2008). In the CY 2011 OPPS final rule with comment period (75 FR 72212), we established regulations at 42 CFR 413.79(o) and an application process for qualifying hospitals to apply to CMS to receive direct graduate medical education (DGME) and indirect medical education (IME) FTE resident cap slots from the hospital that closed. We made certain modifications to those regulations in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53434), and we made changes to the section 5506 application process in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50122 through 50134). The procedures we established apply both to teaching hospitals that closed on or after March 23, 2008, and on or before August 3, 2010, and to teaching hospitals that close after August 3, 2010.

B. Notice of Closure of Westlake Community Hospital, Located in Melrose Park, IL, and the Application Process—Round 18

CMS has learned of the closure of Westlake Community Hospital, located in Melrose Park, IL (CCN 140240). Accordingly, this notice serves to notify the public of the closure of this teaching hospital and initiate another round of the section 5506 application and selection process. This round will be the 18th round (''Round 18'') of the application and selection process. Table 75 contains the identifying information and IME and DGME FTE resident caps for the closed teaching hospital, which are part of the Round 18 application process under section 5506 of the Affordable Care Act.

TABLE 75. IME and DGME FTE Resident Caps for Westlake Community Hospital

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME FTE Resident Cap (including +/- MMA Sec. 422[1])	Direct GME FTE Resident Cap (including +/- MMA Sec. 422[1])
140240	Westlake Community Hospital	Melrose Park, IL	16984	August 14, 2019	36.87 - 0.54 = 36.33[2]	41.24 - 1.96 = 39.28[3]

[1] Section 422 of the MMA, Pub. L. 108-173, redistributed unused IME and DGME residency slots effective July 1, 2005.
[2] Westlake Community Hospital's 1996 IME FTE resident cap is 36.87. Under section 422 of the MMA, the hospital received a reduction of 0.54 to its IME FTE resident cap: 36.87 – 0.54 = 36.33
[3] Westlake Community Hospital's 1996 DGME FTE resident cap is 41.24. Under section 422 of the MMA, the hospital received a reduction of 1.96 to its DGME FTE resident cap: 41.24 – 1.96 = 39.28

C. Notice of Closure of Astria Regional Medical Center, Located in Yakima, WA, and the Application Process—Round 19

CMS has learned of the closure of Astria Regional Medical Center, located in Yakima, WA (CCN 500012). Accordingly, this notice serves to notify the public of the closure of this teaching hospital and initiate another round of the section 5506 application and selection process. This round will be the 19th round (''Round 19'') of the application and selection process. Table 76 contains the identifying information and IME and DGME FTE resident caps for the closed teaching hospital, which are part of the Round 19 application process under section 5506 of the Affordable Care Act.

TABLE 76. IME and DGME FTE Resident CAPS for Astria Regional Medical Center

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME FTE Resident Cap (including +/- MMA Sec. 422[1])	Direct GME FTE Resident Cap (including +/- MMA Sec. 422[1])
500012	Astria Regional Medical Center	Yakima, WA	49420	January 15, 2020	3.74 + 8.29 = 12.03[2]	8.18 – 0.16 + 5.00 = 13.02[3]

[1] Section 422 of the MMA, Pub. L. 108-173, redistributed unused IME and DGME residency slots effective July 1, 2005.
[2] Astria Regional Medical Center's 1996 IME FTE resident cap is 3.74. Under section 422 of the MMA, the hospital received an increase of 8.29 to its IME FTE resident cap: 3.74 + 8.29 = 12.03. Note that the slots associated with an IME cap increase under section 422 of the MMA are paid under 42 CFR 412.105(d)(4) using a special multiplier of 0.66.
[3] Astria Regional Medical Center's 1996 DGME FTE resident cap is 8.18. Under section 422 of the MMA, the hospital received a reduction of 0.16 and an increase of 5.00 to its DGME FTE resident cap: 8.18 – 0.16 + 5.00 = 13.02. Note that the slots associated with a DGME cap increase under section 422 of the MMA are paid under 42 CFR 413.77(g) using the appropriate locality-adjusted national average per resident amount (PRA).

D. Application Process for Available Resident Slots

The application period for hospitals to apply for slots under section 5506 of the Affordable Care Act is 90 days following notice to the public of a hospital closure (77 FR 53436). Therefore, hospitals that wish to apply for and receive slots from the above hospitals' FTE resident caps, must submit applications (Section 5506 Application Form posted on DGME website as noted at the end of this section) directly to the CMS Central Office no later than March 29, 2021. The mailing address for the CMS Central Office is included on the application form. Applications must be received by the CMS Central Office by the March 29, 2021 deadline date. It is not sufficient for applications to be postmarked by this date.

After an applying hospital sends a hard copy of a section 5506 slot application to the CMS Central Office mailing address, the hospital is encouraged to notify the CMS Central Office of the mailed application by sending an email to: *ACA5506application@cms.hhs.gov*. In the email, the hospital should state: ''On behalf of [insert hospital name and Medicare CCN#], I, [insert your name], am sending this email to notify CMS that I have mailed to CMS a hard copy of a section 5506 application under Round [18 or 19] due to the closure of [Westlake Community Hospital or Astria Regional Medical Center]. If you have any questions, please contact me at [insert phone number] or [insert your email address].'' An applying hospital should not attach an electronic copy of the application to the email. The email will only serve to notify the CMS Central Office to expect a hard copy

application that is being mailed to the CMS Central Office.

We have not established a deadline by when CMS will issue the final determinations to hospitals that receive slots under section 5506 of the Affordable Care Act. However, we review all applications received by the deadline and notify applicants of our determinations as soon as possible. We refer readers to the CMS DGME website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/DGME* to download a copy of the section 5506 application form (Section 5506 Application Form) that hospitals must use to apply for slots under section 5506 of the Affordable Care Act. Hospitals should also access this same website for a list of additional section 5506 guidelines for the policy and procedures for applying for slots, and the redistribution of the slots under sections 1886(h)(4)(H)(vi) and 1886(d)(5)(B)(v) of the Act.

XXI. Radiation Oncology (RO) Model

A. Revised Model Performance Period for the Radiation Oncology Model

On September 29, 2020, we published a final rule in the **Federal Register** (85 FR 61114) entitled ''Specialty Care Models to Improve Quality of Care and Reduce Expenditures'' that finalized the Radiation Oncology Model (RO Model, the Model). Since the publication of that rule, we have received feedback from stakeholders requesting that the RO Model be delayed due to concerns around implementing the RO Model during the public health emergency (PHE) for the Coronavirus disease 2019 (COVID–19) pandemic. These concerns included revenue losses for RO participants due to decreased patient volumes and lay-offs or staff reallocations due to the PHE. Specifically, RO participants have limited capacity to operationalize RO Model requirements this year because of the unprecedented PHE that continues to strain health care resources. To ensure that participation in the RO Model does not further strain RO participants' capacity, potentially hindering the delivery of safe and efficient health care to beneficiaries receiving radiotherapy (RT) services, we are finalizing the RO Model's Model performance period to begin on July 1, 2021. We believe that this will give RO participants an additional 6 months necessary to learn the RO billing requirements and train staff on new procedures for 2021, and as a consequence of the revised Model performance period, an additional 12 months to prepare for required quality measure and clinical data element reporting beginning in 2022. Additionally, under this delay, RO participants will have more time to understand their participant-specific case mix and historical experience adjustments and the payment they expect to receive under the RO Model.

The September 29, 2020 final rule's effective date is November 30, 2020 (85 FR 61114). This interim final rule with comment period revises the following regulations at 42 CFR part 512, which are to become effective on December 4, 2021: Number 25 amending definitions of Model performance period and Performance year (PY) at 42 CFR 512.205; number 26 amending 42 CFR 512.210(a) and (c); number 27 amending 42 CFR 512.217 (c); number 28 amending 42 CFR 512.220(b); number 29 amending 42 CFR 512.245(a); number 30 amending 42 CFR 512.255(c)(10); and number 31 amending 42 CFR 512.285(d).

This interim final rule with comment period revises the following RO Model policies. The Model performance period will be 4.5 years, beginning on July 1, 2021, and ending December 31, 2025. PY1 will be 6 months, beginning on July 1, 2021, and ending on December 31, 2021; each subsequent PY will be a full calendar year, beginning on January 1 and ending on December 31. Revising the Model performance period requires revising other components of the RO Model including: How episodes and RO episodes are used to determine eligibility for the low volume opt-out for PY3 and RO episodes are used to determine eligibility for the low volume opt-out for PY4 through PY5; Certified Electronic Health Record Technology (CEHRT) requirements; submission of quality measures and clinical data elements; the quality withhold; quality reconciliation amount; and the status of the RO Model as an Advanced APM and MIPS APM.

We finalized at § 512.205 the RO Model's Model performance period to last five performance years, beginning January 1, 2021 and ending December 31, 2025 (with each performance year being the 12-month period beginning on January 1 and ending on December 31 of each year during the Model performance period. In this interim final rule with comment period, we are revising the Model performance period to be 4.5 years beginning July 1, 2021 and ending December 31, 2025.

A 4.5-year Model performance period will still be sufficient to test the proposed prospective payment approach, stimulate the development of new evidence-based knowledge, acquire additional knowledge related to patterns of inefficient utilization of health care services, and formulate methods to incentivize the improvement of high-quality delivery of RT services. A Model performance period of 4.5 years will provide RO participants an additional 6 months to address implementation issues prior to the start of the Model performance period. It will also provide sufficient time for the Model evaluation pursuant to section 1115A(b)(4) of the Social Security Act (the Act) to obtain sufficient data to compute a reliable impact estimate and to determine next steps regarding potential expansion or extension of the Model. Based upon the updated savings projection (see section XXVI.C.10) and accounting for the reduced number of cumulative episodes accrued in PY1 since the final rule was published (85 FR 61149), CMS determined that the Model savings will be able to reach the 3.75 percent level that is the threshold indicated by the Model power analysis enabling the evaluation to detect with statistical significance that level of impact. Starting the Model performance period on July 1, 2021 will not require a re-randomization of participation and will not affect the list of participating ZIP Codes posted on the RO Model website. Notably, the RO Model's evaluation will analyze data on the impact of the RO Model on an ongoing basis. To the extent that evaluation results are definitive sooner than the end of the RO Model, we will consider next steps at that time rather than waiting until the RO Model ends.

Because we are revising the Model performance period to begin July 1, 2021, both episodes and RO episodes from 2021 will determine eligibility for the low volume opt-out for PY3. To clarify the type of episodes used to determine eligibility for the low volume opt-out in each performance year, episodes, as defined at § 512.205, are used to determine eligibility in PY1 and PY2 and RO episodes, as defined at § 512.205 and described at § 512.245(a), are used to determine eligibility in PY4 and PY5, and both episodes and RO episodes are used to determine eligibility in PY3. Specifically, for PY3, eligibility for the low volume opt-out is determined by counting episodes from January 1, 2021 through June 30, 2021 and RO episodes from July 1, 2021 through December 31, 2021. We are revising our regulations at §§ 512.210(c) and 512.245(a) to reflect this clarification.

Because we finalized the specifications for the RO Model quality measure reporting to be based on a calendar year of data (85 FR 61220 through 61223), the RO Model quality

measures requirements will be delayed to PY2 (January 1, 2022 through December 31, 2022). RO participants will submit quality measure data finalized in the 2020 Specialty Care Models to Improve Quality of Care and Reduce Expenditures final rule (85 FR 61215 through 61220), unless CMS specifies different individual measure specifications.

The revised Model performance period requires modifications to the RO Model's form, manner, and timing policy for data reporting. We finalized that, beginning in PY1, RO participants must submit quality measure data annually by March 31 following the end of the previous PY to the RO Model secure data portal, with the first annual submission in March 2022 and continuing thereafter (85 FR 61220 through 61223). This interim final rule with comment period revises this policy so that RO participants must, beginning in PY2, submit in March 2023 quality measures data from January 1, 2022, through December 31, 2022.

For PY2, three measures will be pay-for-performance: (1) Plan of Care for Pain; (2) Screening for Depression and Follow-Up Plan; and (3) Advance Care Plan. The fourth measure, Treatment Summary Communication—Radiation Oncology, will be a pay-for-reporting measure. Data collected for this measure will be used to propose a benchmark to re-specify it as a pay-for-performance measure, for PY4. All four measures will still be scored in accordance with our Aggregate Quality Scoring Methodology (85 FR 61226 through 61231).

We also finalized to have a CMS-approved contractor administer the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Cancer Care Survey for Radiation Therapy, beginning in April 2021 (85 FR 61220). This interim final rule with comment period revises this policy so that a CMS-approved contractor will administer the CAHPS® Cancer Care Survey for Radiation Therapy beginning in October 2021.

We finalized under the Model's clinical data collection policy that RO participants must collect certain clinical information not available in claims or quality measures, with data collecting starting in PY1 (85 FR 61223 through 61226). This interim final rule with comment period revises this policy so that the collection period for clinical data elements (CDEs) will begin on January 1, 2022. The first submission of the clinical data elements for January 1, 2022, through June 30, 2022, will be due in July 2022.

We finalized at § 512.255(c)(10) to apply a 2 percent quality withhold from each professional episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, and discount factor to the national base rate. RO participants may earn back this withhold, in part or in full, based on their AQS. Since this interim final rule with comment period delays the reporting of quality measures (QM) and CDEs until PY2, there will be no quality withhold in PY1. Beginning in PY2, a 2 percent quality withhold for the PC will be applied to the applicable trended national base rates after the case mix and historical experience adjustments. Accordingly, § 512.255(c)(10) is revised.

Revising the quality reporting requirements and quality withhold requires revising the reconciliation payment and the repayment amounts calculations for PY1, as described at § 512.285(d). Since submission of QMs and CDEs will begin in PY2, the AQS will be applied beginning in PY2, and Professional participants and Dual participants will not have a quality reconciliation amount for PY1. The reconciliation amount for PY1 will be based solely on the incorrect episode payment reconciliation amount and any stop-loss reconciliation amount, if applicable. Professional participants and Dual participants will have a quality reconciliation amount only for PY2 through PY5. Accordingly, § 512.285(d) is revised.

We have previously stated that we expect the RO Model will meet the criteria to be an Advanced Alternative Payment Model (APM) and a Merit-based Incentive Payment System (MIPS) APM under the Quality Payment Program beginning in PY1 (85 FR 61231 through 61238). Because we are revising the quality measure policy so that quality measure data will not be collected in PY1, the RO Model will not meet the criteria to be either an Advanced APM or a MIPS APM under the Quality Payment Program in PY1. We anticipate that the RO Model will meet the criteria to be both an Advanced APM and a MIPS APM under the Quality Payment Program starting in PY2 (January 1, 2022). Effective January 1, 2022, at least one of the quality measures upon which the RO Model bases payment will meet at least one of the following criteria: (a) Finalized on the MIPS final list of measures, as described in 42 CFR 414.1330; (b) endorsed by a consensus-based entity; or (c) determined by CMS to be evidenced-based, reliable, and valid. Final CMS determinations of Advanced APMs and MIPS APMs for the 2022 performance period will be announced via the Quality Payment Program website at *https://qpp.cms.gov/*.

For PY1, all requirements concerning the review and certification of the individual practitioner list codified at § 512.217 will remain in effect, but because the RO Model will not meet the criteria to be either an Advanced APM or a MIPS APM under the Quality Payment Program in PY1, the individual practitioner list will not be used for Qualifying APM Participant determinations or for determining participants in a MIPS APM for purposes of MIPS reporting and scoring rules in PY1. The individual practitioner list will only be used for the Quality Payment Program in PY1 to assign an automatic 50 percent score for the Improvement Activity performance category in MIPS for RO participants. Starting in PY2 (January 1, 2022), the individual practitioner list will be used to identify the relevant eligible clinicians for purposes of making Qualifying APM Participant (QP) determinations and for certain aspects of MIPS under the Quality Payment Program. Dual participants and Professional participants must review and certify the individual practitioner list within 30 days of receipt of the individual practitioner list that is created and provided by CMS. Accordingly, § 512.217(c) is revised.

We finalized at § 512.220(b) that the requirement that RO participants must use CEHRT in a manner sufficient to meet the applicable requirements of the Advanced APM criteria before each PY. Due to the revised Model performance period, this requirement that RO participants must use CEHRT in a manner sufficient to meet the applicable requirements of the Advanced APM criteria will now begin in PY2, on January 1, 2022, and be required for PY2 through PY5. RO participants must annually certify their use of CEHRT for PY2 through PY5, and RO participants will be required to certify their use of CEHRT within 30 days of the start of PY2. Delaying the quality reporting and CEHRT use requirements until PY2 means that the RO Model will not meet the criteria to be considered an Advanced APM in PY1. Therefore, RO participants will not be eligible for the 5 percent APM Incentive Payment for QPs in PY1 based on their participation in the RO Model.

We note that there is a 60-day public comment period following publication of this final rule for the public to comment on these final amendments to our regulations. We refer readers to the **ADDRESSES** section of the final rule for instructions on submitting public comments. Comments are due by the

''Comment date'' specified in the **DATES** section of this rule.

B. Waiver of Proposed Rulemaking

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of proposed rulemaking that includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved in the **Federal Register** before the provisions of a rule take effect. Section 553(c) of the APA further requires the agency to give interested parties opportunity to participate in the rulemaking through public comments before the provisions of the rule take effect. Similarly, section 1871(b)(1) of the Social Security Act (the Act) requires the Secretary of the Department of Health and Human Services (Secretary) to provide for notice of the proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize the agency to waive these procedures if the agency finds good cause that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

At the time of this publication, the U.S. continues to respond to a PHE of unprecedented magnitude. Specifically, the nation is responding to an outbreak of ''severe acute respiratory syndrome coronavirus 2'' (SARS–CoV–2), the disease it causes has been named ''coronavirus disease 2019'' (COVID–19).

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a ''Public Health Emergency of International Concern''.[372] On January 31, 2020, pursuant to section 319 of the Public Health Services Act (42 U.S.C. 247d), the Secretary declared a PHE for the U.S., retroactively effective from January 27, 2020, to aid the nation's health care community in responding to COVID–19.[373] On March 11, 2020, the WHO publicly declared COVID–19 a pandemic.[374] On March 13, 2020, President Donald J. Trump declared the COVD–19 pandemic a national emergency.[375] Effective July 25, 2020, the Secretary renewed the January 31, 2020 determination that was previously renewed on April 21, 2020, that a PHE for COVID–19 exists and has existed since January 27, 2020.[376] October 2, 2020, the Secretary renewed the January 31, 2020, PHE for COVID–19 determination effective October 23, 2020.[377] As with each PHE declaration, this renewal of the PHE for COVID–19 determination lasts until the Secretary declares that the PHE no longer exists or upon the expiration of the 90-day period beginning on the date the Secretary declared a PHE exists, whichever occurs first.

On September 29, 2020, we published a final rule entitled ''Specialty Care Models To Improve Quality of Care and Reduce Expenditures'' (Specialty Care Models Rule) in the **Federal Register** (85 FR 61114). In the Specialty Care Models Rule, we adopted a Model performance period that begins on January 1, 2021. At the time of the Specialty Care Models Rule publication, had the Secretary's renewal of the PHE effective July 25, 2020 lasted 90 days, it would have ended prior to the beginning of the Model's performance period.

The COVID–19 pandemic continues to strain health care resources, and CMS understands that those selected for participation in the RO Model may have limited capacity to continue normal operations while also preparing to meet the requirements set forth in the RO Model. We understand that many RO participants have had to furlough or cut staff. Revising the Model performance period to begin July 1, 2021, would provide RO participants with an additional 6 months prior to the start of the Model performance period to operationalize the RO Model while continuing to respond to the COVID–19 pandemic.

We do not presume to know when the Secretary will declare that the PHE no longer exists, but we are erring on the side of caution that this most recent renewal of the PHE for COVID–19 will most likely extend for the entire 90-day period. By erring on the side of caution, this most recent renewal period by the Secretary will likely overlap with the beginning of the RO Model's Model performance period, January 1, 2021. Because of the current state of the pandemic, this most recent renewal of the PHE for COVID–19, and the effect of the PHE on RO participants, we are revising the RO Model's Model performance period to begin on July 1, 2021 and to now be 4.5 years instead of 5 years. As we are still in the midst of the PHE, we find good cause to waive notice and comment rulemaking as we believe it would be impracticable and contrary to the public interest for us to undertake normal notice and comment rulemaking procedures, as that would delay giving RO participants adequate time to respond to the ongoing impacts of COVID–19 while also preparing for participation in the RO Model.

Revising the Model performance period to begin on July 1, 2021, will require modifying other RO Model requirements, including those related to the types of episodes used to determine eligibility for the low volume opt-out for PY3, CEHRT requirements, submission of quality measures and clinical data elements, the quality withhold, quality reconciliation amount, eligibility for the low volume opt-out, and the status of the RO Model as an Advanced APM and MIPS APM.

We find that there is good cause to waive the notice and comment requirements under sections 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act. We find the notice and comment procedure impracticable and contrary to the public interest because, based on the Secretary's recent renewal of the PHE for the COVID–19, it is in the public's interest to revise the Model performance period in order to provide RO participants an additional 6 months prior to the start of the Model performance period to prepare for participation in the RO Model to ensure that the RO Model does not potentially hinder delivery of safe and efficient delivery of RT services to RO beneficiaries. Therefore, we find good cause to waive notice-and-comment procedures and to issue this interim final rule with comment period. We are providing a 60-day public comment period as specified in the **DATES** section of this document.

[372] *https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov).*

[373] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[374] *https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020.*

[375] *https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.*

[376] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.aspx; https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-23June2020.aspx.*

[377] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx.*

XXII. COVID–19 Therapeutic Inventory and Usage Data Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) and Reporting Requirements for Hospitals and CAHs To Report Acute Respiratory Illness During the PHE for COVID–19 Interim Final Rule With Comment Period (IFC)

A. Conditions of Participation (CoP) Requirements for Hospitals and CAHs To Report COVID–19 Therapeutic Inventory and Usage and To Report Acute Respiratory Illness Data As Specified by the Secretary During the PHE for COVID–19

Under sections 1866 and 1902 of the Social Security Act (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, long-term care hospitals (LTCHs), rehabilitation hospitals, psychiatric hospitals, cancer hospitals, and children's hospitals) and CAHs seeking to be Medicare and Medicaid providers of services must be certified as meeting federal participation requirements. Our conditions of participation (CoPs), conditions for coverage (CfCs), and requirements for long term care facilities 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 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 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 42 CFR 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 to best practices 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 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. On March 4, 2020, we issued guidance (*https://www.cms.gov/files/document/qso-20-13-hospitalspdf.pdf-2*) stating that hospitals should inform infection prevention and control services, local and state public health authorities, and other healthcare facility staff as appropriate about the presence of a person under investigation for COVID–19. We followed this guidance with an interim final rule with comment (IFC),[378] published in the September 2, 2020 **Federal Register** (85 FR 54820), that requires hospitals and CAHs to report important data critical to support the fight against COVID–19. The CoP provisions require that hospitals and CAHs report this information in accordance with a frequency as specified by the Secretary on COVID–19, as well as in a standardized format specified by the Secretary. Examples of data elements that may be required to be reported include: The number of staffed beds in a hospital and the number of those that are occupied; information about its ventilator and personal protective equipment (PPE) supplies; and a count of patients currently hospitalized who have laboratory-confirmed COVID–19. This list is not exhaustive of those data items that we may require hospitals and CAHs to submit, as specified by the Secretary (see *https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf* for the current list of data items specified). In fact, as new therapeutics are issued Emergency Use Authorizations by the Food and Drug Administration, and because these new therapeutics are in very scarce supply in the United States, HHS is actively working with manufacturers to ensure that they are distributed efficiently and effectively. Effective distribution methods use a variety of indicators, tailored to the specific therapeutic, to estimate the geographic distribution that is recommended for that particular therapeutic. However, without a real-time and real-world understanding of the usage patterns specific to each new therapeutic and lacking accurate information on the current inventory on hand for that therapeutic, scarce therapeutic supplies might be sent to areas that already have adequate inventories on hand. An inefficient and uninformed distribution strategy for these therapeutics such as this negatively and severely impacts areas of the nation that already have inadequate supplies and creates an untenable situation as new therapeutics are introduced.

Therefore, we are revising our current COVID–19 PHE hospital and CAH CoP reporting requirements at 42 CFR 482.42(e) for hospitals and at 42 CFR 485.640(d) for CAHs, to now require hospitals and CAHs to report data elements that must include, but not be limited to, the following: (1) The hospital's (or the CAH's) current inventory supplies of any COVID–19-related therapeutics that have been distributed and delivered to the hospital (or CAH) under the authority and direction of the Secretary; and (2) the hospital's (or 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.

All participating hosptials and CAHs will now track their inventory supplies and usage rates in real time for those COVID–19-related therapeutics that have been distributed and delivered by HHS so that public health officials will have a more robust and accurate database in order to efficiently and effectively manage the distribution and delivery ofthese therapeutics, particularly to those regions of the country that might be experiencing shortages of these crucial supplies. The importance of this particular data reporting, along with the information provided, cannot be overestimated as we continue to make advances to more effectively address the continuing COVID–19 PHE and to greatly diminish its negative impact on the nation.

In this IFC, we are also now requiring hospitals and CAHs to report information with a frequency, and in such standardized format as specified by the Secretary during the COVID–19 PHE, on Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness,

[378] *https://www.govinfo.gov/content/pkg/FR-2020-09-02/pdf/2020-19150.pdf.*

and Severe Acute Respiratory Infection). Examples of data elements that we would ask to be reported include things such as diagnoses, admissions, and counts of patients currently hospitalized who have diagnoses of Acute Respiratory Illnesses (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection). In addition, as with the current COVID–19 reporting requirements, we firmly believe these elements are essential for planning, monitoring, and resource allocation during the PHE for COVID–19, especially as the nation enters the seasonal influenza season, when hospitals and CAHs are likely to see an increase in the number of patients presenting with the signs and symptoms of a variety acute respiratory illnesses along with a continuing and unknown number of patients presenting with both suspected and confirmed COVID–19. The new rules make reporting a requirement of participation in the Medicare and Medicaid programs and the required reporting is needed to support broad surveillance of COVID–19 in conjunction with other acute respiratory illnesses that may further burden and strain hospital and CAH resources.

We believe that universal acute respiratory illness reporting, in tandem with the current COVID–19 reporting, by all hospitals and CAHs, will be an important tool for supporting surveillance of COVID–19, as well as for future planning to prevent the spread of these respiratory viruses and infections, especially to those most vulnerable and at-risk. As with the current COVID–19 reporting requirements, we are cognizant of the crucial need for acute respiratory illness data reporting options to reduce duplicative and competing reporting requests and associated burden on hospitals and CAHs whose resources are already stressed during this PHE for COVID–19.

We expect that the new reporting data that will be requested by the Secretary would include reporting channel options similar to, if not the same as, those currently in place for COVID–19, to make submission of data as user-friendly as possible to reduce the potential strain and burden on hospitals and CAHs. The new standards will ask hospitals and CAHs to report information on Acute Respiratory Illness in a standardized format, frequency, and manner specified by the Secretary.

We believe that a streamlined approach to reporting data will greatly assist the White House Coronavirus Task Force (COVID–19 Task Force) in tracking the movement of these respiratory viruses and infections, along with the continuing movement of COVID–19. Similarly, this data may help identify potential problems in the healthcare delivery system as we continue to deal with COVID–19 cases along with potentially concurrent cases of respiratory viruses and infections. The completeness, accuracy, and timeliness of the data will inform the COVID–19 Task Force decisions on capacity and resource needs to ensure a fully coordinated effort across the nation. Furthermore, we believe that consistent processes and streamlined methods for the reporting of acute respiratory illness data in conjunction with the reporting of COVID–19 information will possibly reduce future, urgent requests for such data.

We note here that the new reporting requirements at §§ 482.42(f) and 485.640(e) do not relieve a hospital or a CAH, respectively, of its obligation to continue to comply with § 482.42(a)(3) or § 485.640(a)(3), each of which requires a facility to address any infection prevention and control issues identified by public health authorities. We believe that the requirements, as described in this IFC, to collect and transmit these data, will also encourage greater awareness and promotion of best practices in infection prevention and control within these facilities.

This reporting requirement supports our responsibility to protect and ensure the health and safety of hospital and CAH patients through, for example, ensuring that these facilities follow infection prevention and control protocols based on recognized standards of practice. We believe that these 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 acute respiratory illnesses coupled with COVID–19 on patients, the staff who care for them, and the general public. We believe that this action reaffirms our commitment to protecting the health and safety of all patients who receive care at the approximately 6,200 Medicare- and Medicaid-participating hospitals and CAHs nationwide.

As discussed in section XXV.B of this IFC, ''Waiver of Proposed Rulemaking for Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) to Report Acute Respiratory Illness During the PHE for COVID–19 Interim Final Rule with Comment Period (IFC),'' we believe the urgency of this PHE for COVID–19 and the impending and traditional seasonal influenza virus (and acute respiratory illness) season constitutes good cause to waive the normal notice-and-comment process under the Administrative Procedure Act (APA) and section 1871(b)(2)(C) of the Act. Waiving notice and comment is in the public interest because as it is necessary to expeditiously track the continuing incidence and impact of COVID–19 in conjunction with the impending incidence and impact of other acute respiratory illnesses in hospitals and CAHs; such information will assist public health officials in detecting outbreaks and responding appropriately in order to save lives.

The applicability date for § 482.42(e) and (f) for hospitals and for § 485.640(d) and (e) for CAHs is the date of the publication of this rule as noted in the **DATES** section of this IFC.

B. Enforcement of Requirements for Hospitals and Critical Access Hospitals (CAHs) To Report Acute Respiratory Illness (Including, but Not Limited to, Seasonal Influenza Virus, Influenza-Like Illness, and Severe Acute Respiratory Infection) Data

We believe reporting by hospitals and CAHs is an important tool for supporting surveillance of both COVID–19 and other acute respiratory illness cases that are likely to present simultaneously in hospitals and CAHs. We will enforce violations of reporting requirements to the extent permitted by law. Should a hospital or CAH consistently fail to report data related to patient diagnoses of Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection) throughout the duration of the PHE for COVID–19, it will be non-compliant with the hospital and the CAH CoPs set forth at §§ 482.42(f) and 485.640(e), respectively, and subject to termination as defined at 42 CFR 489.53(a)(3). We have taken a position on the importance of COVID–19 reporting in other provider areas, including use of civil money penalties (CMPs) for nursing homes that fail to report, and find it prudent to enact penalties for hospitals and CAHs that similarly fail to report Acute Respiratory Illness data. We currently lack the statutory authority to impose CMPs against hospitals and CAHs. However, we will continue to utilize all enforcement and payment authorities available to incentivize and promote compliance with all health and safety requirements, as allowed by statute and regulation.

XXIII. Files Available to the Public via the Internet

The Addenda to the OPPS/ASC proposed rules and the final rules with comment period are published and available via the internet on the CMS website. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59154), for CY 2019, we changed the format of the OPPS Addenda A, B, and C, by adding a column entitled ''Copayment Capped at the Inpatient Deductible of $1,364.00'' where we flag, through use of an asterisk, those items and services with a copayment that is equal to or greater than the inpatient hospital deductible amount for any given year (the copayment amount for a procedure performed in a year cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year). For CY 2021, we are retaining these columns, updated to reflect the amount of the 2021 inpatient deductible. For CY 2021, we proposed to add a new column to the OPPS Addenda, A, B, and C, entitled ''Drug Pass-Through Expiration during Calendar Year'' where we would flag through the use of an asterisk, each drug for which pass-through payment is expiring prior to December 31 of the calendar year. We requested public comments on this proposed change to the OPPS Addenda A, B, and C for CY 2021.

We did not receive any public comments regarding the proposed CY 2021 format changes for the OPPS Addenda A, B, and C. Therefore, for CY 2021, we are finalizing our proposal to add an additional column entitled ''Drug Pass-Through Expiration during Calendar Year'' where we would flag through the use of an asterisk, each drug for which pass-through payment is expiring prior to December 31 of the calendar year.

To view the Addenda to the CY 2021 OPPS/ASC final rule with comment period, pertaining to CY 2021 payments under the OPPS, we refer readers to the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*; select ''CMS–1736–FC'' from the list of regulations. All OPPS Addenda to the CY 2021 OPPS/ASC final rule with comment period, are contained in the zipped folder entitled ''2021 NFRM OPPS Addenda'' at the bottom of the page. To view the Addenda to the CY 2021 OPPS/ASC final rule with comment period, pertaining to CY 2021 payments under the ASC payment system, we refer readers to the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html*; select ''CMS–1736–FC'' from the list of regulations. The ASC Addenda to the CY 2021 OPPS/ASC final rule with comment period, are contained in a zipped folder entitled ''Addendum AA, BB, DD1, DD2, and EE.'' in the related links section at the bottom of the page.

XXIV. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act 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 Paperwork Reduction Act 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 final rule with comment period, we are soliciting comments on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

B. ICRs for the Hospital OQR Program

1. Background

The Hospital Outpatient Quality Reporting (OQR) Program is generally aligned with the CMS quality reporting program for hospital inpatient services known as the Hospital IQR Program. We refer readers to the CY 2011 through CY 2020 OPPS/ASC final rules with comment periods (75 FR 72111 through 72114; 76 FR 74549 through 74554; 77 FR 68527 through 68532; 78 FR 75170 through 75172; 79 FR 67012 through 67015; 80 FR 70580 through 70582; 81 FR 79862 through 79863; 82 FR 59476 through 59479; 83 FR 59155 through 59156; and 84 FR 61468 through 61469, respectively) for detailed discussions of the previously finalized Hospital OQR Program ICRs. The ICRs associated with the Hospital OQR Program are currently approved under OMB control number 0938–1109, which expires on March 31, 2023. Below we discuss only the changes in burden that will result from the finalized policies in this final rule with comment period.

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59477), we finalized a proposal to utilize the median hourly wage rate for Medical Records and Health Information Technicians, in accordance with the Bureau of Labor Statistics (BLS), to calculate our burden estimates for the Hospital OQR Program. The BLS describes Medical Records and Health Information Technicians as those responsible for organizing and managing health information data; therefore, we believe it is reasonable to assume that these individuals will be tasked with abstracting clinical data for submission to the Hospital OQR Program. The latest data (May 2019) from the BLS reflects a median hourly wage of $19.40 per hour for a Medical Records and Health Information Technician professional.[379] We have finalized a policy to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage (82 FR 59477). This is necessarily a rough adjustment, both because fringe benefits and overhead costs can vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($19.40 × 2 = $38.80) to estimate the total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

2. *Summary*

We are finalizing our proposals to: (1) Codify the statutory authority for the Hospital OQR Program; (2) revise and codify the previously finalized public display of measure data policy that hospitals sharing the same CCN must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes; (3) revise existing § 419.46(a)(2) by replacing the term ''security administrator'' with the term ''security official'' and codifying this language; (4) move all deadlines falling on nonwork days forward consistent with section 216(j) of the Social Security Act (the Act), 42 U.S.C. 416(j), ''Periods of Limitation Ending on Nonwork Days,'' beginning with the effective date of this rule; (5) revise our policy regarding submission deadlines at

[379] Occupational Employment and Wages, May 2019. Available at: *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm*. Accessed March 30, 2020.

existing § 419.46(c)(2) to reflect the finalized deadlines policy consistent with section 216(j) of the Act, 42 U.S.C. 416(j); (6) expand the existing review and corrections policy for chart-abstracted data to apply to measure data submitted via the CMS web-based tool beginning with data submitted for the CY 2023 payment determination and subsequent years; (7) codify at 42 CFR 419.46 the review and corrections period policy for measure data submitted to the Hospital OQR Program for chart-abstracted measure data, as well as for the newly finalized policy for measure data submitted directly to CMS via the CMS web-based tool; (8) codify the previously finalized Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures; (9) revise existing § 419.46(b) (redesignated § 419.46(c)) by removing the phrase ''submit a new participation form'' to align with previously finalized policy; and (10) update internal cross-references as a result of the redesignations.

We note that our finalized policies for the CY 2021 OPPS/ASC final rule will not yield a change in burden for the hospitals participating in the Hospital OQR Program as our policies seek only to refine existing regulatory text for current processes or to codify existing processes. As such, we note that the burden hours for the CY 2023 payment determination will be consistent with the previously finalized burden for the CY 2022 payment determination. We refer readers to the information collection request that has been approved by OMB control number 0938–1109 (expiration date March 31, 2023).[380]

C. ICRs for the ASCQR Program

1. Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74554), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53672), and the CY 2013, CY 2014, CY 2015, CY 2016, CY 2017, CY 2018, CY 2019, and CY 2020 OPPS/ASC final rules with comment period (77 FR 68532 through 68533; 78 FR 75172 through 75174; 79 FR 67015 through 67016; 80 FR 70582 through 70584; 81 FR 79863 through 79865; 82 FR 59479 through 59481; 83 FR 59156 through 59157; and 84 FR 61469, respectively) for detailed discussions of the Ambulatory Surgical Center Quality Reporting (ASCQR) Program ICRs we have previously finalized. The ICRs associated with the ASCQR Program for the CY 2014 through CY 2023 payment determinations are currently approved under OMB control number 0938–1270 which expires on December 31, 2022.

2. Summary

We are finalizing our proposals to: (1) Use the term ''security official'' instead of ''security administrator'' and revise § 416.310(c)(1)(i) by replacing the term ''security administrator'' with the term ''security official;'' (2) remove the phrase ''data collection time period'' in all instances where it appears in § 416.310 and replace it with the phrase ''data collection period''; (3) move forward all program deadlines falling on a nonwork day consistent with section 216(j) of the Act, 42 U.S.C. 416(j) and codify this policy; and (4) formalize the process by which ASCs identify errors and resubmit data before the established submission deadline by creating a review and corrections period that aligns with the Hospital OQR Program as finalized in section XIV.D.7. and that runs concurrent with the existing ASCQR data submission period, and codify this policy. We note that our finalized proposals for the CY 2021 OPPS/ASC final rule with comment period will not yield a change in burden for the facilities participating in the ASCQR Program as our policies seek only to refine existing regulatory text for current processes or to codify existing processes. As such, we note that the burden hours for the CY 2023 payment determination will be consistent with the previously finalized burden for the CY 2022 payment determination. We refer readers to the currently approved information collection request (OMB control number 0938–1270).[381]

D. ICRs for Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Act, which allows the Secretary to develop a method for controlling unnecessary increases in the volume of covered OPD services. (84 FR 61142).[382] The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

In accordance with paragraph (b) of 42 CFR 419.83, we are finalizing our proposal to add two new service categories to § 419.83(a): Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators. The ICR associated with prior authorization requests for these covered outpatient department services is the required documentation submitted by providers. The prior authorization request must include all relevant documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules and the request must be submitted before the service is provided to the beneficiary and before the claim is submitted for processing.

The burden associated with the prior authorization process for the two new categories, Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators, will be the time and effort necessary for the submitter to locate and obtain the relevant supporting documentation to show that the service meets applicable coverage, coding, and payment rules, and to forward the information to CMS or its contractor (MAC) for review and determination of a provisional affirmation. We expect that this information will generally be maintained by providers within the normal course of business and that this information will be readily available. We estimate that the average time for office clerical activities associated with this task will be 30 minutes, which is equivalent to that for normal prepayment or post payment medical review. We anticipate that most prior authorization requests will be sent by means other than mail. However, we estimate a cost of $5 per request for mailing medical records. Due to the July 1, 2021 start date, the first year of prior authorization for the two new service categories will only include 6 months. Based on CY 2018 data, we estimate that for those first 6 months there will be 6,808 initial requests mailed during the year. In addition, we estimate there will be 2,234 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total mailing cost is estimated to be $45,210 (9,042 mailed requests × $5). Based on CY 2018 data for the two new service categories, we estimate that annually there will be 13,615 initial requests mailed during a year. In addition, we estimate there will be 4,468 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total annual mailing cost is estimated to be $90,415 (18,083 mailed requests × $5). We also

[380] CY 2020 Final Rule Hospital OQR Program ''Supporting Statement-A''. Available at: *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201911-0938-015.*

[381] CY 2020 Final Rule ASCQR Program ''Supporting Statement-A''. Available at: *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201911-0938-016.*

[382] See also Correction notification issued January 3, 2020 (85 FR 224).

estimate that an additional 3 hours will be required for attending educational meetings, training staff on what services require prior authorization, and reviewing training documents.

The average labor costs (including 100 percent fringe benefits) used to estimate the costs were calculated using data available from the Bureau of Labor Statistics (BLS). Based on the BLS information, we estimate an average clerical hourly rate of $16.63 with a loaded rate of $33.26. The prior authorization program for these two service categories will not create any new documentation or administrative requirements. Instead, it will just require the same documents needed to support claim payments to be submitted earlier in the claim process. The estimate uses the clerical rate since we do not believe that clinical staff will need to spend more time on completing the documentation than will be needed in the absence of the prior authorization policy. The hourly rate reflects the time needed for the additional clerical work of submitting the prior authorization request itself. CMS believes providers will have provided education to their staff on what services are included in the prior authorization process. Following this education, the staff will know which services will need prior authorization and will not need additional time or resources to determine if a service requires prior authorization. We estimate that the total number of submissions for the first year (6 months) will be 30,140 (21,098 submissions through fax or electronic means + 9,042 mailed submissions). Therefore, we estimate that the total burden for the first year (6 months) for the two new service categories, allotted across all providers, will be 24,820 hours (.5 hours × 30,140 submissions plus 3 hours × 3,250 providers for education). The burden cost for the first year (6 months) is $870,723 (24,820 hours × $33.26 plus $45,210 for mailing costs). In addition, we estimate that the total annual number of submissions will be 60,277 (42,194 submissions through fax or electronic means + 18,083 mailed submissions). The annual burden hours for the two new service categories, allotted across all providers, will be 39,889 hours (.5 hours × 60,277 submissions plus 3 hours × 3,250 providers for education). The annual burden cost will be $1,417,107 (39,889 hours × $33.26 plus $90,416 for mailing costs). For the total burden and associated costs for the two new service categories, we estimate the annualized burden to be 34,866 hours and $1,234,979. The annualized burden is based on an average of 3 years, that is, 1 year at the 6-month burden and 2 years at the 12-month burden. The ICR approved under OMB control number 0938–1368 will be revised and submitted to OMB for approval.

Below is a chart reflecting the total burden and associated costs for the provisions included in the CY 2021 OPPS/ASC proposed rule.

Information Collection Requests	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
Overall Star Rating[4]	0.0	0.0
Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process	+34,866	+$1.2 million

* Numbers rounded.

[1] Burden changes for the Hospital IQR Program reflect total changes over a four-year period from the CY 2021 reporting period/FY 2023 payment determination through the CY 2024 reporting period/FY 2026 payment determination.

[2] Because the FY 2022 Hospital VBP Program will use data that are also used to calculate quality measures in other programs and Medicare fee-for-service claims data that hospitals are already submitting to CMS for payment purposes, the program does not anticipate any change in burden associated with this final rule.

[3] Because the Hospital Readmissions Reduction Program measures are all collected via Medicare fee-for service- claims that hospitals are already submitting to CMS for payment purposes, there is no unique information collection burden associated with the program.

[4] Because the Overall Star Rating uses measure data already collected and reported by other programs, the burden is captured in the respective programs and represents no increased burden.

E. ICRs for the Overall Hospital Quality Star Rating

The Overall Star Rating uses measures that are publicly reported on Hospital Compare or its successor websites under the public reporting authority of each individual hospital program furnishing measure data. We believe the burden associated with measures included in the Overall Star Rating, including requesting withholding of measures from public reporting, is already captured in the respective hospital programs' ICRs and represents no increased information collection burden to hospitals.

F. ICRs for Physician-Owned Hospitals

As discussed in section XIX. of this final rule with comment period, we are finalizing our proposal to modify the physician-owned hospital expansion exception process under the rural provider and hospital ownership exceptions to the physician self-referral law. Specifically, we are modifying the frequency of submission such that a high Medicaid facility could request an exception to the prohibition on expansion of facility capacity at any time, provided that it has not submitted another request for an exception to the prohibition on facility expansion to CMS for which CMS has not issued a decision. We continue to believe this modification will not result in any changes in burden under the PRA. First, we do not anticipate any changes in the annual number of respondents. Although a high Medicaid facility would be permitted to request an expansion exception more frequently than under current regulations, we believe that removing the cap on the size of an expansion would make more

frequent expansion exception requests unlikely. Also, we are not changing the information being collected.

Based on our experience with the expansion exception process to date, we estimate that approximately one physician-owned hospital per year will request an expansion exception on the grounds that it is a high Medicaid facility. This estimate aligns with the total number of expansion exception requests received to date. We estimate that it takes approximately 6 hours and 45 minutes to prepare an expansion exception request and that a request is prepared by a lawyer. To estimate the cost to prepare a request, we use a 2019 wage rate of $69.86 for lawyers from the Bureau of Labor Statistics,[383] and we double that wage to account for overhead and benefits. The total estimated annual cost is $943.11. We received the following comments:

Comment: A few commenters stated that our estimate relating to the number of expansion exception requests we will receive on an annual basis is understated. The commenters stated that, based on their analysis, approximately 25 physician-owned hospitals either currently qualify as high Medicaid facilities or could soon qualify. A commenter recommended that CMS release the data upon which it based its estimate.

Response: We continue to estimate that approximately one physician-owned hospital per year will request an expansion exception on the grounds that it is a high Medicaid facility. The modifications in this rule do not change the definition of a high Medicaid facility and therefore would not change the number of high Medicaid facilities that could seek an expansion exception. We believe it is highly unlikely that every physician-owned hospital that could meet the definition of a high Medicaid facility would seek an expansion exception. Instead, only those physician-owned hospitals that meet the definition and that also have the desire to expand, the resources to expand, and are able to meet any applicable state or local requirements (such as certificate of need) would seek an expansion exception. We believe it is reasonable to use our experience with the expansion exception process to date to estimate the number of requests we may receive in the future. Since the enactment of section 6001 of the Affordable Care Act of 2010, we have received only a handful of expansion exception requests, and only four physician-owned hospitals have been granted expansion exceptions as high Medicaid facilities. All expansion exceptions issued to date have been posted on our website (*https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Physician_Owned_Hospitals*).

G. ICRs for COVID–19 Therapeutic Inventory and Usage Data Reporting and Acute Respiratory Illness (Including, but Not Limited to, Seasonal Influenza Virus, Influenza-Like Illness, and Severe Acute Respiratory Infection) Data Reporting in Hospitals and CAHs

In this IFC, we are revising our current COVID–19 PHE hospital and CAH CoP reporting requirements at 42 CFR 482.42(e) for hospitals and at 42 CFR 485.640(d) for CAHs, to now require hospitals and CAHs to report data elements that must include, but not be limited to, the following: (1) The hospital's (or the CAH's) current inventory supplies of any COVID–19-related therapeutics that have been distributed and delivered to the hospital (or CAH) under the authority and direction of the Secretary; and (2) the hospital's (or 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.

As part of the overall hospital and CAH COVID–19 reporting data, users will most likely report these data on a daily basis, as is currently recommended by the CDC, and that this new data will take users, on average, an additional 15 minutes to complete. As with the other hospital and CAH data elements associated with the PHE that are required through the guidance to be reported, and because OMB PRA approval is requested for 180 days, the total number of responses per respondent is 180 for a six-month period.

We are also revising the regulations by adding provisions to the CoPs (§ 482.42 for hospitals and § 485.640 for CAHs), and are now requiring hospitals and CAHs to report information in accordance with a frequency, and in a standardized format, as specified by the Secretary during the PHE for Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection). The burden associated with these reporting activities will be submitted under OMB control number 0938–NEW. For purposes of burden estimates, we do not differentiate among general acute care and CAHs, as they all complete the same data collection.

We have estimated that the Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection) forms will take an average of 90 minutes to complete, with the acknowledgement that the reporting burden includes surveillance and data entry. We further estimate that users will most likely report these data on a daily basis, as is currently recommended by the CDC for COVID–19 data, and will most likely use a data collection channel and format similar, if not identical, to that currently being used for the hospital and CAH COVID–19 reporting data, as recommended in the most current (as of October 6, 2020) COVID–19 Guidance for Hospital Reporting document (*https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf*) and (*https://healthdata.gov/covid-19_hospital_reporting*). Because OMB PRA approval is requested for 180 days, the total number of responses per respondent is 180 for a six month period.

This PRA package will then be merged with the HHS PRA package for Teletracking that is currently seeking OMB approval and was announced in the **Federal Register** on September 23, 2020 (85 FR 59809). Details of these burden estimates and the costs can be found in Tables 77 and 78.

[383] U.S. Department of Labor, Bureau of Labor Statistics, May 2019 National Occupational Employment and Wage Estimates United States, *https://www.bls.gov/oes/current/oes_nat.htm.*

TABLE 77: Hospital and CAH Reporting of Acute Respiratory Illness/Tracking of COVID-19 Therapeutic Inventory and Usage Estimated Burden Hours

Type of respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average burden per response (in hours)	Total burden hours
Hospitals and CAHs	HHS Teletracking COVID–19 Portal	6,200	180	1.5	1,674,000
Hospitals and CAHs	HHS Teletracking COVID–19 Portal	6,200	180	0.25	279,000

TABLE 78: Hospital and CAH Reporting of Acute Respiratory Illness/Tracking of COVID-19 Therapeutic Inventory and Usage Estimated Costs

Type of respondent: Hospital Staff—Registered Nurses	Total burden hours	Hourly wage rate	Total respondent costs
	1,674,000	*$70.48	$117,983,520
	279,000	*$70.48	$19,663,920
Total	1,953,000	*$70.48	$137,647,440

* The hourly wage rate (Accessed at https://www.bls.gov/oes/current/oes291141.htm) includes overhead and fringe benefits.

XXV. Waiver of the 30-Day and 60-Day Delayed Effective Dates for the Final Rule With Comment Period and Waiver of Proposed Rulemaking for the COVID–19 Therapeutic Inventory and Usage Reporting Requirements and for the Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) To Report Acute Respiratory Illness During the PHE for COVID–19 Interim Final Rule With Comment Period (IFC)

A. Waiver of the 30-Day and 60-Day Delayed Effective Dates for the Final Rule With Comment Period

We are committed to ensuring that we fulfill our statutory obligation to update the OPPS as required by law and have worked diligently in that regard. We ordinarily provide a 60-day delay in the effective date of final rules after the date they are issued in accordance with the Congressional Review Act (CRA) (5 U.S.C. 801(a)(3)). However, section 808(2) of the CRA provides that, if an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the rule shall take effect at such time as the agency determines.

In addition, the Administrative Procedure Act, (5 U.S.C. 553(d)), ordinarily requires a 30-day delay in the effective date of a final rule from the date of its public availability in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds good cause to support an earlier effective date. Section 1871(e)(1)(B)(ii) of the Act, also permits a substantive rule to take effect less than 30 days after its publication if the Secretary finds that waiver of the 30-day period is necessary to comply with statutory requirements or that the 30-day delay would be contrary to the public interest.

The United States is responding to an outbreak of respiratory disease caused by a novel (new) coronavirus that has now been detected in more than 190 locations internationally, including in all 50 States and the District of Columbia. The virus has been named ''SARS–CoV–2'' and the disease it causes has been named ''coronavirus disease 2019'' (abbreviated ''COVID–19'').

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a ''Public Health Emergency of international concern'' (PHEIC). On January 31, 2020, Health and Human Services Secretary, Alex M. Azar II, declared a PHE for the United States to aid the nation's healthcare community in responding to COVID–19. On March 11, 2020, the WHO publicly characterized COVID–19 as a pandemic. On March 13, 2020 the President of the United States declared the COVID–19 outbreak a national emergency.

The COVID–19 PHE has required the agency to divert energy and personnel resources that would otherwise have been used to complete this OPPS/ASC payment system final rule with comment period to other priority matters, including four interim final rules necessary because of the PHE. (See 85 FR 19230 (April 6, 2020); 85 FR 27550 (May 8, 2020); 85 FR 54820 (September 2, 2020); 85 FR 71142 (November 6, 2020)). Although we have devoted significant resources to completing the OPPS/ASC payment system final rule with comment period, it was impracticable for CMS to complete the work needed on the rule in accordance with our usual schedule for this rulemaking or in sufficient time to ensure a full 60-day period of public notice prior to the next calendar year that begins on January 1, 2021. The OPPS/ASC payment system final rule with comment period is necessary to annually review and update the payment systems, and it is critical to ensure that the payment policies for these systems are effective on the first day of the calendar year to which they are intended to apply. Therefore, in

light of the COVID–19 PHE, and the resulting strain on CMS's resources, it was impracticable for CMS to publish this final rule either 30 or 60 days prior to the beginning of the upcoming year, and CMS has determined that, for good cause, it would be contrary to the public interest to delay the effective date of this final rule with comment period beyond January 1, 2021, and we are waiving both the 30-day and 60-day delayed effective date requirements for this final rule with comment period.

B. Waiver of Proposed Rulemaking for the COVID–19 Therapeutic Inventory and Usage Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) and for the Reporting Requirements for Hospitals and CAHs To Report Acute Respiratory Illness During the PHE for COVID–19 Interim Final Rule With Comment Period (IFC)

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule before the provisions of the rule are finalized, either as proposed or as amended in response to public comments, and take effect, in accordance with the APA (Pub. L. 79–404), 5 U.S.C. 553, and, where applicable, section 1871 of the Act. Specifically, 5 U.S.C. 553 requires the agency to publish a notice of the proposed rule in the **Federal Register** that includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. Further, 5 U.S.C. 553 requires the agency to give interested parties the opportunity to participate in the rulemaking through public comment before the provisions of the rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and a period of not less than 60 days for public comment for rulemaking carrying out the administration of the insurance programs under title XVIII of the Act. Section 1871(b)(2)(C) of the Act and 5 U.S.C. 553 authorize the agency to waive these procedures, however, if the agency for good cause finds that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

Section 553(b)(B) of title 5 of the U.S. Code ordinarily requires a 30-day delay in the effective date of a final rule from the date of its publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds good cause to support an earlier effective date. Section 1871(e)(1)(B)(i) of the Act also prohibits a substantive rule from taking effect before the end of the 30-day period beginning on the date the rule is issued or published. However, section 1871(e)(1)(B)(ii) of the Act permits a substantive rule to take effect before 30 days have passed, if the Secretary finds that a waiver of the 30-day period is necessary to comply with statutory requirements or that the 30-day delay would be contrary to the public interest. Furthermore, section 1871(e)(1)(A)(ii) of the Act permits a substantive change in regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability under Title XVIII of the Act to be applied retroactively to items and services furnished before the effective date of the change if the failure to apply the change retroactively would be contrary to the public interest. Finally, the Congressional Review Act (CRA) (Pub. L. 104–121, Title II) requires a delay in the effective date for major rules unless an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, in which case the rule shall take effect at such time as the agency determines. 5 U.S.C. 801(a)(3), 808(2).

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a ''Public Health Emergency of international concern.'' On January 31, 2020, pursuant to section 319 of the PHSA, the Secretary determined that a PHE exists for the United States to aid the nation's healthcare community in responding to COVID–19. On March 11, 2020, the WHO publicly declared COVID–19 a pandemic. On March 13, 2020, the President declared the COVID–19 pandemic a national emergency. Effective July 25, 2020, the Secretary renewed the January 31, 2020 determination that was previously renewed on April 21, 2020, that a PHE exists and has existed since January 27, 2020. This declaration, along with the Secretary's January 30, 2020 declaration of a PHE, conferred on the Secretary certain waiver authorities under section 1135 of the Act. On March 13, 2020, the Secretary authorized waivers under section 1135 of the Act, effective March 1, 2020.

On March 4, 2020, we issued guidance (*https://www.cms.gov/files/document/qso-20-13-hospitalspdf.pdf-2*) stating that hospitals should inform infection prevention and control services, local and state public health authorities, and other healthcare facility staff as appropriate about the presence of a person under investigation for COVID–19. CMS followed this guidance with an interim final rule with comment (IFC), published on September 2, 2020 (85 FR 54820), that now requires hospitals and CAHs to report important data critical to support the fight against COVID–19. The CoP provisions require that hospitals and CAHs report this information in accordance with a frequency as specified by the Secretary on COVID–19 as well as in a standardized format specified by the Secretary. Examples of data elements that may be required to be reported include things such as the number of staffed beds in a hospital and the number of those that are occupied, information about its supplies, and a count of patients currently hospitalized who have laboratory-confirmed COVID–19. This list is not exhaustive of those data items that we may require hospitals and CAHs to submit, as specified by the Secretary (see *https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf* for the current list of data items specified). These elements are essential for planning, monitoring, and resource allocation during the COVID–19 Public Health Emergency (PHE). The new rules make reporting a requirement of participation in the Medicare and Medicaid programs. This reporting is needed to support broader surveillance of COVID–19.

As we discussed in Section XXII., promising new COVID–19-related therapeutics are being issued Emergency Use Authorizations by the Food and Drug Administration. Because these new therapeutics are in very scarce supply in the United States, HHS is actively working with manufacturers to ensure that they are distributed efficiently and effectively. Effective distribution methods use a variety of indicators, tailored to the specific therapeutic, to estimate the geographic and regional distribution that is recommended for that particular therapeutic. However, as we previously noted, analysing and understanding the usage patterns specific to each new therapeutic requires real-world information in real time. Lacking accurate information on the usage rates and current inventory on hand for a particualr therapeutic, can possibly result in scarce therapeutic supplies being sent to areas that already have adequate inventories on hand. Such an inefficient and ill-informed distribution strategy for these therapeutics could

very quickly lead to a situation that could negatively impact areas of the nation that already have inadequate supplies and resources.

In response to this situation and as a pre-emptive means of avoiding the disastrous consequences of inadequate planning, we are revising our current COVID–19 PHE hospital and CAH CoP reporting requirements at 42 CFR 482.42(e) for hospitals and at 42 CFR 485.640(d) for CAHs, to now require hospitals and CAHs to report data elements that must include, but not be limited to, the following: (1) The hospital's (or the CAH's) current inventory supplies of any COVID–19-related therapeutics that have been distributed and delivered to the hospital (or CAH) under the authority and direction of the Secretary; and (2) the hospital's (or 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. The importance of this particular data reporting, along with the information provided, cannot be overestimated as we continue to make advances to more effectively address the continuing COVID–19 PHE and to greatly diminish its negative impact on the nation.

Therefore, we believe that the lack of real data on hospital and CAH inventory supplies and usage rates of COVID–19-related therapeutics, coupled with the overarching and continuing urgency of the PHE for COVID–19, constitutes good cause to waive notice and comment rulemaking as we believe it would be impracticable and contrary to the public interest for us to undertake normal notice and comment rulemaking procedures. For the same reasons, because we cannot afford any delay in effectuating this IFC, we find good cause to waive the 30-day delay in the effective date and, moreover, to establish these policies in this IFC applicable as of the date this rule is published.

Ensuring the health and safety of all Americans, including Medicare beneficiaries, Medicaid recipients, and healthcare workers, is of primary importance. This IFC directly supports that goal by requiring, in addition to the current COVID–19 reporting by hospitals and CAHs as well as the new COVID–19-related therapeutic inventory and usage data reporting requirements discussed here, the additional reporting of Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection) data. It is critically important that we implement the policies in this IFC as quickly as possible. As we are already in the midst of the PHE for the COVID–19 pandemic, we now find our nation also fully entering the seasonal influenza season for North America, which will include increased patient case presentations of a variety of respiratory infections and viral diseases, the most significant of which will be cases of seasonal influenza virus and influenza-like illness as well as cases of other acute respiratory illness as defined by the Centers for Disease Control and Prevention (CDC) (*https://www.cdc.gov/flu/about/glossary.htm*).

According to *Scientific American,* (*https://www.scientificamerican.com/article/coronavirus-and-the-flu-a-looming-double-threat/*), the ''overlap of COVID–19 and influenza has epidemiologists and some policy makers concerned,'' and that, ''the U.S. may soon face two epidemics at the same time,'' precipitating ''a crisis unlike any other.'' The article further states that, ''the worst-case scenario is both [the coronavirus and the flu] are spreading fast and causing severe disease, complicating diagnoses and presenting a double burden on the health care system.'' The most recent data from the CDC regarding the 2017–2018 influenza season and hospitalizations show that, ''30,453 laboratory-confirmed influenza-related hospitalizations were reported through the *Influenza Hospitalization Surveillance Network* (FluSurv-NET), which covers approximately 9% of the U.S. population,'' and that, ''people 65 years and older accounted for approximately 58% of reported influenza-associated hospitalizations,'' and that ''overall hospitalization rates (all ages) during 2017–2018 were the highest ever recorded in this surveillance system, breaking the previously recorded high recorded during 2014–2015'' (*https://www.cdc.gov/flu/about/season/flu-season-2017-2018.htm#anchor_1534865852732*). We believe that these 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 acute respiratory illnesses coupled with COVID–19 on patients, the staff who care for them, and the general public. We believe that this action reaffirms our commitment to protecting the health and safety of all patients who receive care at the approximately 6,200 Medicare- and Medicaid-participating hospitals and CAHs nationwide.

Therefore, we believe that the impending seasonal influenza virus (and acute respiratory illness) season with its potential for increased hospitalizations, coupled with the continuing urgency of the PHE for COVID–19, constitutes good cause to waive notice and comment rulemaking as we believe it would be impracticable and contrary to the public interest for us to undertake normal notice and comment rulemaking procedures. For the same reasons, because we cannot afford any delay in effectuating this IFC, we find good cause to waive the 30-day delay in the effective date and, moreover, to establish these policies in this IFC applicable as of the date this rule is published.

XXVI. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this final rule with comment period and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

XXVII. Economic Analyses

A. Statement of Need

This final rule with comment period is necessary to update the Medicare hospital OPPS rates and to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2021. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We are revising the APC relative payment weights using claims data for services furnished on and after January 1, 2019, through and including December 31, 2019, and processed through June 30, 2020, and updated cost report information.

This final rule with comment period also is necessary to update the ASC payment rates for CY 2021 and make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in ASCs in CY 2021. Because ASC payment rates are based on the OPPS relative payment weights for most of the procedures

performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS relative payment weights. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC, not less frequently than every 2 years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59079), we finalized a policy to update the ASC payment system rates using the hospital market basket update instead of the CPI–U for CY 2019 through 2023. We believe that this policy will help stabilize the differential between OPPS payments and ASC payments, given that the CPI–U has been generally lower than the hospital market basket, and encourage the migration of services to lower cost settings as clinically appropriate.

B. Overall Impact of Provisions of This Final Rule With Comment Period

We have examined the impacts of this final rule with comment period, 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 (UMRA) (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017). This section of this final rule with comment period contains the impact and other economic analyses for the provisions we are finalizing for CY 2021.

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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule with comment period has been designated as an economically significant rule under section 3(f)(1) of Executive Order 12866 and a major rule under the Congressional Review Act. Accordingly, this final rule with comment period has been reviewed by the Office of Management and Budget. We have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of the provisions of this final rule with comment period. We solicited public comments on the regulatory impact analysis in the proposed rule, and we address any public comments we received in this final rule, as appropriate.

We estimate that the total increase in Federal Government expenditures under the OPPS for CY 2021, compared to CY 2020, due only to the changes to the OPPS in this final rule with comment period, will be approximately $1.49 billion. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2021, we estimate that the OPPS expenditures, including beneficiary cost-sharing, for CY 2021 would be approximately $83.9 billion, which is approximately $7.5 billion higher than estimated OPPS expenditures in CY 2020. Because the provisions of the OPPS are part of a final rule that is economically significant, as measured by the threshold of an additional $100 million in expenditures in 1 year, we have prepared this regulatory impact analysis that, to the best of our ability, presents its costs and benefits. Table 79 of this final rule with comment period displays the distributional impact of the CY 2021 changes in OPPS payment to various groups of hospitals and for CMHCs.

We note that under our CY 2021 policy, drugs and biologicals that are acquired under the 340B Program will continue to be paid at ASP minus 22.5 percent, WAC minus 22.5 percent, or 69.46 percent of AWP, as applicable. We also note that in the impact tables as displayed in this impact analysis, we have modeled current and prospective payments as if separately payable drugs acquired under the 340B program from hospitals not excepted from the policy are paid under the OPPS in CY 2021 at ASP minus 22.5 percent.

We estimate that the final rule update to the conversion factor, the CY 2021 frontier wage index adjustment, and other adjustments (not including the effects of outlier payments or the pass-through payment estimates) will increase total OPPS payments by 0.2 percent in CY 2021. The changes to the APC relative payment weights, the changes to the wage indexes, the continuation of a payment adjustment for rural SCHs, including EACHs, and the payment adjustment for cancer hospitals will not increase OPPS payments because these changes to the OPPS are budget neutral. However, these updates will change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2020 and CY 2021, considering all final budget neutral payment adjustments, changes in estimated total outlier payments, pass-through payments, and the application of the frontier State wage adjustment, in addition to the application of the OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G), and 1833(t)(17) of the Act, will increase total estimated OPPS payments by 2.4 percent.

We estimate the total increase (from changes to the ASC provisions in this final rule with comment period as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures (not including beneficiary cost-sharing) under the ASC payment system for CY 2021 compared to CY 2020, to be approximately $120 million. Because the provisions for the ASC payment system are part of a final rule that is economically significant, as measured by the $100 million threshold, we have prepared a regulatory impact analysis of the changes to the ASC payment system that, to the best of our ability, presents the costs and benefits of this portion of this final rule with comment period. Tables 80 and 81 of this final rule with comment period display the redistributive impact of the CY 2021 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

C. Detailed Economic Analyses

1. Estimated Effects of OPPS Changes in This Final Rule With Comment Period

a. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the CY 2021 policy changes on various hospital groups. We post on the CMS website our hospital-specific estimated payments for CY 2021 with the other supporting documentation for this final rule with comment period. To view the hospital-specific estimates, we refer readers to the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* At the website, select ''regulations and notices'' from the left side of the page and then select ''CMS–1736–FC'' from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this

final rule with comment period. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 79. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A. of this final rule with comment period for a discussion of the hospitals whose claims we do not use for ratesetting or impact purposes.

We estimate the effects of the individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our policy changes in order to isolate the effects associated with specific policies or updates, but any policy that changes payment could have a behavioral response. In addition, we have not made adjustments for future changes in variables, such as service volume, service-mix, or number of encounters.

b. Estimated Effects of the 340B Program Payment Policy

In section V.B. of this final rule with comment period with comment period, we discuss our policy to adjust the payment amount for nonpass-through, separately payable drugs acquired by certain 340B participating hospitals through the 340B Program. We are finalizing that rural SCHs, children's hospitals, and PPS-exempt cancer hospitals will continue to be excepted from this payment policy in CY 2021 and subsequent years. Specifically, in this final rule with comment period for CY 2021, for hospitals paid under the OPPS (other than those that are excepted for CY 2021), we are not finalizing our proposal to pay for separately payable drugs and biologicals that are obtained with a 340B discount, excluding those on pass-through payment status and vaccines, at ASP minus 28.7 percent. Instead, we are finalizing our alternative proposal that we will continue the current Medicare payment policy for CY 2021. Under our alternative proposal, we will pay for separately payable drugs and biologicals acquired under the 340B program, excluding those on pass-through payment status and vaccines, at ASP minus 22.5 percent. Because we are continuing current Medicare payment policy for CY 2021, there is no change to the budget neutrality adjustment as a result of the 340B drug payment policy.

c. Estimated Effects of OPPS Changes on Hospitals

Table 79 shows the estimated impact of this final rule with comment period on hospitals. Historically, the first line of the impact table, which estimates the change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-BBA amount. We also include CMHCs in the first line that includes all providers. We include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 79, and we discuss them separately below, because CMHCs are paid only for partial hospitalization services under the OPPS and are a different provider type from hospitals. In CY 2021, we are continuing to pay CMHCs for partial hospitalization services under APC 5853 (Partial Hospitalization for CMHCs) and to pay hospitals for partial hospitalization services under APC 5863 (Partial Hospitalization for Hospital-Based PHPs).

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor, as discussed in detail in section II.B. of this final rule with comment period.

Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The IPPS market basket percentage increase for FY 2021 is 2.4 percent. Section 1833(t)(3)(F)(i) of the Act reduces that 2.4 percent by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. However, the most recent MFP estimated from the IGI June 2020 macroeconomic forecast for FY 2021 is estimated to be −0.1 percentage point. This MFP value would have led to an increase in the IPPS market basket. Section 1886(b)(3)(B)(xi)(I) of the Act requires the Secretary to reduce (not increase) the hospital market basket percentage increase by changes in economy-wide productivity. That means the MFP adjustment for the OPPS as described by section 1833(t)(3)(F)(i) of the Act is set to 0.0 percentage points (which is also the MFP adjustment for FY 2021 in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58797)). Accordingly, we are applying a 0.0 percentage point MFP adjustment to the CY 2021 market basket percentage increase for the OPPS, which causes the OPD fee schedule increase factor to be 2.4 percent. We are using the OPD fee schedule increase factor of 2.4 percent in the calculation of the CY 2021 OPPS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.0000. The amounts attributable to this frontier State wage index adjustment are incorporated in the CY 2020 estimates in Table 79 of this final rule with comment period.

To illustrate the impact of the CY 2021 changes, our analysis begins with a baseline simulation model that uses the CY 2020 relative payment weights, the FY 2020 final IPPS wage indexes that include reclassifications, and the final CY 2020 conversion factor. Table 79 shows the estimated redistribution of the increase or decrease in payments for CY 2021 over CY 2020 payments to hospitals and CMHCs as a result of the following factors: The impact of the APC reconfiguration and recalibration changes between CY 2020 and CY 2021 (Column 2); the wage indexes and the provider adjustments (Column 3); the combined impact of all of the changes described in the preceding columns plus the 2.4 percent OPD fee schedule increase factor update to the conversion factor (Column 4); the estimated impact taking into account all payments for CY 2021 relative to all payments for CY 2020, including the impact of changes in estimated outlier payments, and changes to the pass-through payment estimate (Column 5).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we are maintaining the current adjustment percentage for CY 2021. Because the updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2021 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services will change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this final rule with comment period will redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between

CY 2020 and CY 2021 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the rates for CY 2021 will increase Medicare OPPS payments by an estimated 2.4 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in an estimated 2.4 percent increase in Medicare payments to all other hospitals. These estimated payments will not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 79 shows the total number of facilities (3,665), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2019 hospital outpatient and CMHC claims data to model CY 2020 and CY 2021 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not plausibly estimate CY 2020 or CY 2021 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A. of this final rule with comment period. At this time, we are unable to calculate a DSH variable for hospitals that are not also paid under the IPPS because DSH payments are only made to hospitals paid under the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number of OPPS hospitals (3,558), excluding the hold-harmless cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to their ''pre-BBA amount'' as specified under the terms of the statute, and therefore, we removed them from our impact analyses. We show the isolated impact on the 39 CMHCs at the bottom of the impact table (Table 79) and discuss that impact separately below.

Column 2: APC Recalibration—All Changes

Column 2 shows the estimated effect of APC recalibration. Column 2 also reflects any changes in multiple procedure discount patterns or conditional packaging that occur as a result of the changes in the relative magnitude of payment weights. As a result of APC recalibration, we estimate that urban hospitals will experience no change, with the impact ranging from a decrease of 0.4 percent to an increase of 0.3, depending on the number of beds. Rural hospitals will experience no change overall. Major teaching hospitals will see an expected decrease of 0.5 percent.

Column 3: Wage Indexes and the Effect of the Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the APC recalibration; the updates for the wage indexes with the FY 2021 IPPS post-reclassification wage indexes; the rural adjustment; the frontier adjustment, and the cancer hospital payment adjustment. We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year, and using a CY 2020 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indexes.

Column 3 reflects the independent effects of the final updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis, as well as the CY 2021 final changes in wage index policy discussed in section II.C. of this CY 2021 OPPS/ASC final rule with comment period. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we are continuing the rural payment adjustment of 7.1 percent to rural SCHs for CY 2021, as described in section II.E. of this final rule with comment period. We also did not model a budget neutrality adjustment for the final cancer hospital payment adjustment because the payment-to-cost ratio target for the cancer hospital payment adjustment in CY 2021 is 0.89, the same as the ratio that was reported for the CY 2020 OPPS/ASC final rule with comment period (84 FR 61191). We note that, in accordance with section 16002 of the 21st Century Cures Act, we are applying a budget neutrality factor calculated as if the cancer hospital adjustment target payment-to-cost ratio was 0.90, not the 0.89 target payment-to-cost ratio we are applying in section II.F. of this final rule with comment period.

We modeled the independent effect of updating the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the CY 2021 scaled weights and a CY 2020 conversion factor that included a budget neutrality adjustment for the effect of the changes to the wage indexes between CY 2020 and CY 2021.

Column 4: All Budget Neutrality Changes Combined With the Market Basket Update

Column 4 demonstrates the combined impact of all of the changes previously described and the update to the conversion factor of 2.4 percent. Overall, these changes will increase payments to urban hospitals by 2.6 percent and to rural hospitals by 2.9 percent. The increase for classes of rural hospitals will vary with sole community hospitals receiving a 3.0 percent increase and other rural hospitals receiving an increase of 2.7 percent.

Column 5: All Changes for CY 2021

Column 5 depicts the full impact of the final CY 2021 policies on each hospital group by including the effect of all changes for CY 2021 and comparing them to all estimated payments in CY 2020. Column 5 shows the combined budget neutral effects of Columns 2 and 3; the OPD fee schedule increase; the impact of estimated OPPS outlier payments, as discussed in section II.G. of this final rule with comment period; the change in the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XIV. of this final rule with comment period); and the difference in total OPPS payments dedicated to transitional pass-through payments.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2020 update (and assumed, for modeling purposes, to be the same number for CY 2021), we included 18 hospitals in our model because they had both CY 2019 claims data and recent cost report data. We estimate that the cumulative effect of all final changes for CY 2021 will increase payments to all facilities by 2.4 percent for CY 2021. We modeled the independent effect of all changes in Column 5 using the final relative payment weights for CY 2020 and the final relative payment weights for CY 2021. We used the final conversion factor for CY 2020 of $80.793 and the final CY 2021 conversion factor of $82.797 discussed in section II.B. of this final rule with comment period.

Column 5 contains simulated outlier payments for each year. We used the 1-year charge inflation factor used in the

FY 2021 IPPS/LTCH PPS final rule (85 FR 59039) of 6.4 percent (1.06404) to increase individual costs on the CY 2019 claims, and we used the most recent overall CCR in the October 2020 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2020. Using the CY 2019 claims and a 6.4 percent charge inflation factor, we currently estimate that outlier payments for CY 2020, using a multiple threshold of 1.75 and a fixed-dollar threshold of $5,075, will be approximately 0.97 percent of total payments. The estimated current outlier payments of 0.97 percent are incorporated in the comparison in Column 5. We used the same set of claims and a charge inflation factor of 13.2 percent (1.13218) and the CCRs in the October 2020 OPSF, with an adjustment of 0.974495, to reflect relative changes in cost and charge inflation between CY 2019 and CY 2021, to model the final CY 2020 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of $5,300. The charge inflation and CCR inflation factors are discussed in detail in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59039).

Overall, we estimate that facilities will experience an increase of 2.4 percent under this final rule with comment period in CY 2021 relative to total spending in CY 2020. This projected increase (shown in Column 5) of Table 79 reflects the 2.4 percent OPD fee schedule increase factor, minus 0.04 percent for the change in the pass-through payment estimate between CY 2020 and CY 2021, minus the difference in estimated outlier payments between CY 2020 (0.97 percent) and CY 2021 (1.0 percent). We estimate that the combined effect of all final changes for CY 2021 will increase payments to urban hospitals by 2.4 percent. Overall, we estimate that rural hospitals will experience a 2.4 percent increase as a result of the combined effects of all the final changes for CY 2021.

Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all changes will include an increase of 1.9 percent for major teaching hospitals and an increase of 2.7 percent for nonteaching hospitals. Minor teaching hospitals will experience an estimated increase of 2.6 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals will experience an increase of 2.3 percent, proprietary hospitals will experience an increase of 3.2 percent, and governmental hospitals will experience an increase of 2.2 percent.

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TABLE 79—ESTIMATED IMPACT OF THE CY 2021 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

	(1)	(2)	(3)	(4)	(5)
	Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 and 3) with Market Basket Update**	**All Changes**
ALL PROVIDERS *	3,665	0.0	0.2	2.6	2.4
ALL HOSPITALS	3,558	0.0	0.2	2.7	2.4
(excludes hospitals held harmless and CMHCs)					
URBAN HOSPITALS	2,806	0.0	0.2	2.6	2.4
LARGE URBAN	1,449	0.0	0.2	2.6	2.4
(GT 1 MILL.)					
OTHER URBAN	1,357	0.1	0.2	2.7	2.4
(LE 1 MILL.)					
RURAL HOSPITALS	752	0.0	0.4	2.9	2.5
SOLE COMMUNITY	367	0.0	0.5	3.0	2.6
OTHER RURAL	385	0.0	0.2	2.7	2.4
BEDS (URBAN)					
0 - 99 BEDS	961	0.2	0.3	2.9	2.6
100-199 BEDS	786	0.3	0.3	2.9	2.6
200-299 BEDS	447	0.3	0.2	2.9	2.7
300-499 BEDS	386	0.2	0.2	2.8	2.5
500 + BEDS	226	-0.4	0.0	2.1	2.0
BEDS (RURAL)					
0 - 49 BEDS	330	0.0	0.5	2.9	2.5
50- 100 BEDS	256	0.1	0.5	3.1	2.6
101- 149 BEDS	90	0.0	0.3	2.6	2.3
150- 199 BEDS	38	-0.1	0.4	2.8	2.6
200 + BEDS	38	0.0	0.2	2.6	2.5
REGION (URBAN)					
NEW ENGLAND	132	-0.3	1.0	3.1	2.0
MIDDLE ATLANTIC	327	-0.2	0.1	2.4	2.3
SOUTH ATLANTIC	455	0.1	0.1	2.6	2.6
EAST NORTH CENT.	440	-0.1	-0.1	2.3	2.2
EAST SOUTH CENT.	163	0.0	-0.1	2.3	2.3
WEST NORTH CENT.	186	0.0	0.5	2.9	1.9
WEST SOUTH CENT.	474	0.5	0.1	3.0	3.0
MOUNTAIN	213	0.2	0.1	2.8	2.1
PACIFIC	368	0.1	0.2	2.8	2.7
PUERTO RICO	48	0.2	-0.2	2.4	2.3
REGION (RURAL)					

NEW ENGLAND	20	-0.3	0.1	2.2	2.1
MIDDLE ATLANTIC	50	-0.2	0.1	2.4	2.4
SOUTH ATLANTIC	113	0.0	-0.2	2.2	2.1
EAST NORTH CENT.	120	0.2	0.6	3.3	3.2
EAST SOUTH CENT.	146	0.0	0.0	2.5	2.4
WEST NORTH CENT.	91	0.0	1.1	3.5	2.4
WEST SOUTH CENT.	141	0.5	0.0	2.9	2.8
MOUNTAIN	48	-0.2	2.2	4.4	2.4
PACIFIC	23	-0.2	-0.2	2.0	2.0
TEACHING STATUS					
NON-TEACHING	2,391	0.3	0.2	2.9	2.7
MINOR	792	0.2	0.3	3.0	2.6
MAJOR	375	-0.5	0.1	2.0	1.9
DSH PATIENT PERCENT					
0	13	0.1	-0.3	2.1	2.0
GT 0 - 0.10	267	0.6	0.0	3.0	2.7
0.10 - 0.16	241	0.4	0.2	3.1	2.8
0.16 - 0.23	579	0.5	0.2	3.1	2.8
0.23 - 0.35	1,101	0.0	0.3	2.7	2.4
GE 0.35	899	-0.3	0.1	2.3	2.1
DSH NOT AVAILABLE **	458	0.0	0.1	2.5	2.3
URBAN TEACHING/DSH					
TEACHING & DSH	1,048	-0.1	0.2	2.5	2.3
NO TEACHING/DSH	1,307	0.4	0.1	2.9	2.7
NO TEACHING/NO DSH	13	0.1	-0.3	2.1	2.0
DSH NOT AVAILABLE2	438	0.0	0.1	2.5	2.3
TYPE OF OWNERSHIP					
VOLUNTARY	1,976	0.0	0.2	2.6	2.3
PROPRIETARY	1,132	0.9	0.3	3.5	3.2
GOVERNMENT	450	-0.3	0.1	2.2	2.2
CMHCs	39	9.7	-0.1	12.2	11.9

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all final CY 2021 OPPS policies and compares those to the CY 2020 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the final FY 2021 hospital inpatient wage index and the non-budget neutral frontier adjustment. The final rural SCH adjustment continues our current policy of 7.1 percent so the budget neutrality factor is 1. The budget neutrality adjustment for the cancer hospital adjustment is 1.0000 because in CY 2021 the final target payment-to-cost ratio is the same as that of CY 2020 (0.90 and reduced to 0.89 in accordance with the 21st Century Cures Act)

Column (4) shows the impact of all budget neutrality adjustments and the addition of the 2.4 percent OPD fee schedule update factor (2.4 percent reduced by 0.0 percentage point for the productivity adjustment).

Column (5) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate, and adding estimated outlier payments. Note that previous years included the frontier adjustment in this column, but we have the frontier adjustment to Column 3 in this table.

These 3,665 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

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d. Estimated Effects of OPPS Changes on CMHCs

The last line of Table 79 demonstrates the isolated impact on CMHCs, which furnish only partial hospitalization services under the OPPS. In CY 2020, CMHCs are paid under APC 5853 (Partial Hospitalization (3 or more services) for CMHCs). We modeled the impact of this APC policy assuming CMHCs will continue to provide the same number of days of PHP care as seen in the CY 2019 claims used for ratesetting in the final rule. We excluded days with 1 or 2 services because our policy only pays a per diem rate for partial hospitalization when 3 or more qualifying services are provided to the beneficiary. We estimate that CMHCs will experience an overall 11.9 percent increase in payments from CY 2020 (shown in Column 5). We note that this includes the trimming methodology as well as the final CY 2021 geometric mean costs used for developing the PHP payment rates described in section VIII.B. of this final rule with comment period.

Column 3 shows that the estimated impact of adopting the final FY 2021 wage index values will result in a decrease of 0.1 percent to CMHCs. Column 4 shows that combining this final OPD fee schedule increase factor, along with final changes in APC policy for CY 2021 and the final FY 2021 wage index updates, will result in an estimated increase of 12.2 percent. Column 5 shows that adding the final changes in outlier and pass-through payments will result in a total 11.9 percent increase in payment for CMHCs. This reflects all finalized changes for CMHCs for CY 2021.

e. Estimated Effect of OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary's payment would increase for services for which the OPPS payments will rise and will decrease for services for which the OPPS payments will fall. For further discussion of the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.I. of this CY 2021 OPPS/ASC final rule with comment period. In all cases, section 1833(t)(8)(C)(i) of the Act limits beneficiary liability for copayment for a procedure performed in a year to the hospital inpatient deductible for the applicable year.

We estimate that the aggregate beneficiary coinsurance percentage would be 18.3 percent for all services paid under the OPPS in CY 2021. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the final CY 2021 comprehensive APC payment policy discussed in section II.A.2.b. of this final rule.

f. Estimated Effects of OPPS Changes on Other Providers

The relative payment weights and payment amounts established under the OPPS affect the payments made to ASCs, as discussed in section XIII of the final rule. No types of providers or suppliers other than hospitals, CMHCs, and ASCs will be affected by the final changes in the final rule.

g. Estimated Effects of OPPS Changes on the Medicare and Medicaid Programs

The effect on the Medicare program is expected to be an increase of $1.49 billion in program payments for OPPS services furnished in CY 2021. The effect on the Medicaid program is expected to be limited to copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We estimate that the changes in this final rule would increase these Medicaid beneficiary payments by approximately $105 million in CY 2021. Currently, there are approximately 10 million dual-eligible beneficiaries, which represent approximately thirty percent of Medicare Part B fee-for-service beneficiaries. The impact on Medicaid was determined by taking thirty percent of the beneficiary cost-sharing impact. The national average split of Medicaid payments is 57 percent Federal payments and 43 percent state payments. Therefore, for the estimated $105 million Medicaid increase, approximately $60 million will be from the federal government and $45 million would be from state government.

h. Alternative OPPS Policies Considered

• Column 3—Estimated CY 2021 Percent Change is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty or ancillary items and services group that is attributable to updates to ASC payment rates for CY 2021 compared to CY 2020.

As shown in Table 80, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the update to ASC payment rates for CY 2021 will result in a 3-percent increase in aggregate payment amounts for eye and ocular adnexa procedures, a 2-percent increase in aggregate payment amounts for nervous system procedures, 4-percent increase in aggregate payment amounts for digestive system procedures, a 4-percent increase in aggregate payment amounts for musculoskeletal system procedures, a 2-percent increase in aggregate payment amounts for cardiovascular system procedures, and a 5-percent increase in aggregate payment amounts for genitourinary system procedures. We note that these changes can be a result of different factors, including updated data, payment weight changes, and changes in policy. In general, spending in each of these categories of services is increasing due to the 2.4 percent payment rate update. After the payment rate update is accounted for, aggregate payment increases or decreases for a category of services can be higher or lower than a 2.4-percent increase, depending on if payment weights in the OPPS APCs that correspond to the applicable services increased or decreased or if the most recent data show an increase or a decrease in the volume of services performed in an ASC for a category. For example, we estimate a 4-percent increase in aggregate gastrointestinal procedure payments due to an increase in hospital reported costs for Level 1 and Level 2 upper and lower gastrointestinal payment categories under the OPPS. The increases in payment weights for gastrointestinal procedure payments is further increased by the 2.4 percent ASC rate update for these procedures. For estimated changes for selected procedures, we refer readers to Table 81 provided later in this section.

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TABLE 80: ESTIMATED IMPACT OF THE CY 2021 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2021 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2020 ASC Payments (in Millions) (2)	Estimated CY 2021 Percent Change (3)
Total	$5,455	2
Eye and ocular adnexa	$1,815	3
Nervous system	$1,180	2
Digestive system	$909	4
Musculoskeletal system	$695	4
Cardiovascular system	$274	2
Genitourinary system	$201	5

Table 81 shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2021. The table displays 30 of the procedures receiving the greatest estimated CY 2020 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2020 program payment.

- Column 1—CPT/HCPCS code.
- Column 2—Short Descriptor of the HCPCS code.
- Column 3—Estimated CY 2020 ASC Payments were calculated using CY 2019 ASC utilization (the most recent full year of ASC utilization) and the CY 2020 ASC payment rates. The estimated CY 2020 payments are expressed in millions of dollars.
- Column 4—Estimated CY 2021 Percent Change reflects the percent differences between the estimated ASC payment for CY 2020 and the estimated payment for CY 2021 based on the update.

TABLE 81: ESTIMATED IMPACT OF THE FINAL CY 2021 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2020 ASC Payment (in millions) (3)	Estimated CY 2021 Percent Change (4)
66984	Xcapsl ctrc rmvl w/o ecp	$1,228	3
63685	Insrt/redo spine n generator	$285	2
45380	Colonoscopy and biopsy	$240	4
63650	Implant neuroelectrodes	$186	-1
43239	Egd biopsy single/multiple	$180	4
45385	Colonoscopy w/lesion removal	$178	4
0191T	Insert ant segment drain int	$121	4
64483	Inj foramen epidural l/s	$118	2
66982	Xcapsl ctrc rmvl cplx wo ecp	$90	3
64635	Destroy lumb/sac facet jnt	$85	1
64493	Inj paravert f jnt l/s 1 lev	$78	2
36902	Intro cath dialysis circuit	$78	1
29827	Sho arthrs srg rt8tr cuf rpr	$73	5
66821	After cataract laser surgery	$67	0
64590	Insrt/redo pn/gastr stimul	$59	4
C9740	Cysto impl 4 or more	$56	2
62323	Njx interlaminar lmbr/sac	$54	2
22869	Insj stablj dev w/o dcmprn	$52	3
G0105	Colorectal scrn; hi risk ind	$51	4
15823	Revision of upper eyelid	$39	6
G0121	Colon ca scrn not hi rsk ind	$38	4
45378	Diagnostic colonoscopy	$37	4
64721	Carpal tunnel surgery	$37	1
63655	Implant neuroelectrodes	$31	5
65820	Relieve inner eye pressure	$29	3
64561	Implant neuroelectrodes	$28	-2
67042	Vit for macular hole	$27	2
64490	Inj paravert f jnt c/t 1 lev	$27	2
62362	Implant spine infusion pump	$27	3
29881	Knee arthroscopy/surgery	$27	4

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c. Estimated Effects of ASC Payment System Policies on Beneficiaries

We estimate that the CY 2021 update to the ASC payment system will be generally positive (that is, result in lower cost-sharing) for beneficiaries with respect to the new procedures we are adding to the ASC list of covered surgical procedures and for those we designate as office-based for CY 2021. For example, using 2019 utilization data and CY 2021 OPPS and ASC payment rates, we estimate that if 10 percent of colpopexy procedures migrate from the hospital outpatient setting to the ASC setting as a result of this policy, Medicare payments will be reduced by approximately $7 million in CY 2021 and total beneficiary copayments will decline by approximately $1.4 million in CY 2021. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with sections 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs under the OPPS, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment (other than for certain preventive services), although the majority of HOPD procedures have a 20-percent copayment. Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance amount under the ASC

payment system will almost always be less than the OPPS copayment amount for the same services. (The only exceptions will be if the ASC coinsurance amount exceeds the hospital inpatient deductible since the statute requires that OPPS copayment amounts not exceed the hospital inpatient deductible. Therefore, in limited circumstances, the ASC coinsurance amount may exceed the hospital inpatient deductible and, therefore, the OPPS copayment amount for similar services.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the ASC payment system, depending on the particular service and the relative payment amounts under the MPFS compared to the ASC. While the ASC payment system bases most of its payment rates on hospital cost data used to set OPPS relative payment weights, services that are performed a majority of the time in a physician office are generally paid the lesser of the ASC amount according to the standard ASC ratesetting methodology or at the nonfacility practice expense based amount payable under the PFS. For those additional procedures that we designate as office-based in CY 2021, the beneficiary coinsurance amount under the ASC payment system generally will be no greater than the beneficiary coinsurance under the PFS because the coinsurance under both payment systems generally is 20 percent (except for certain preventive services where the coinsurance is waived under both payment systems).

Alternatives to the OPPS changes we are finalizing and the reasons for our selected alternatives are discussed throughout this final rule with comment period.

- Alternatives Considered for the Payment Adjustment for Separately Paid Drugs Acquired through the 340B Program.

We refer readers to section V.B.6. of this final rule with comment period for a discussion of our final policy to apply a payment adjustment of ASP minus 22.5 percent for separately paid non-pass through drugs acquired under the 340B Program, which was originally adopted in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59350 through 59369). We also proposed but did not finalize a policy to pay ASP minus 28.7 percent for 340B drugs in CY 2021, based on hospital survey data. We note that the effects of this proposal, which was not finalized, and its corresponding budget neutrality adjustment compared to our finalized proposal were provided in Column 4 of Table 55 of the CY 2021 OPPS/ASC proposed rule (85 FR 49047 through 49049).

2. Estimated Effects of CY 2021 ASC Payment System Changes

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XIII. of this final rule with comment period, we are setting the CY 2021 ASC relative payment weights by scaling the CY 2021 OPPS relative payment weights by the ASC scalar of 0.8591. The estimated effects of the updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 80 and 81.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system (which, in CY 2019, we adopted a policy to be the hospital market basket for CY 2019 through CY 2023) after application of any quality reporting reduction be reduced by a productivity adjustment. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (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). For ASCs that fail to meet their quality reporting requirements, we are requiring that the CY 2021 payment determinations would be based on the application of a 2.0 percentage point reduction to the annual update factor, which is the hospital market basket for CY 2021. We calculated the CY 2021 ASC conversion factor by adjusting the CY 2020 ASC conversion factor by 1.0012 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2020 and CY 2021 and by applying the CY 2021 MFP-adjusted hospital market basket update factor of 2.4 percent (which is equal to the projected hospital market basket update of 2.4 percent minus an MFP adjustment of 0.0 percentage point). The CY 2021 ASC conversion factor is $48.952 for ASCs that successfully meet the quality reporting requirements.

a. Limitations of Our Analysis

Presented here are the projected effects of the changes for CY 2021 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2019 and CY 2021 with precision. We believe the net effect on Medicare expenditures resulting from the CY 2021 changes will be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups, as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs will experience changes in payment that differ from the aggregated estimated impacts presented below.

b. Estimated Effects of ASC Payment System Policies on ASCs

Some ASCs are multispecialty facilities that perform a wide range of surgical procedures from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as eye, digestive system, or orthopedic procedures. The combined effect on an individual ASC of the update to the CY 2021 payments will depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion presents tables that display estimates of the impact of the CY 2021 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services, as reflected in our CY 2019 claims data. Table 80 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2020 payments to estimated CY 2021 payments, and Table 81 shows a comparison of estimated CY 2020 payments to estimated CY 2021 payments for procedures that we estimate will receive the most Medicare payment in CY 2020.

In Table 80, we have aggregated the surgical HCPCS codes by specialty group, grouped all HCPCS codes for covered ancillary items and services into a single group, and then estimated the effect on aggregated payment for surgical specialty and ancillary items and services groups. The groups are sorted for display in descending order by estimated Medicare program payment to ASCs. The following is an explanation of the information presented in Table 80.

- Column 1—Surgical Specialty or Ancillary Items and Services Group indicates the surgical specialty into which ASC procedures are grouped and

the ancillary items and services group which includes all HCPCS codes for covered ancillary items and services. To group surgical procedures by surgical specialty, we used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes, as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.

- Column 2—Estimated CY 2020 ASC Payments were calculated using CY 2019 ASC utilization data (the most recent full year of ASC utilization) and CY 2020 ASC payment rates. The surgical specialty and ancillary items and services groups are displayed in descending order based on estimated CY 2020 ASC payments.

3. Accounting Statements and Tables

As required by OMB Circular A–4 (available on the Office of Management and Budget website at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/circulars/a004/a-4.html*), we have prepared accounting statements to illustrate the impacts of the OPPS and ASC changes in this final rule with comment period and the impact of the changes to the RO Model in this interim final rule with comment period. The first accounting statement, Table 82, illustrates the classification of expenditures for the CY 2021 estimated hospital OPPS incurred benefit impacts associated with the final CY 2021 OPD fee schedule increase. The second accounting statement, Table 83, illustrates the classification of expenditures associated with the 2.4 percent CY 2021 update to the ASC payment system, based on the provisions of the final rule with comment period and the baseline spending estimates for ASCs. Both tables classify most estimated impacts as transfers. The third accounting statement, Table 84, shows the classification of expenditures, which represent savings associated with the RO Model, which are classified as transfers. The estimated costs of ICR Burden and Regulatory Familiarization are included in Table 84.

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TABLE 82: ACCOUNTING STATEMENT: CY 2021 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2020 TO CY 2021 ASSOCIATED WITH THE FINAL CY 2020 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$1,490 million
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS
Total	$1,490 million

TABLE 83: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2020 TO CY 2021 AS A RESULT OF THE FINAL CY 2021 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$100 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	$100 million

TABLE 84: Accounting Statement Estimated Impacts for the Radiation Oncology Model

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Transfers				
Annualized Monetized ($million/year)	-$38 million	2019	7%	2021 – 2025
	-$40 million	2019	3%	2021 – 2025
From Whom to Whom	From the federal government to healthcare providers			

TABLE 85: ESTIMATED COSTS IN CY 2021

CATEGORY	Costs
ICR Burden	$139 million*
Regulatory Familiarization	$1.195 million**

*The annual estimates are in 2019 year dollars which includes the impact of hospital outpatient QRP, prior authorization process and requirements for certain OPD services, and flu reporting provisions.
** Regulatory familiarization costs occur upfront only.

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4. Effects of Changes in Requirements for the Hospital OQR Program

a. Background

We refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59492 through 59494), for the previously estimated effects of changes to the Hospital Outpatient Quality Reporting (OQR) Program for the CY 2018, CY 2019, and CY 2020 payment determinations. Of the 3,144 hospitals that met eligibility requirements for the CY 2020 payment determination, we determined that 78 hospitals did not meet the requirements to receive the full OPD fee schedule increase factor. We did not propose to add or remove any quality measures to the Hospital OQR Program measure set for the CY 2022 or CY 2023 payment determinations.

b. Impact of CY 2021 Finalized Policies

We do not anticipate that any of the CY 2021 Hospital OQR Program finalized policies will impact the number of facilities that will receive payment reductions. In this final rule with comment period, we are finalizing our proposals to: (1) Codify the statutory authority for the Hospital OQR Program; (2) revise and codify the previously finalized public display of measure data policy that hospitals sharing the same CCN must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes; (3) revise existing § 419.46(a)(2) by replacing the term ''security administrator'' with the term ''security official'' and codify this language; (4) move all deadlines falling on nonwork days forward consistent with section 216(j) of the Social Security Act (the Act), 42 U.S.C. 416(j), ''Periods of Limitation Ending on Nonwork Days,'' beginning with the effective date of this rule; (5) revise our policy regarding submission deadlines at existing § 419.46(c)(2) to reflect the proposed deadlines policy consistent with section 216(j) of the Act, 42 U.S.C. 416(j); (6) expand the existing review and corrections policy for chart-abstracted data to apply to measure data submitted via the CMS web-based tool beginning with data submitted for the CY 2023 payment determination and subsequent years; (7) codify at § 419.46 the review and corrections period policy for measure data submitted to the Hospital OQR Program for chart-abstracted measure data, as well as for the proposed policy for measure data submitted directly to CMS via the CMS web-based tool; (8) codify the previously finalized Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures; (9) revise existing § 419.46(b) (redesignated § 419.46(c)) by removing the phrase ''submit a new participation form'' to align with previously finalized policy, and (10) update internal cross-references as a result of the redesignations.

We do not anticipate that the requirements affecting the Hospital OQR Program in this final rule with comment period will impact the number of hospitals that will receive payment reductions.

5. Effects of Requirements for the ASCQR Program

a. Background

In section XV.B. of this final rule with comment period, we discuss our finalized policies affecting the Ambulatory Surgical Centers Quality Reporting (ASCQR) Program. For the CY 2020 payment determination, of the 6,651 ASCs that met eligibility requirements for the ASCQR Program, 195 ASCs did not meet the requirements to receive the full annual payment update. We did not propose any quality measure additions or removals for the ASCQR Program measure set for future calendar year payment determinations.

b. Impact of CY 2021 Finalized Policies

In sections XV.C. and XV.D. of this final rule with comment period, we are finalizing our proposals to: (1) Use the term ''security official'' instead of ''security administrator'' and revise § 416.310(c)(1)(i) by replacing the term ''security administrator'' with the term ''security official;'' (2) remove the phrase ''data collection time period'' in all instances where it appears in § 416.310, replace it with the phrase ''data collection period,'' and use the phrase ''data collection period'' wherever the phrase ''data collection time period'' is found in the preamble of this final rule with comment period; (3) move forward all program deadlines falling on a nonwork day consistent with the section 216(j) of the Act, 42 U.S.C. 416(j) and codify this policy; and (4) formalize the process by which ASCs identify errors and resubmit data before the established submission deadline by creating a review and corrections period similar to that finalized for the Hospital OQR Program in section XIV.D.7. of this final rule with comment period that runs concurrent with the existing data submission period from January 1 through May 15 and codify this policy.

We do not anticipate that the finalized policies affecting the ASCQR Program in this final rule with comment period will impact the number of ASCs that will receive payment reductions.

6. Effects of Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process

a. Overall Impact

In the CY 2020 OPPS/ASC final rule with comment period, we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Act, which allows the Secretary to develop ''a method for controlling unnecessary increases in the volume of covered OPD services'' (84 FR 61142).[384] The regulations governing the prior authorization process are located in subpart I of 42 CFR part 419, specifically at §§ 419.80 through 419.89.

In accordance with § 419.83(b), we are finalizing our proposal requiring prior authorization for two new service categories: Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators. We are adding those service categories to § 419.83(a). We are requiring that the prior authorization process for these two additional service categories will be effective for dates of services on or after July 1, 2021. The addition of these service categories is consistent with our authority under section 1833(t)(2)(F) of the Act and is based upon our determination that there has been an unnecessary increase in the volume of these services.

The overall economic impact on the health care sector to require prior authorization for two additional service categories is dependent on the number of claims affected. Table 86, Overall Economic Impact to the Health Sector, lists an estimate for the overall economic impact to the health sector for the two new service categories combined. The values populating this table were obtained from the cost reflected in Table 87, Annual Private Sector Costs, and Table 88, Estimated Annual Administrative Costs to CMS. Together, Tables 87 and 88 combine to convey the overall economic impact to the health sector for the two new service categories, which is illustrated in Table 86. It should be noted that due to the July start date for prior authorization for these two new service categories, year one includes only 6 months of prior authorization requests.

Based on the estimate, the overall economic cost impact is approximately $2.9 million in the first year based on 6 months for the two new service categories. The 5-year impact is approximately $22.9 million, and the 10-year impact is approximately $47.9 million. The 5- and 10-year impacts account for year one including only 6 months. Additional administrative paperwork costs to private sector providers and an increase in Medicare spending to conduct reviews combine to create the financial impact; however, this impact is offset by Medicare savings. Annually, we estimate an overall Medicare savings of $31,844,388. We believe there are likely to be other benefits that result from the prior authorization requirement for the two new service categories, though many of those benefits are difficult to quantify. For instance, we expect to see savings in the form of reduced fraud, waste, and abuse, including a reduction in improper Medicare fee-for-service payments (we note that not all improper payments are fraudulent). We solicited public comments on the potential increased costs and benefits associated with the proposed provision for the two new service categories. As part of a larger comment on a previous section of this rule, one commenter stated that our costs and hours were under-estimated. The response to this part of the comment is included in the overall response to the comment in the previous section.

TABLE 86: Overall Economic Cost Impact to the Health Sector

	Year 1	5 Years	10 Years
Private Sector Costs	$870,723	$6,539,151	$13,624,686
Administrative Costs to CMS	$2,017,317	$16,349,353	$34,264,398
Total Economic Impact to Health Sector	$2,888,040	$22,888,504	$47,889,084

According to the RFA's use of the term, most suppliers and providers are small entities. Likewise, the vast majority of physician and nurse practitioner (NP) practices are considered small businesses according to the SBA's size standards of having total revenues of $10 million or less in any 1 year. While the economic costs and benefits are substantial in the aggregate, the economic impact on individual entities compliant with Medicare program coverage and utilization rules and regulations will be relatively small. We estimate that 90 to 95 percent of providers who provide these services are small entities under the RFA definition. The rationale behind requiring prior authorization is to control unnecessary increases in the volume of covered OPD services. The impact on providers not in compliance with Medicare coverage, coding, and payment rules and regulations could be significant, as the finalized rule will change the billing practices of those providers. We believe that the purpose of the statute and this rule is to avoid unnecessary increases in utilization of OPD services. Therefore, we do not view decreased revenues from the two additional OPD services categories subject to unnecessary utilization by providers to be a condition that we must mitigate. We believe that the effect will be minimal on providers who are compliant with Medicare coverage, coding, and payment rules and requirements. Adding these two services will offer an additional protection to a provider's cash flow as the provider will know in advance if the Medicare requirements are met.

b. Anticipated Specific Cost Effects

1. Private Sector Costs

We do not believe that this rule will significantly affect the number of legitimate claims submitted for these new service categories. However, we do expect a decrease in the overall amount paid for the services resulting from a reduction in unnecessary utilization of the services requiring prior authorization.

We estimate that the private sector's per-case time burden attributed to submitting documentation and associated clerical activities in support of a prior authorization request for the two additional service categories is equivalent to that of submitting

[384] See also Correction notification issued January 3, 2020 (85 FR 224).

documentation and clerical activities associated for prepayment review, which is 0.5 hours. We apply this time burden estimate to initial submissions and resubmissions.

TABLE 87: Year 1 (6 Month) Private Sector Costs

Activity	Responses Per Year (i.e. number of reviewed claims)	Time Per Response (hours) or Dollar Cost	Total Burden Per Year (hours)	Total Burden Costs Per Year Using Loaded Rate
Fax and Electronic Submitted Requests-Initial Submissions	15,884	0.5	7,942	$264,158
Fax and Electronic Submitted Requests-Resubmissions	5,214	0.5	2,607	$86,702
Mailed in Requests-Initial Submissions	6,808	0.5	3,404	$113,210
Mailed in Requests-Resubmissions	2,234	0.5	1,117	$37,158
Mailing Costs	9,042	$5	NA	$45,210
Provider Demonstration-Education	3,250	3	9,750	$324,285
Total			24,820	$870,723

2. Administrative Costs to CMS

CMS will incur additional costs associated with processing the prior authorization requests for the two new service categories. We use the range of potentially affected cases (submissions and resubmissions) and multiply it by $50, the estimated cost to review each request. The combined cost also includes other elements such as appeals, education and outreach, and system changes.

TABLE 88: Year 1 (6 Month) Estimated Administrative Costs to CMS

Cervical Fusion with Disc Removal	Implanted Spinal Neurostimulators	Combined
$489,916	$1,077,401	$2,017,317

3. Estimated Beneficiary Costs

We expect a reduction in the utilization of the two new Medicare OPD service categories when such utilization does not comply with one or more of Medicare's coverage, coding, and payment rules. While there may be an associated burden on beneficiaries while they wait for the prior authorization decision, we are unable to quantify that burden. Although the rule is designed to permit utilization that is medically necessary, OPD services that are not medically necessary may still provide convenience or usefulness for beneficiaries; any rule-induced loss of such convenience or usefulness constitutes a cost of the rule that we lack data to quantify. Additionally, beneficiaries may have out-of-pocket costs for those services that are determined not to comply with Medicare requirements and thus, are not eligible for Medicare payment. We lack the data to quantify these costs as well.

c. Estimated Benefits

There will be quantifiable benefits for this rule because we expect a reduction in the unnecessary utilization of those two new Medicare OPD service categories subject to prior authorization. It is difficult to project the exact

decrease in unnecessary utilization; however, based on other prior authorization programs, we estimate our savings based on a 50 percent reduction in improper payments, using a 10 percent improper payment rate. We estimate that for the first 6 months, there would be savings of $15,922,194 overall. Annually, we estimate an overall gross savings of $31,844,388. This savings represents a Medicare benefit from a more efficient use of health care resources while still maintaining the same health outcomes for necessary services. We will closely monitor utilization and billing practices. The expected benefits would also include changed billing practices that would also enhance the coordination of care for the beneficiary. For example, requiring prior authorization for the two additional OPD services categories would ensure that the primary care practitioner recommending the service and the facility collaborate more closely to provide the most appropriate OPD services to meet the needs of the beneficiary. The practitioner recommending the service would evaluate the beneficiary to determine what services are medically necessary based on the beneficiary's condition. This would require the facility to collaborate closely with the practitioner early on in the process to ensure the services are truly necessary and meet all requirements and that their supporting documentation is complete and correct. Improper payments made because the practitioner did not evaluate the patient or the patient does not meet the Medicare requirements would likely be reduced by the requirement that a provider submit clinical documentation created as part of its prior authorization request.

7. Effects of Revision to the Laboratory Date of Service Policy

In section XVIII. of this final rule with comment period, we discuss our policy to include cancer-related protein-based Multianalyte Assays with Algorithmic Analyses (MAAAs) and the test described by CPT code 81490 in the laboratory date of service (DOS) exception at § 414.510(b)(5). We are also excluding these tests from the OPPS packaging policy, which is discussed in section II.a.3 of this final rule with comment period. Under these policies, Medicare will pay for certain protein-based MAAAs under the CLFS instead of the OPPS and the performing laboratory will bill Medicare directly for the test if the test meets all the laboratory DOS requirements specified in § 414.510(b)(5). While there may be some impact under the hospital OPPS resulting from additional tests being excluded from OPPS packaging policy and paid at the CLFS rate instead of the OPPS bundled rate, we expect this change to be budget neutral for scoring purposes. Accordingly, the discussion in sections II.a.3. and XVIII of this final rule with comment period is not reflected in Table 79 in the regulatory impact analysis under section XXVII of this final rule with comment period.

8. Effects of Requirements for the Overall Hospital Quality Star Ratings

In section E. Current and Proposed Overall Star Rating Methodology of this final rule with comment period, we discussed our proposal as it relates to the Overall Star Rating methodology. The Overall Star Rating uses measures that are publicly reported on *Hospital Compare* or its successor websites under the public reporting authority of each individual hospital program furnishing measure data. The burden associated with measures included in the Overall Star Rating, including forms used to request withholding of publicly reported measure data and the Overall Star Rating (for Critical Access Hospitals (CAHs)), is already captured in the respective hospital programs' burden estimates and represents no increased information collection burden to hospitals.

In this CY 2021 OPPS/ASC final rule with comment period, however, we are finalizing that hospitals have the opportunity to review confidential reports containing their measure, measure group, and Overall Star Rating results for at least 30 days prior to publication of the Overall Star Rating. We believe that reviewing the Overall Star Rating in confidential reports prior to public reporting represents additional burden to hospitals.

In this CY 2021 OPPS/ASC final rule with comment period, we are using the most recent data from the Bureau of Labor Statistics, which reflects a median hourly wage of $19.40 [385] per hour for a Medical Records and Health Information Technician professional. We calculate the cost of overhead, including fringe benefits, at 100 percent of the hourly wage estimate, consistent with the previous year. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($19.40 × 2 = $38.80) to estimate total cost is a reasonably accurate estimation method. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $38.80 per hour.

We estimate that the non-information collection burden associated with all non-Veterans Health Administration (VHA) hospitals reviewing their Overall Star Rating preview report prior to public reporting to be 2 hours per hospital, which includes time to review the report and ask any questions about the calculation necessary to increase comprehension. Estimating that 4,500 hospitals that will receive an Overall Star Rating hospital specific report (HSR), regardless if they meet the reporting thresholds to be assigned a star rating, we estimate the overall non-information collection burden to be $397,710 annually [$38.80 × 2 hours per preview report × once per year × 4,500 hospitals]. For CAHs specifically, which are included in the estimate above, we estimate that half of CAHs will be eligible for an Overall Star Rating (using an estimate of 1,300 total CAHs in the U.S.), which represents a burden of $100,890 annually [650 CAHs × 2 hours per preview report × once per year × $38.80].

Within this rule, for CY 2021 Overall Star Rating and subsequent years, we are finalizing the continuation of the Overall Star Rating methodology, as currently implemented, with the following modifications: (1) Elimination of measure score Winsorization; (2) grouping measures into five, rather than seven, measure groups, consisting of Mortality, Safety of Care, Readmission, Patient Experience, and Timely and Effective Care; (3) using a simple average of measure scores to calculate measure group scores; (4) standardization of measure group scores; (5) weighting measure groups so that Mortality, Safety of Care, Readmission, and Patient Experience each are weighted 22 percent and Timely and Effective Care is weighted 12 percent with proportional reweighting when hospitals have too few measures in one or more measure groups; (6) requiring three measures in at least three measure groups, one of which must be Mortality or Safety of Care; and (7) peer grouping hospitals based on the number of measure groups for which hospitals reports at least three measures. As a result of continued stakeholder concerns with the dual-eligibility variable and that stratification may be confusing to patients, analyses that indicate stratification of the Readmission measure group would not

[385] Bureau of Labor Statistics. (2019, September 4). *Occupational Outlook Handbook: Medical Records and Health Information Technicians.* Retrieved from *www.bls.gov*: *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

have the intended effect, and ASPE's recent report to Congress, we are not finalizing our proposal to stratify the Readmission measure group score based on the proportion of dual-eligible patients.

To simulate the impact of the final Overall Star Rating methodology, we used October 2020 *Hospital Compare* data to describe the overall distribution of star ratings, reclassification of star ratings, and distribution of star ratings across different types of hospitals

The final Overall Star Rating methodology for CY 2021 and subsequent years results in a similar distribution of star ratings but with slightly more hospitals receiving a star rating, primarily due to combining the existing three process measure groups into one measure group, Timely and Effective Care. Specifically, using October 2020 *Hospital Compare* data, the final Overall Star Rating methodology results in 3,350 (74 percent) hospitals receiving a star rating and more three (30 percent) and four (28 percent) star ratings and fewer one (7 percent), two (21 percent), and five (14 percent) star ratings (Table 89).

Given the substantial change in methods, particularly using a simple average of measure scores to calculate measure group scores instead of the LVM, we expect considerable shifts in hospital star ratings from the current methodology to the final methodology for CY 2021 and subsequent years. When comparing the current methodology to the final methodology for CY 2021 and subsequent years, 1,585 (50 percent) hospitals would receive the same star rating, 1,423 (45 percent) hospitals would increase or decrease one star rating, 150 (5 percent) hospitals would increase or decrease two star ratings, 9 (0.3 percent) hospitals would increase or decrease three star ratings, and 0 (0 percent) hospitals would increase or decrease four star ratings (Table 90).

With the final methodology for CY 2021 and subsequent years, most hospital characteristics have a similar distribution of star ratings to that of all hospitals with some variations (Tables 91 and 92). The variations in the distribution of star ratings across hospital characteristics compared to all hospitals are listed below.

- Specialty hospitals have a smaller proportion of one (1 percent specialty, 5 percent non-specialty), two (0 percent specialty, 16 percent non-specialty), three (6 percent specialty, 23 percent non-specialty), and four (6 percent specialty, 22 percent non-specialty) star ratings and a higher proportion of five (15 percent specialty, 10 percent specialty) star ratings than non-specialty hospitals.
- Teaching hospitals have a higher proportion of all star rating categories with a higher proportion of one (10 percent major teaching, 7 percent minor teaching, 3 percent non-teaching), two (21 percent major teaching, 20 percent minor teaching, 12 percent non-teaching), three (26 percent major teaching, 26 percent minor teaching, 20 percent non-teaching), four (28 percent major teaching, 27 percent minor teaching,19 percent non-teaching), and five (14 percent major teaching, 13 percent minor teaching, 8 percent non-teaching) star ratings than non-teaching hospitals.
- Safety net hospitals have a slightly higher proportion of two (21 percent safety net, 18 percent non-safety net) and slightly smaller proportion of four (27 percent safety net, 31 percent non-safety net) star ratings than non-safety net hospitals.
- DSH hospitals have a higher proportion of one (6 percent DSH, 2 percent non-DSH), two (21 percent DSH, 8 percent non-DSH), three (29 percent DSH, 14 percent non-DSH), and four (27 percent DSH, 23 percent non-DSH) and a smaller proportion of five (11 percent DSH, 22 percent non-DSH) star ratings than non-DSH; with increasing DSH quintiles, hospitals have a higher proportions of one (2 percent DSH quintile 1, 3 percent DSH quintile 2, 5 percent DSH quintile 3, 6 percent DSH quintile 4, 15 percent DSH quintile 5), two (11 percent DSH quintile 1, 18 percent DSH quintile 2, 18 percent DSH quintile 3, 25 percent DSH quintile 4, 30 percent DSH quintile 5), and a smaller proportions of four (34 percent DSH quintile 1, 31 percent DSH quintile 2, 30 percent DSH quintile 3, 23 percent DSH quintile 4, 15 percent DSH quintile 5) and five (21 percent DSH quintile 1, 13 percent DSH quintile 2, 11 percent DSH quintile 3, 7 percent DSH quintile 4, 5 percent DSH quintile 5) star ratings.
- CAHs have a smaller proportion of all star rating categories with a smaller proportion of one (2 percent CAHs, 6 percent non-CAHs), two (7 percent CAHs, 19 percent non-CAHs), and three (13 percent CAHs, 27 percent non-CAHs), four (12 percent CAHs, 26 percent non-CAHs), and five (3 percent CAHs, 13 percent non-CAHs) star ratings than non-CAHs.
- Urban hospitals have a higher proportion of one (8 percent large urban, 5 percent other urban, 3 percent rural) and two (19 percent large urban, 18 percent other urban, 20 percent rural) and a smaller proportion of three (25 percent large urban, 27 percent other urban, 29 percent rural) and four (25 percent large urban, 29 percent other urban, 25 percent rural) star ratings than rural hospitals.

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TABLE 89: Overall Star Rating Distribution by Current Methodology and Final Methodology for CY 2021 and Subsequent Years (October 2020 Hospital Compare Data)

Star Rating	Current Methodology	Final Methodology
1	208 (6.4%)	230 (6.9%)
2	597 (18.5%)	704 (21.0%)
3	1000 (31.0%)	1005 (30.0%)
4	1049 (32.5%)	947 (28.3%)
5	375 (11.61%)	464 (13.9%)
N/A	1308	1187

TABLE 90: Overall Star Rating Reclassification, Current Methodology vs Final Methodology for CY 2021 and Subsequent Years (October 2020 Hospital Compare Data)

Star Rating (Current Methodology)	Star Rating (Final Methodology)					
	1	**2**	**3**	**4**	**5**	**Total**
1	117	81	10	0	0	208
	56.25%	38.94	4.81	0	0	
2	78	306	180	25	2	591
	13.2	51.78	30.46	4.23	0.34	
3	19	240	462	238	30	989
	1.92	24.27	46.71	24.06	3.03	
4	4	48	296	496	176	1020
	0.39	4.71	29.02	48.63	17.25	
5	0	3	18	134	204	359
	0	0.84	5.01	37.33	56.82	
Total	218	678	966	893	412	3167

TABLE 91: Distribution of Star Ratings by Hospital Characteristics, Current Methodology (October 2020 *Hospital Compare* Data)

Hospital Characteristic	1	2	3	4	5	N/A
All hospitals	208 (4.58%)	597 (13.16%)	1000 (22.04%)	1049 (23.12%)	375 (8.27%)	1308 (28.83%)
Specialty	0 (0%)	0 (0%)	4 (3.25%)	8 (6.50%)	27 (21.95%)	84 (68.29%)
Non-Specialty	208 (4.78%)	595 (13.67%)	992 (22.79%)	1038 (23.85%)	344 (7.90%)	1175 (27.00%)
N/A	0 (0%)	2 (3.23%)	4 (6.45%)	3 (4.84%)	4 (6.45%)	49 (79.03%)
Major Teaching	41 (17.52%)	64 (27.35%)	50 (21.37%)	53 (22.65%)	24 (10.26%)	2 (0.85%)
Minor Teaching	119 (7.33%)	288 (17.73%)	464 (28.57%)	410 (25.25%)	185 (11.39%)	158 (9.73%)
Non-Teaching	48 (1.83%)	243 (9.29%)	482 (18.42%)	583 (22.28%)	162 (6.19%)	1099 (41.99%)
N/A	0 (0%)	2 (3.23%)	4 (6.45%)	3 (4.84%)	4 (6.45%)	49 (79.03%)
Safety-Net	3 (3.66%)	17 (20.73%)	17 (20.73%)	25 (30.49%)	9 (10.98%)	11 (13.41%)
Non-Safety-Net	16 (6.35%)	44 (17.46%)	67 (26.59%)	72 (28.57%)	28 (11.11%)	25 (9.92%)
N/A	189 (4.50%)	536 (12.75%)	916 (21.79%)	952 (22.65%)	338 (8.04%)	1272 (30.26%)
Non-DSH	3 (3.66%)	17 (20.73%)	17 (20.73%)	25 (30.49%)	9 (10.98%)	11 (13.41%)
DSH	16 (6.35%)	44 (17.46%)	67 (26.59%)	72 (28.57%)	28 (11.11%)	25 (9.92%)
Quintile 1	189 (4.50%)	536 (12.75%)	916 (21.79%)	952 (22.65%)	338 (8.04%)	1272 (30.26%)
Quintile 2	3 (3.66%)	17 (20.73%)	17 (20.73%)	25 (30.49%)	9 (10.98%)	11 (13.41%)
Quintile 3	16 (6.35%)	44 (17.46%)	67 (26.59%)	72 (28.57%)	28 (11.11%)	25 (9.92%)
Quintile 4	189 (4.50%)	536 (12.75%)	916 (21.79%)	952 (22.65%)	338 (8.04%)	1272 (30.26%)
Quintile 5	3 (3.66%)	17 (20.73%)	17 (20.73%)	25 (30.49%)	9 (10.98%)	11 (13.41%)
N/A	16 (6.35%)	44 (17.46%)	67 (26.59%)	72 (28.57%)	28 (11.11%)	25 (9.92%)
CAH	0 (0%)	15 (1.13%)	108 (8.17%)	217 (16.41%)	42 (3.18%)	940 (71.10%)
Non-CAH	208 (6.47%)	582 (18.10%)	892 (27.74%)	832 (25.88%)	333 (10.36%)	368 (11.45%)
1-99 beds	13 (1.12%)	100 (8.64%)	293 (25.30%)	356 (30.74%)	133 (11.49%)	263 (22.71%)
100-199 beds	48 (5.32%)	209 (23.15%)	281 (31.12%)	228 (25.25%)	81 (8.97%)	56 (6.20%)
200-299 beds	59 (12.29%)	108 (22.50%)	147 (30.63%)	108 (22.50%)	44 (9.17%)	14 (2.92%)

Hospital Characteristic	1	2	3	4	5	N/A
300-399 beds	35 (12.92%)	68 (25.09%)	73 (26.94%)	61 (22.51%)	30 (11.07%)	4 (1.48%)
400 or more beds	53 (14.21%)	95 (25.47%)	98 (26.27%)	79 (21.18%)	45 (12.06%)	3 (0.80%)
N/A	0 (0%)	17 (1.26%)	108 (7.99%)	217 (16.05%)	42 (3.11%)	968 (71.60%)
Large Urban	96 (7.74%)	242 (19.50%)	330 (26.59%)	292 (23.53%)	137 (11.04%)	144 (11.60%)
Other Urban	90 (7.56%)	216 (18.14%)	332 (27.88%)	305 (25.61%)	133 (11.17%)	115 (9.66%)
Rural	22 (2.92%)	122 (16.20%)	230 (30.54%)	235 (31.21%)	63 (8.37%)	81 (10.76%)
N/A	0 (0%)	17 (1.26%)	108 (7.99%)	217 (16.05%)	42 (3.11%)	968 (71.60%)

TABLE 92: Distribution of Star Ratings by Hospital Characteristics, Final Methodology for CY 2021 and Subsequent Years (October 2020 *Hospital Compare* Data)

Hospital Characteristic	1	2	3	4	5	N/A
All hospitals	204 (4.50%)	690 (15.21%)	1019 (22.46%)	988 (21.78%)	455 (10.03%)	1181 (26.03%)
Specialty	1 (0.81%)	0 (0%)	7 (5.69%)	7 (5.69%)	18 (14.63%)	90 (73.17%)
Non-Specialty	202 (4.64%)	689 (15.83%)	1008 (23.16%)	977 (22.45%)	435 (10.00%)	1041 (23.92%)
N/A	1 (1.61%)	1 (1.61%)	4 (6.45%)	4 (6.45%)	2 (3.23%)	50 (80.65%)
Major Teaching	24 (10.26%)	49 (20.94%)	60 (25.64%)	66 (28.21%)	33 (14.10%)	2 (0.85%)
Minor Teaching	109 (6.71%)	317 (19.52%)	420 (25.86%)	433 (26.66%)	206 (12.68%)	139 (8.56%)
Non-Teaching	70 (2.67%)	323 (12.34%)	535 (20.44%)	485 (18.53%)	214 (8.18%)	990 (37.83%)
N/A	1 (1.61%)	1 (1.61%)	4 (6.25%)	4 (6.45%)	2 (3.23%)	50 (80.65%)
Safety-Net	1 (1.22%)	17 (20.73%)	22 (26.83%)	22 (26.83%)	10 (12.20%)	10 (12.20%)
Non-Safety-Net	6 (2.38%)	45 (17.86%)	71 (28.17%)	77 (30.56%)	29 (11.51%)	24 (9.52%)
N/A	197 (4.69%)	628 (14.94%)	926 (22.03%)	889 (21.15%)	416 (9.90%)	1147 (27.29%)

Hospital Characteristic	1	2	3	4	5	N/A
Non-DSH	8 (1.68%)	40 (8.39%)	67 (14.05%)	111 (23.27%)	105 (22.01%)	146 (30.61%)
DSH	168 (6.20%)	556 (20.53%)	784 (28.95%)	720 (26.59%)	305 (11.26%)	175 (6.46%)
Quintile 1	11 (2.03%)	62 (11.46%)	148 (27.36%)	184 (34.01%)	114 (21.07%)	22 (4.07%)
Quintile 2	15 (2.76%)	97 (17.86%)	160 (29.47%)	167 (30.76%)	69 (12.71%)	35 (6.45%)
Quintile 3	26 (4.81%)	98 (18.11%)	174 (32.16%)	161 (29.76%)	58 (10.72%)	24 (4.44%)
Quintile 4	34 (6.27%)	134 (25.09%)	172 (31.73%)	129 (23.80%)	38 (7.01%)	33 (6.09%)
Quintile 5	82 (15.16%)	163 (30.13%)	130 (24.03%)	79 (14.60%)	26 (4.81%)	61 (11.28%)
N/A	28 (2.07%)	94 (6.95%)	168 (12.43%)	157 (11.61%)	45 (3.33%)	146 (30.61%)
CAH	26 (1.97%)	94 (7.11%)	166 (12.56%)	157 (11.88%)	45 (3.40%)	834 (63.09%)
Non-CAH	178 (5.54%)	596 (18.54%)	853 (26.53%)	831 (25.85%)	410 (12.75%)	347 (10.79%)
1-99 beds	23 (1.99%)	170 (14.68%)	252 (21.76%)	276 (23.83%)	168 (14.51%)	269 (23.23%)
100-199 beds	44 (4.87%)	164 (18.16%)	266 (29.46%)	270 (29.90%)	112 (12.40%)	47 (5.20%)
200-299 beds	51 (10.63%)	104 (21.67%)	142 (29.58%)	123 (25.63%)	56 (11.67%)	4 (0.83%)
300-399 beds	28 (10.33%)	73 (26.94%)	83 (30.63%)	56 (20.66%)	30 (11.07%)	1 (0.37%)
400 or more beds	30 (8.04%)	85 (22.79%)	108 (28.95%)	106 (28.42%)	44 (11.80%)	0 (0%)
N/A	28 (2.07%)	94 (6.95%)	168 (12.43%)	157 (11.61%)	45 (3.33%)	860 (63.61%)
Large Urban	94 (7.57%)	234 (18.86%)	305 (24.58%)	306 (24.66%)	165 (13.30%)	137 (11.04%)
Other Urban	57 (4.79%)	210 (17.63%)	324 (27.20%)	340 (28.55%)	149 (12.51%)	111 (9.32%)
Rural	25 (3.32%)	152 (20.19%)	222 (29.48%)	185 (24.57%)	96 (12.75%)	73 (9.69%)

Hospital Characteristic	1	2	3	4	5	N/A
N/A	28 (2.07%)	94 (6.95%)	168 (12.43%)	157 (11.61%)	45 (3.33%)	860 (63.61%)

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Alternatives Considered

Overall Hospital Quality Star Rating

We considered a number of alternatives to our proposals discussed in section XVI of this final rule with comment period. Proposed Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years of the preamble of the CY 2021 OPPS/ASC proposed rule. As described more fully in section E. Current and Proposed Overall Star Rating Methodology of this final rule with comment period, we considered alternatives to measure group weighting, calculation of measure group scores, stratifying the Readmission group based on proportion of dual-eligible patients, and peer grouping by number of measures.

We considered an alternative to equally weight the five measure groups instead of the proposal to weight the four outcome and patient experience measure groups at 22 percent (Morality, Safety of Care, Readmission, and Patient Experience) and the newly proposed Timely and Effective Care process group at 12 percent. Because past stakeholder comments have recommended that outcome groups receive the most weight, we recommended our proposal but are sought comment on the alternative presented.

We considered keeping the Latent Variable Model (LVM) as an alternative to the proposed simple average of measure group scores since it is a data driven model where the measure loadings, or measure contribution to the measure group score, are empirically derived and are able to account for sampling variation and missing data. Because past stakeholder comments have indicated that the use of LVM is difficult to understand and the weights of measures and their subsequent impact on the group score changes depending on the underlying data, we proposed to use a simple average of measure group scores but are seeking comment on the alternative presented.

We also considered not stratifying the Readmission measure group based on dual-eligibility peer groups and retaining the current approach, without stratification. This consideration was based on the premise that, although select stakeholders have requested social risk factor adjustment of the Readmission measure group in alignment with Hospital Readmission Reduction Program (HRRP),[386] other stakeholder groups expressed concern that social risk factor adjustment would be confusing to patients and consumers, resulting in misrepresentation of quality of care at hospitals providing acute inpatient and outpatient care, specifically for dual-eligible patients, while others were concerned that the dual-eligibility variable would not adequately account for social risk in the Overall Star Rating. [387] [388] [389] Furthermore, this consideration was in response to a HHS report titled ''Social Risk Factors and Performance in Medicare's Value-Based Purchasing Programs,'' submitted to Congress by ASPE, that sets forth new recommendations regarding social risk factors, wherein ASPE does not recommend adjusting quality measure for social risk in public reporting.[390] Due to these considerations, we sought comment on the alternative to not stratify the Readmission measure group by proportion of dual-eligible patients.

Within the proposal to stratify the Readmission measure group scores based on dual-eligibility peer groups, we also considered recalculating the peer group quintiles based on all hospitals in the Overall Star Rating, and not solely based on those participating in HRRP. However, calculating quintiles based on all hospitals would create potential misalignment between HRRP quintiles and Overall Star Rating quintiles, and therefore peer group assignment. Because of this potential misalignment, we proposed to recalculate peer group quintiles based on those in the HRRP but sought public comment on our proposal and alternative to recalculate the quintiles based on all hospitals included in the Overall Star Rating.

Finally, we considered not peer grouping by number of measures. Because past stakeholder feedback suggested that CMS consider some type of peer grouping to enable more similar comparisons among hospital types, we proposed to peer group by number of measure groups to achieve this aim. This would enable more similar comparisons among hospitals where smaller hospitals that submit the fewest number of measures are more likely to be in the three measure group peer group and larger hospitals that submit the most measures are more likely to be in the five measure group peer group. We also stated that if we did not finalize our proposal to include CAHs in the Overall Star Ratings, we would not be able to peer group since CAHs make up the majority of the three measure group peer group. Ultimately, we decided to propose peer grouping but solicited public comment on our proposal as well as the alterative considered to not peer group. We solicited comment on our alternative considered to not peer group even if we finalized our proposal to include CAHs.

9. Effects of Requirements for the Physician-Owned Hospitals

The physician-owned hospital provisions are discussed in section XIX. of this final rule with comment period. We proposed and are finalizing regulatory updates to the process under which a hospital that qualifies as a high Medicaid facility can request an exception to the prohibition on facility expansion. Specifically, we will permit a high Medicaid facility to request an exception to the prohibition on expansion of facility capacity more frequently than once every 2 years. With respect to a hospital that qualifies as a high Medicaid facility, we have

[386] Centers for Medicare & Medicaid Services. (2019, June). *Public Comment Summary Report.* Retrieved from *www.CMS.gov*: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods#a0815.*

[387] Ibid.

[388] Centers for Medicare & Medicaid Services. (2019, October 24) Patient and Patient Advocate Work Group Minutes—October 2019.

[389] National Quality Forum. (2019, November 6). *National Quality Forum Hosptial Quality Star Ratings Summit.* Retrieved from *www.qualityforum.org*: *http://www.qualityforum.org/NQF_Hospital_Quality_Star_Rating_Summit.aspx.*

[390] Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation (ASPE). (2020) *Second Report to Congress: Social Risk Factors and Performance in Medicare's Value-based Purchasing Programs.* Retrieved from: *https://aspe.hhs.gov/system/files/pdf/263676/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report.pdf.* Accessed July 2, 2020.

removed the restrictions that permitted expansion of facility capacity: (1) May not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed exceeding 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds; and (2) must occur only in facilities on the hospital's main campus. We expect these changes will reduce burden on high Medicaid facilities and give them additional flexibility to expand. As we explained in the proposed rule, we believe that the existing regulations impose unnecessary burden on high Medicaid facilities. In alignment with our Patients over Paperwork initiative, we are finalizing our proposals to remove this unnecessary burden. Finally, are we are codifying in regulations our longstanding policy, currently set forth in a frequently asked question on the CMS website, that explains CMS' deference to state law for purposes of determining the number of beds for which a hospital is licensed. As this final policy reflects current policy, we do not anticipate that it will have an impact.

In the past decade, the Secretary has granted six expansion exception requests. Neither the statute nor our regulations require that a hospital report to the Secretary whether and when it expands its facility capacity. Based on our own review of the websites of the hospitals granted expansion exception requests, it does not appear that any of the hospitals have yet expanded to 200 percent of their baseline capacity (the current regulatory limit). We are unable to predict with certainty whether any hospital qualifying as a high Medicaid facility would request to, or utilize permitted expansion of facility capacity to, expand beyond 200 percent of its baseline facility capacity.

As noted in the ICR section for physician-owned hospitals, we expect the final policies will impact one physician-owned hospital per year. We do not anticipate any impact on Medicare expenditures for several reasons. First, although an expansion of a physician-owned hospital's capacity may increase access to patients seeking care, it does not affect the type of services being received. Second, the regulations will not affect the payment for Medicare covered items and services. The regulations do not permit development of a new hospital, but rather expansion of an existing hospital. All services furnished by the hospital will be paid at the applicable Medicare payment rates for the existing hospital. Further, existing Medicare billing and claims submission requirements, including the requirement that the services are reasonable and necessary, will continue to apply. Although we believe these changes potentially increase access for patients seeking care, we do not believe there would be any impact to the type or range of services sought, or the amount paid for the services furnished.

We received no comments concerning the burden associated with our proposal to codify in regulations the policy in an existing frequently asked question that explains CMS' deference to state law for purposes of determining the number of beds for which a hospital is licensed. This reflects current policy, and we continue to believe that it will not have an impact. We received the following comments regarding the impact of our proposals to remove the regulatory limitations on high Medicaid facilities not imposed in section 1877(i) of the Act. Our response follows:

Comment: We received many comments stating that removing existing regulatory limitations would allow physician-owned hospitals to serve greater numbers of Medicaid patients and allow physicians more options to care for patients in various and appropriate sites of service. Several commenters stated that the restrictions on hospitals that qualify as high Medicaid facilities have hampered economic growth in communities that rely upon them, contributed to inflated prices through reduced competition between providers, limited patient choice, and decreased the ability of specific hospitals to meet the needs of their communities. The commenters added that removal of the restrictions on high Medicaid facilities would help increase access to vital health care services for the most vulnerable patients.

In contrast, some commenters noted that certain hospitals that qualify as high Medicaid facilities have Medicaid discharge percentages that are extremely low and potentially significantly lower than that of hospitals in surrounding counties where they could locate the large facility expansion capacity permitted under our proposals. Another commenter stated that, if we finalize our proposals, physician-owned hospitals could expand and move into markets without large Medicaid patient populations, creating additional campuses far away from the patients the expansion is intended by statute to serve.

Response: As we explained in section XX of this final rule, to determine whether a hospital qualifies as a high Medicaid facility, the statute requires a relativity analysis based on the location of the existing hospital; that is, a hospital that has the highest Medicaid discharge percentage relative to the hospitals in the same county will qualify as a high Medicaid facility even if the overall number of Medicaid discharges in the county is low. The statute does not require the Secretary to compare a high Medicaid facility to the hospitals in the county where it plans to locate the expansion capacity (if approved). However, Medicare rules and regulations regarding the location of hospital facilities, including the expansion capacity, such as distance limitations related to the location of off campus facilities and provider-based departments remain applicable. (See section 1833(t)(B)(i) of the Act and § 413.65(e)(3)(v)(F)).

The physician self-referral law does not prohibit a hospital granted an exception to the prohibition on expansion of facility capacity from relocating operating rooms, procedure rooms, or beds that were licensed on March 23, 2010 (baseline facility capacity) from the hospital's main campus to a remote location in order to make room for the approved expansion facility capacity. (See *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/FAQs-Physician-Self-Referral-Law.pdf.*) Therefore, we believe that removing the requirement that permitted expansion of facility capacity must occur only in facilities on the hospital's main campus would have minimal, if any, impact, as developing the permitted expansion of facility capacity in a location other than the hospital's main campus derives generally the same result as relocating baseline facility capacity to a remote location of the hospital and locating expansion capacity on the hospital's main campus.

10. Effects of Requirements for the Radiation Oncology (RO) Model

We have examined the impact of this interim final rule with comment period (IFC) as required by Executive Order 12866 and other laws and Executive Orders requiring economic analysis of the effects of final rules. We are revising the Model performance period that was finalized in the Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures final rule (Specialty Care Models final rule) (85 FR 61114) on September 29, 2020, and have updated our net estimate of the RO Model impact. Accordingly, we have prepared an RIA that, to the best of our ability, reflects the economic impact of the policies contained in this IFC.

a. Statement of Need for the Radiation Oncology (RO) Model

The statement of need for the RO Model described in the Specialty Care Models final rule (85 FR 61114) remains unchanged with this IFC. However, as described in detail in section XXI.A of this IFC, RO participants will not be required to collect or submit quality measure data or clinical data in PY1 due to the revised Model performance period. Instead, submission of quality measure data and clinical data will begin in PY2 with the final data submission ending in early 2026 (specifically January 2026 for the clinical data, and March 2026 for the quality measure data). Due to the change in the Model performance period, CMS's collection of patient experience surveys will start in October 2021 rather than April 2021 as finalized under 85 FR 61220.

b. Impact of RO Model

Based on the finalized RO Model policies of the Specialty Care Models final rule (see 85 FR 61114), we expected a savings of $230 million for Medicare. We now expect that revising the Model performance period to a July 1, 2021 start date, which shortens the Model performance period to 4.5 years, will reduce savings from $230 million to $220 million for Medicare.

c. Anticipated Effects

(1). Scale of the Radiation Oncology (RO) Model

In the Specialty Care Models final rule (85 FR 61114), we finalized our policy to include 30 percent of radiation oncology episodes (§ 512.210(d)) and a low volume opt-out policy (§ 512.210(c)). We performed a simulation based on our final rule policies. Based on this simulation, we expected to have approximately 500 physician group practices (PGPs) (of which 275 are freestanding radiation therapy centers) and 450 HOPDs furnishing RT services in those simulated selected CBSAs. We further expected the RO Model to include approximately 348,000 RO episodes, 309,000 beneficiaries, and $5.3 billion in total episode spending of allowed charges over the Model performance period. Revising the Model performance period to begin on July 1, 2021, and end on December 31, 2025 does not affect the number of PGPs or HOPDs we expect to furnish RT services in the simulated selected CBSAs. However, we expect the duration of the revised Model performance period, which shortens the Model performance period to 4.5 years, will reduce the number of RO episodes, the number of beneficiaries, and total spending. We expect the revised Model performance period will include approximately 315,000 RO episodes, 279,000 beneficiaries, and $4.8 billion in total episode spending of allowed charges over the Model performance period.

(2). Effects of the RO Model on the Medicare Program

(a). Overview

Under the current FFS payment system, RT services are paid on a per service basis to both PGPs (including freestanding radiation therapy centers) and HOPDs through the PFS and the OPPS, respectively. The RO Model will be a mandatory model designed to test a prospectively determined episode payment for RT services furnished to Medicare beneficiaries during RO episodes initiated between July 1, 2021 and December 31, 2025 (§ 512.245(a)).

(b). Data and Methods

A stochastic simulation based on the policies in this IFC was created to estimate the financial impacts of the RO Model relative to baseline expenditures.

(c). Medicare Estimate

Table 93 summarizes the estimated impact of the RO Model with a revised Model performance period that begins on July 1, 2021 and ends December 31, 2025. We estimate that on net the Medicare program will save $220 million over the Model performance period. This is the net Medicare Part B impact that includes both Part B premium and Medicare Advantage United States Per Capita Costs (MA USPCC) rate financing interaction effects. This estimate excludes changes in beneficiary cost sharing liability to the extent it is not a federal outlay under the policy.

We project that 83 percent of physician participants (measured by unique NPI) will receive the APM incentive payment under the Quality Payment Program at some point (at least one QP Performance Period) during the Model performance period. This assumption is based on applying the 2020 Quality Payment Program final rule qualification criteria to simulated billing and treatment patterns for each Quality Payment Program performance year during the Model performance period. Episode-initiating physicians were assumed to form an APM entity with the TIN(s) under which they bill for RT services. For each APM entity, counts of total treated patients and spending for covered physician services under the RO Model were estimated and applied to Quality Payment Program qualification criteria based on CY 2018 physician billing patterns.

The APM incentive payment will apply only to the professional episode payment amounts and not the technical episode payment amounts. Moreover, due to the 2-year lag in Quality Payment Program performance and payment periods and with quality data reporting starting in 2022, APM incentive payments will only be made during 2024.

Complete information regarding the data sources and underlying methodology used to determine amounts for reconciliation were not available at the time of this forecast. In the case of the incomplete payment withhold, we assume CMS retains payment only in the event that offsetting payment errors were made elsewhere. Past CMS experience in other value-based payment initiatives that included a penalty for not reporting have shown high rates of reporting compliance. Given the limited spending being withheld, scoring criteria, and specified timeframes involved, we assume that quality and patient experience withholds, on net, have a negligible financial impact to CMS.

A key assumption underlying of the impact estimate is that the volume and intensity (V&I) of the bundled services per episode remains unchanged between the period used for rate setting and when payments are made. If V&I were to decrease by 1.0 percent annually for the bundled services absent the RO Model, then we estimate the impact of the RO Model to Medicare spending to be approximately budget neutral between July 1, 2021 and December 31, 2025. Similarly if V&I increases by 1.0 percent annually then net outlays would be reduced by $440 million for this projection period as opposed to $470 million for the Specialty Care Models final rule projection period of 5 full performance years between January 1, 2021 and December 31, 2025. Although V&I growth from 2014 through 2018 fell within this 1.0 percent range and did not exhibit a secular trend, actual experience may differ. Please also note that due to the current PHE caused by the COVID–19 virus, the forecasted impacts for the RO Model are subject to an additional level of uncertainty. The duration of the current COVID–19 pandemic, its severity, and the policy measures taken as a response are variables that are significant but unknown at this time. This forecast assumes that Medicare Fee-for-Service billing and treatment patterns for beneficiaries observed during the 2016–2018 baseline period resume by the

middle of 2021. To the extent that this assumption does not hold, actual experience may vary significantly.

This table summarizes our estimated impacts of this IFC:

TABLE 93. Estimates of Medicare Program Savings (Millions $) for Radiation Oncology Model (Starting July 1, 2021)

	Year of Model					
	2021	2022	2023	2024	2025	Total*
Net Impact To Medicare Program Spending	-10	-40	-50	-50	-60	-220
Changes to Incurred FFS Spending	-10	-30	-40	-40	-50	-170
Changes to MA Capitation Payments	-10	-20	-30	-30	-40	-120
Part B Premium Revenue Offset	10	10	20	20	20	70
Total APM Incentive Payments	0	0	0	10	0	10
Episode Allowed Charges	490	1030	1050	1100	1120	4790
Episode Medicare Payment	390	800	820	860	880	3740
Total Number of Episodes	33,000	68,000	70,000	71,000	72,000	315,000
Total Number of Beneficiaries	33,000	67,000	68,000	69,000	70,000	279,000

*Negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase.
*Totals may not sum due to rounding and from beneficiaries that have cancer treatment spanning multiple years.

(3). Effects on RO Participants

We believe that the revised Model performance period will not affect the total cost of learning the billing system for the RO Model but will, however, affect the burden estimate for reporting quality measures and clinical data elements.

We believe the burden estimate for quality measure and clinical data element reporting requirements that is provided for Small Businesses applies to RO participants that are not considered small entities. The burden estimate for collecting and reporting quality measures and clinical data for the RO Model may be less than or equal to that for small businesses, which we estimate to be approximately $1,845 per entity per year based on 2020 wages. Since we estimate approximately 950 RO participants, the total annual burden estimate for collecting and reporting quality measures and clinical data is approximately $1,752,750 for a total of $7,011,000 over the Model performance period of four and a half years. Since RO participants are not required to collect nor submit quality measure or clinical data in PY1 due to the change in start date, this reduces burden to RO participants by $1,752,750 as compared to a 5-year submission period of quality measure and clinical data finalized under 85 FR 61211 through 61231.

11. Effects of CoP Requirements for Hospitals and CAHS To Report COVID–19 Therapeutic Inventory and Usage and to Report Acute Respiratory Illness (Including, but not Limited to, Seasonal Influenza Virus, Influenza-Like Illness, and Severe Acute Respiratory Infection) as Specified by the Secretary During the PHE for COVID–19

Section XXII. of this IFC revises the infection prevention and control requirements for hospitals and CAHs to add new COVID–19 PHE hospital and CAH CoP reporting provisions at 42 CFR 482.42(e)(1) and (2) for hospitals and at 42 CFR 485.640(d)(1) and (2) for CAHs, to now require hospitals and CAHs to report data elements that must include, but not be limited to, the following: (1) The hospital's (or the CAH's) current inventory supplies of any COVID–19-related therapeutics that have been distributed and delivered to the hospital (or CAH) under the authority and direction of the Secretary; and (2) the hospital's (or 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. We currently estimate the cost of these new COVID–19 data elements to total $19,663,920.

Additionally, we are revising the infection prevention and control requirements for hospitals and CAHs to more effectively respond to the specific challenges posed by the impending seasonal influenza virus season in the midst of the COVID–19 pandemic. Specifically, we are adding provisions to require facilities to electronically report information related to Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection) cases in a standardized format specified by the Secretary. As detailed in section XXII. of this IFC, we currently estimate the cost of these reporting requirements to total $117,983,520.

These estimates are likely overestimates of 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. We anticipate that the need for reporting will be temporary in direct relationship to the duration of the PHE. Existing guidance on reporting, which may be revised in the future, can be found at *https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf* and at *https://healthdata.gov/covid-19_hospital_reporting*. Data reported to the Secretary is used by federal agencies and states, to provide data for the unified hospital picture, as well as guidance on the distribution of resources.

D. Regulatory Review Costs

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 will review a rule, we assumed that the number of commenters on this CY 2021 OPPS/ASC proposed rule (1,349) will be the number of reviewers of the CY 2021 OPPS/ASC final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing the final rule. It is possible that not all commenters will review the final rule in detail, and it is also possible that some reviewers will choose not to comment on the final rule. Nonetheless, we believe that the number of commenters on the CY 2021 OPPS/ASC proposed rule would be a fair estimate of the number of reviewers of the final rule. We welcomed any comments on the approach in estimating the number of entities that will review the final rule. We also recognize that different types of entities are, in many cases, affected by mutually exclusive sections of the final rule with comment period, and, therefore, for the purposes of our estimate, we assumed that each reviewer reads approximately 50 percent of the rule.

Using the wage information from the 2019 BLS for medical and health service managers (Code 11–9111), we estimated that the cost of reviewing this rule is $110.74 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 will take approximately 8 hours for the staff to review half of the final rule. For each facility that reviewed the final rule, the estimated cost is $885.92 (8 hours × $110.74). Therefore, we estimated that the total cost of reviewing the final rule is $1,195,106 ($885.92 × 1,349 reviewers on the CY 2021 proposed rule).

E. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, many hospitals are considered small businesses either by the Small Business Administration's size standards with total revenues of $41.5 million or less in any single year or by the hospital's not-for-profit status. Most ASCs and most CMHCs are considered small businesses with total revenues of $16.5 million or less in any single year. For details, we refer readers to the Small Business Administration's ''Table of Size Standards'' at *http://www.sba.gov/content/table-small-business-size-standards*. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this final rule with comment period. As a result, the Secretary has determined that this final rule with comment period will not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule 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. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this final rule with comment period will increase payments to small rural hospitals by approximately 3 percent; therefore, it should not have a significant impact on approximately 586 small rural hospitals. We note that the estimated payment impact for any category of small entity will depend on both the services that they provide as well as the payment policies and/or payment systems that may apply to them. Therefore, the most applicable estimated impact may be based on the specialty, provider type, or payment system.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis.

F. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) 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. That threshold level is currently approximately $156 million. This final rule with comment period does not mandate any requirements for State, local, or tribal governments, or for the private sector.

G. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. It has been determined that this final rule with comment period, will be a regulatory action for the purposes of Executive Order 13771. We estimate that this final rule with comment period will generate $7.01 million in annualized cost at a 7-percent discount rate, discounted relative to 2016, over a perpetual time horizon.

H. Conclusion

The changes we are making in this final rule with comment period will affect all classes of hospitals paid under the OPPS and will affect both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS will experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2021. Table 79 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that will result in a 2.4 percent increase in payments for all services paid under the OPPS in CY 2021, after considering all of the changes to APC reconfiguration and recalibration, as well as the OPD fee schedule increase factor, wage index changes, including the frontier State wage index adjustment, estimated payment for outliers, and changes to the pass-through payment estimate. However, some classes of providers that are paid under the OPPS will experience more significant gains or losses in OPPS payments in CY 2021.

The updates we are finalizing to the ASC payment system for CY 2021 will affect each of the approximately 5,600 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC would depend on its mix of patients, the proportion of the ASC's patients who are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under the ASC payment system, and the extent to which the ASC provides a different set of procedures in the coming year.

Table 80 demonstrates the estimated distributional impact among ASC surgical specialties of the MFP-adjusted hospital market basket update factor of 2.4 percent for CY 2021.

XXVIII. Federalism Analysis

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 costs on State and local governments, preempts State law, or otherwise has federalism implications. We have examined the OPPS and ASC provisions included in this final rule with comment period in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on State, local or tribal governments, preempt State law, or otherwise have a federalism implication. As reflected in Table 79 of this final rule with comment period, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) will increase by 2.2 percent under this final rule with comment period. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. The analyses we have provided in this section of this final rule with comment period, in conjunction with the remainder of this document, demonstrate that this final rule with comment period is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This final rule with comment period will affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant.

Congressional Review Act

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

List of Subjects

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, 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 512

Administrative practice and procedure, Health facilities, Medicare reporting and recordkeeping requirements.

For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 1. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 2. Section 410.27 is amended by—
■ a. Adding the word ''and'' at the end of paragraph (a)(1)(iv)(C);
■ b. Revising paragraph (a)(1)(iv)(D); and
■ c. Removing paragraph (a)(1)(iv)(E).

The revision reads as follows:

§ 410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.

(a) * * *

(1) * * *

(iv) * * *

(D) For purposes of this section, direct supervision means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed. For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor of medicine or a doctor of osteopathy, as specified in §§ 410.47 and 410.49, respectively. Until the later of the end of the calendar year in which the PHE as defined in § 400.200 of this chapter ends or December 31, 2021, the presence of the physician includes virtual presence through audio/video real-time communications technology (excluding audio-only); and

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 3. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

■ 4. Section 411.362 is amended—
■ a. In paragraph (a) by revising the definition of ''Baseline number of operating rooms, procedure rooms, and beds''; and
■ b. By revising paragraphs (c)(1) and (6) introductory text.

The revisions read as follows:

§ 411.362 Additional requirements concerning physician ownership and investment in hospitals.

(a) * * *

Baseline number of operating rooms, procedure rooms, and beds means the number of operating rooms, procedure rooms, and beds for which the applicable hospital or high Medicaid facility is licensed as of March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of such date, but does have a provider agreement in effect on December 31, 2010, the date of effect of such agreement). For purposes of determining the number of beds in a hospital's baseline number of operating rooms, procedure rooms, and beds, a bed is included if the bed is considered licensed for purposes of State licensure, regardless of the specific number of beds identified on the physical license issued to the hospital by the State.

* * * * *

(c) * * *

(1) *General.* An applicable hospital may request an exception from the prohibition on facility expansion up to

once every 2 years from the date of a CMS decision on the hospital's most recent request. A high Medicaid facility may request an exception from the prohibition on facility expansion at any time, provided that it has not submitted another request for an exception to the prohibition on facility expansion for which CMS has not issued a decision.

* * * * *

(6) *Permitted increase in facility capacity.* With respect to an applicable hospital only, a permitted increase under this section—

* * * * *

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 5. The authority citation for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 6. Section 412.3 is amended by revising paragraph (d)(2) to read as follows:

§ 412.3 Admissions.

* * * * *

(d) * * *

(2) An inpatient admission for a surgical procedure specified by Medicare as inpatient only under § 419.22(n) of this chapter is generally appropriate for payment under Medicare Part A regardless of the expected duration of care. Procedures no longer specified as inpatient only under § 419.22(n) of this chapter are appropriate for payment under Medicare Part A in accordance with paragraph (d)(1) or (3) of this section. Claims for services and procedures removed from the inpatient only list under § 419.22 of this chapter on or after January 1, 2020 are exempt from certain medical review activities.

(i) For those services and procedures removed between January 1 and December 31, 2020, the exemption in this paragraph (d)(2) will last for 2 years from the date of such removal.

(ii) For those services and procedures removed on or after January 1, 2021, the exemption in this paragraph (d)(2) will last until the Secretary determines that the service or procedure is more commonly performed in the outpatient setting.

* * * * *

■ 7. Section 412.190 is added to subpart I to read as follows:

§ 412.190 Overall Hospital Quality Star Rating.

(a) *Purpose.* (1) The Overall Hospital Quality Star Rating (Overall Star Rating) is a summary of certain publicly reported hospital measure data for the benefit of stakeholders, such as patients, consumers, and hospitals.

(2) The guiding principles of the Overall Star Rating are as follows. In developing and maintaining the Overall Star Ratings, we strive to:

(i) Use scientifically valid methods that are inclusive of hospitals and measure information and able to accommodate underlying measure changes;

(ii) Align with *Hospital Compare* or its successor website and CMS programs;

(iii) Provide transparency of the methods for calculating the Overall Star Rating; and

(iv) Be responsive to stakeholder input.

(b) *Data included in Overall Star Rating*—(1) *Source of data.* The Overall Star Rating is calculated based on measure data collected and publicly reported on *Hospital Compare* or its successor site under the following CMS hospital inpatient and outpatient programs:

(i) Hospital Inpatient Quality Reporting (IQR) Program—section 1886(b)(3)(B)(viii)(VII) of the Act.

(ii) Hospital-Acquired Condition Reduction Program—section 1886(p)(6)(A) of the Act.

(iii) Hospital Value-based Purchasing Program—section 1886(o)(10)(A) of the Act.

(iv) Hospital Readmissions Reduction Program—section 1886(q)(6)(A) of the Act.

(v) Hospital Outpatient Quality Reporting (OQR) Program—section 1833(t)(17)(e) of the Act.

(2) *Hospitals included in Overall Star Rating.* Subsection (d) hospitals subject to the CMS quality programs specified in paragraph (b)(1) of this section that also have their data publicly reported on one of CMS' websites are included in the Overall Star Rating.

(3) *Critical Access Hospitals.* Critical Access Hospitals (CAHs) that wish to be voluntarily included in the Overall Star Rating must have elected to—

(i) Voluntarily submit quality measures included in and as specified under CMS hospital programs; and

(ii) Publicly report their quality measure data on *Hospital Compare* or its successor site.

(c) *Frequency of publication and data used.* The Overall Star Rating are published once annually using data publicly reported on *Hospital Compare* or its successor website from a quarter within the prior year.

(d) *Methodology*—(1) *Selection of measures.* Measures are selected from those publicly reported on *Hospital Compare* or its successor website through certain CMS quality programs under paragraph (b)(1) of this section.

(i) From this group of measures, measures falling into one or more of the exclusions in paragaphs (d)(1)(i)(A) through (E) of this section will be removed from consideration:

(A) Measures that 100 hospitals or less publicly report. These measures would not produce reliable measure group scores based on too few hospitals;

(B) Measures that cannot be standardized to a single, common scale and otherwise not amenable to inclusion in a summary score calculation alongside process and outcome measures or measures that cannot be combined in a meaningful way. This includes measures that cannot be as easily combined with other measures captured on a continuous scale with more granular data;

(C) Non-directional measures for which it is unclear whether a higher or lower score is better. These measures cannot be standardized to be combined with other measures and form an aggregate measure group score;

(D) Measures not required for reporting on *Hospital Compare* or its successor websites through CMS programs; or

(E) Measures that overlap with another measure in terms of cohort or outcome, including component measures that are part of an already-included composite measure.

(ii) [Reserved]

(2) *Measure score standardization.* All measure scores are standardized by calculating Z-scores so that all measures are on a single, common scale to be consistent in terms of direction (that is, higher scores are better) and numerical magnitude. This is calculated by subtracting the national mean measure score from each hospital's measure score and dividing the difference by the measure standard deviation in order to standardize measures.

(3) *Grouping measures.* Measures are grouped into one of the five clinical groups as follows:

(i) Mortality.

(ii) Safety of Care.

(iii) Readmission.

(iv) Patient Experience.

(v) Timely and Effective Care.

(4) *Calculate measure group scores.* A score is calculated for each measure group for which a hospital has measure data using a simple average of measure scores, as follows:

(i) Each measure group score is standardized by calculating Z-scores for each measure group so that all measure group scores are centered near zero with a standard deviation of one.

(ii) We take 100 percent divided by the number of measures reported in a measure group to determine the percentage of each measure's weight.

(iii) The measure weight is then multiplied by the standardized measure score to calculate the measure's weighted score.

(iv) Then, all of the individual measure weighted scores within a measure group are added together to calculate the measure group score.

(5) *Reporting thresholds.* In order to receive an Overall Star Rating, a hospital must report at least three measures within at least three measure groups, one of which must specifically be the Mortality or Safety of Care outcome group.

(6) *Hospital summary score.* A summary score is calculated by multiplying the standardized measure group scores by the assigned measure group weights and then summing the weighted measure group scores.

(i) *Standard measure group weighting.* (A) Each of the Mortality, Safety of Care, Readmission, and Patient Experience groups are weighted 22 percent; and

(B) The Timely and Effective Care group is weighted 12 percent.

(ii) *Reweighting.* (A) Hospitals may have too few cases to report particular measures and, in those cases, may not report enough measures in one or more measure groups.

(B) When a hospital does not have enough measures in one or more measure groups due to too few cases CMS may re-distribute one or more of the missing measure group's weight proportionally across the remaining measure groups by subtracting the standard weight percentage of the group or groups with insufficient measures from 100 percent; and then dividing the resulting percentage across the remaining measure groups, giving new re-proportioned weights.

(7) *Peer grouping.* Hospitals are assigned to one of three peer groups based on the number of measure groups for which they report at least three measures: three, four, or five measure groups.

(8) *Star ratings assignment.* Hospitals in each peer group are then assigned between one and five stars where one star is the lowest and five stars is the highest using k-means clustering to complete convergence.

(e) *Preview period prior to publication.* CMS provides hospitals the opportunity to preview their Overall Star Rating prior to publication. Hospitals have at least 30 days to preview their results, and if necessary, can reach out to CMS with questions.

(f) *Suppression of Overall Star Rating*—(1) *Subsection (d) hospitals.* CMS may consider suppressing Overall Star Rating for subsection (d) hospitals only under extenuating circumstances that affect numerous hospitals (as in, not an individualized or localized issue) as determined by CMS, or when CMS is at fault, including but not limited to when:

(i) There is an Overall Star Rating calculation error by CMS;

(ii) There is a systemic error at the CMS quality program level that substantively affects the Overall Star Rating calculation; or

(iii) If a Public Health Emergency, as defined in § 400.200 of this chapter, substantially affects the underlying measure data.

(2) *CAHs.* (i) CAHs may request to withhold their Overall Star Rating from publication on *Hospital Compare* or its successor website so long as the request for withholding is made, at the latest, during the Overall Star Rating preview period.

(ii) CAHs may request to have their Overall Star Rating withheld from publication on *Hospital Compare* or its successor website, as well as their data from the public input file, so long as the request is made during the CMS quality program-level 30-day confidential preview period for the *Hospital Compare* refresh data used to calculate the Overall Star Ratings.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 8. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 9. Section 414.510 is amended by revising paragraph (b)(5) introductory text to read as follows:

§ 414.510 Laboratory date of service for clinical laboratory and pathology specimens.

* * * * *

(b) * * *

(5) In the case of a molecular pathology test performed by a laboratory other than a blood bank or center, a test designated by CMS as an ADLT under paragraph (1) of the definition of an advanced diagnostic laboratory test in § 414.502, a test that is a cancer-related protein-based Multianalyte Assays with Algorithmic Analyses, or the test described by CPT code 81490, the date of service of the test must be the date the test was performed only if—

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

■ 10. The authority citation for part 416 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 11. Section 416.166 is revised to read as follows:

§ 416.166 Covered surgical procedures.

(a) *Covered surgical procedures.* (1) Effective for services furnished on or after January 1, 2008 through December 31, 2020, covered surgical procedures are those procedures that meet the general standards described in paragraph (b)(1) of this section (whether commonly furnished in an ASC or a physician's office) and are not excluded under paragraph (c) of this section; and

(2) Effective for services furnished on or after January 1, 2021, covered surgical procedures are those procedures that meet the requirements described in paragraph (b)(2) of this section (whether commonly furnished in an ASC or a physician's office).

(b) *Requirements for covered surgical procedures*—(1) *General standards.* Effective for services furnished on or after January 1, 2008 through December 31, 2020, subject to the exclusions in paragraph (c) of this section, covered surgical procedures are surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the internet on the CMS website that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.

(2) Effective for services furnished on or after January 1, 2021, covered surgical procedures are surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the internet on the CMS website that:

(i) Are separately paid under the OPPS; and

(ii) Are not:

(A) Designated as requiring inpatient care under § 419.22(n) of this subchapter as of December 31, 2020;

(B) Only able to be reported using a CPT unlisted surgical procedure code; or

(C) Otherwise excluded under § 411.15 of this chapter.

(c) *General exclusions effective January 1, 2008 through December 31, 2020.* Notwithstanding paragraph (b)(1)

of this section, covered surgical procedures do not include those surgical procedures that—

(1) Generally result in extensive blood loss;

(2) Require major or prolonged invasion of body cavities;

(3) Directly involve major blood vessels;

(4) Are generally emergent or life-threatening in nature;

(5) Commonly require systemic thrombolytic therapy;

(6) Are designated as requiring inpatient care under § 419.22(n) of this subchapter;

(7) Can only be reported using a CPT unlisted surgical procedure code; or

(8) Are otherwise excluded under § 411.15 of this chapter.

(d) *Physician considerations beginning January 1, 2021.* Physicians consider the following safety factors as to a specific beneficiary when determining whether to perform a covered surgical procedure. The covered procedure—

(1) Is not expected to pose a significant safety risk when performed in an ASC;

(2) Is one for which standard medical practice dictates the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure;

(3) Generally results in extensive blood loss;

(4) Requires major or prolonged invasion of body cavities;

(5) Directly involves major blood vessels;

(6) Is generally emergent or life-threatening in nature; and

(7) Commonly requires systemic thrombolytic therapy.

(e) *Additions to the list of ASC covered surgical procedures beginning January 1, 2021.* On or after January 1, 2021, CMS adds surgical procedures to the list of ASC covered surgical procedures as follows.

(1) CMS identifies a surgical procedure that meets the requirements at paragraph (b)(2) of this section.

(2) CMS is notified of a surgical procedure that could meet the requirements at paragraph (b)(2) of this section and CMS confirms that such surgical procedure meets those requirements.

■ 12. Section 416.310 is amended—

■ a. In paragraphs (a)(2) and (b) by removing the phrase ''data collection time period'' and adding in its place ''data collection period'';

■ b. By revising paragraph (c)(1)(i);

■ c. In paragraph (c)(1)(ii) by removing the phrase ''data collection time period'' and adding in its place ''data collection period'' and removing the phrase ''time period'' and adding in its place ''period'';

■ d. By adding paragraph (c)(1)(iii);

■ e. In paragraph (c)(2) by removing the phrase ''data collection time period'' and adding in its place ''data collection period''; and

■ f. By adding paragraph (f).

The revision and additions read as follows:

§ 416.310 Data collection and submission requirements under the ASCQR Program.

* * * * *

(c) * * *

(1) * * *

(i) *QualityNet account for web-based measures.* ASCs, and any agents submitting data on an ASC's behalf, must maintain a QualityNet account in order to submit quality measure data to the QualityNet website for all web-based measures submitted via a CMS online data submission tool. A QualityNet security official is necessary to set up such an account for the purpose of submitting this information.

* * * * *

(iii) *Review and corrections period.* For measures submitted to CMS via a CMS online tool, ASCs have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, ASCs can enter, review, and correct data submitted. After the submission deadline, this data cannot be changed.

* * * * *

(f) *Data submission deadlines.* All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order are extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order.

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 13. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

■ 14. Section 419.22 is amended by revising paragraph (n) to read as follows:

§ 419.22 Hospital services excluded from payment under the hospital outpatient prospective payment system.

* * * * *

(n) Services and procedures that the Secretary designates as requiring inpatient care. Effective beginning on January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition, with the full list eliminated in its entirety by January 1, 2024.

* * * * *

■ 15. Section 419.32 is amended by adding paragraph (b)(1)(iv)(B)(*11*) to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(*11*) For calendar year 2020 and subsequent years, a multifactor productivity adjustment (as determined by CMS).

* * * * *

■ 16. Section 419.45 is amended by revising paragraphs (b)(1) and (2) to read as follows:

§ 419.45 Payment and copayment reduction for devices replaced without cost or when full or partial credit is received.

* * * * *

(b) * * *

(1) The amount of the reduction to the APC payment made under paragraphs (a)(1) and (2) of this section is calculated as the lesser of the device offset amount that would be applied if the device implanted during a procedure assigned to the APC had transitional pass-through status under § 419.66 or the amount of the credit described in paragraph (a)(2) of this section.

(2) The amount of the reduction to the APC payment made under paragraph (a)(3) of this section is calculated as the lesser of the device offset amount that would be applied if the device implanted during a procedure assigned to the APC had transitional pass-through status under § 419.66 or the amount of the credit described in paragraph (a)(3) of this section.

* * * * *

■ 17. Section 419.46 is amended—

■ a. By redesignating paragraphs (a) through (h) as paragraphs (b) through (i), respectively;

■ b. By adding a new paragraph (a);

■ c. By revising newly redesignated paragraphs (b)(2), (c), and (d)(1) and (2);

■ d. In newly redesignated paragraphs (d)(3)(ii) and (iii) by removing the cross-reference to ''paragraph (c)(2)'' and adding in its place ''paragraph (d)(2)'';

■ e. By adding paragraphs (d)(4) and (f)(4);
■ f. By revising newly redesignated paragraph (g)(1);
■ g. In newly redesignated paragraph (g)(2)(viii) by removing the cross-reference to ''paragraph (e)(1)'' and adding in its place ''paragraph (f)(1)'';
■ h. In newly redesignated paragraph (i)(1) by removing the cross-reference ''paragraphs (h)(2) and (3)'' and adding in its place ''paragraphs (i)(2) and (3)'';
■ i. In newly redesignated paragraph (i)(3) introductory text by removing the cross-reference ''paragraph (h)(2)'' and adding in its place ''paragraph (i)(2)''; and
■ j. In newly redesignated paragraph (i)(3)(ii) introductory text by removing the cross-reference ''paragraph (h)(3)(i)(A)'' and adding in its place ''paragraph (i)(3)(i)(A)''.

The additions and revisions read as follows:

§ 419.46 Participation, data submission, and validation requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

(a) *Statutory authority.* Section 1833(t)(17) of the Act authorizes the Secretary to implement a quality reporting program in a manner so as to provide for a 2.0 percentage point reduction in the OPD fee schedule increase factor for a subsection (d) hospital (as defined in section 1886(d)(1)(B)) that does not submit data required to be submitted on measures in accordance with the Secretary's requirements in this part.

(b) * * *

(2) Identify and register a QualityNet security official as part of the registration process under paragraph (b)(1) of this section; and

* * * * *

(c) *Withdrawal from the Hospital OQR Program.* A participating hospital may withdraw from the Hospital OQR Program by submitting to CMS a withdrawal form that can be found in the secure portion of the QualityNet website. The hospital may withdraw any time up to and including August 31 of the year prior to the affected annual payment updates. A withdrawn hospital will not be able to later sign up to participate in that payment update, is subject to a reduced annual payment update as specified under paragraph (i) of this section, and is required to renew participation as specified in paragraph (b) of this section in order to participate in any future year of the Hospital OQR Program.

(d) * * *

(1) *General rule.* Except as provided in paragraph (e) of this section, hospitals that participate in the Hospital OQR Program must submit to CMS data on measures selected under section 1833(t)(17)(C) of the Act in a form and manner, and at a time, specified by CMS. Hospitals sharing the same CCN must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes.

(2) *Submission deadlines.* Submission deadlines by measure and by data type are posted on the QualityNet website. All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order are extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order.

* * * * *

(4) *Review and corrections period.* For both chart-abstracted and web-based measures, hospitals have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, hospitals can enter, review, and correct data submitted. However, after the submission deadline, this data cannot be changed.

* * * * *

(f) * * *

(4) Hospitals that are selected and receive a score for validation of chart-abstracted measures may request an educational review in order to better understand the results within 30 calendar days from the date the validation results are made available. If the results of an educational review indicate that a hospital's medical records selected for validation for chart-abstracted measures was incorrectly scored, the corrected quarterly validation score will be used to compute the hospital's final validation score at the end of the calendar year.

(g) * * *

(1) A hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital OQR Program in paragraph (b) of this section for a particular calendar year. Except as provided in paragraph (e) of this section, a hospital must submit a reconsideration request to CMS via the QualityNet website, no later than March 17, or if March 17 falls on a nonwork day, on the first day after March 17 which is not a nonwork day as defined in paragraph (d)(2) of this section, of the affected payment year as determined using the date the request was mailed or submitted to CMS.

* * * * *

■ 18. Section 419.66 is amended by revising paragraph (c)(2)(ii) to read as follows:

§ 419.66 Transitional pass-through payments: Medical devices.

* * * * *

(c) * * *

(2) * * *

(ii) For devices for which pass-through payment status will begin on or after January 1, 2020, as an alternative pathway to paragraph (c)(2)(i) of this section, a new device is part of the Food and Drug Administration's (FDA's) Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.

* * * * *

■ 19. Section 419.83 is amended by revising paragraph (a) to read as follows:

§ 419.83 List of hospital outpatient department services requiring prior authorization.

(a) *Service categories for the list of hospital outpatient department services requiring prior authorization.* (1) The following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2020:

(i) Blepharoplasty.
(ii) Botulinum toxin injections.
(iii) Panniculectomy.
(iv) Rhinoplasty.
(v) Vein ablation.

(2) The following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2021:

(i) Cervical Fusion with Disc Removal.
(ii) Implanted Spinal Neurostimulators.

(3) Technical updates to the list of services, such as changes to the name of the service or CPT code, will be published on the CMS website.

* * * * *

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 20. The authority citation for part 482 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr, unless otherwise noted.

■ 21. Section 482.42 is amended, effective December 4, 2021, by revising paragraph (e) and adding paragraph (f) to read as follows:

§ 482.42 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

* * * * *

(e) *COVID–19 reporting.* 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:

(1) 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; and

(2) 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.

(f) *Standard: Reporting of Acute Respiratory Illness, including Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection.* 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.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 22. The authority citation for part 485 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 23. Section 485.640 is amended, effective December 4, 2021, by revising paragraph (d) and adding paragraph (e) to read as follows:

§ 485.640 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

* * * * *

(d) *COVID–19 reporting.* 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:

(1) 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

(2) 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.

(e) *Standard: Reporting of Acute Respiratory Illness, including Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection.* 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.

PART 512—RADIATION ONCOLOGY MODEL AND END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

■ 24. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 25. Section 512.205 is amended, effective December 4, 2021, by revising the definitions ''Model performance period'' and ''Performance year (PY)'' to read as follows:

§ 512.205 Definitions.

* * * * *

Model performance period means July 1, 2021, through December 31, 2025, the last date on which an RO episode may end under the RO Model. No new RO episodes may begin after October 3, 2025, in order for all RO episodes to end by December 31, 2025.

* * * * *

Performance year (PY) means the 6-month period beginning on July 1, 2021, and ending on December 31, 2021, and the 12-month period beginning on January 1 and ending on December 31 of each subsequent year (2022 through 2025) during the Model performance period.

* * * * *

■ 26. Section 512.210 is amended, effective December 4, 2021, by revising paragraphs (a) and (c) to read as follows:

§ 512.210 RO participants and geographic areas.

(a) *RO participants.* Unless otherwise specified in paragraph (b) or (c) of this section, any RO participant that furnishes included RT services in a 5-digit ZIP Code linked to a CBSA selected for participation to an RO beneficiary for an RO episode that begins on or after July 1, 2021, and ends on or before December 31, 2025, must participate in the RO Model.

* * * * *

(c) *Low volume opt-out.* A PGP, freestanding radiation therapy center, or HOPD, which would otherwise be required to participate in the RO Model may choose to opt-out of the RO Model for a given PY if it has fewer than 20 episodes of RT services across all CBSAs selected for participation in the most recent year with claims data available prior to the applicable PY. At least 30 days prior to the start of each PY, CMS notifies RO participants eligible for the low volume opt-out for the upcoming PY. The RO participant must attest to its intention of opting out of the RO Model prior to the start of the upcoming PY. Low volume opt-out eligibility is determined as follows:

(1) *PY1.* Episodes from January 1, 2019 through December 31, 2019 determine eligibility for the low volume opt-out for PY1.

(2) *PY2.* Episodes from January 1, 2020 through December 31, 2020 determine eligibility for the low volume opt-out for PY2.

(3) *PY3.* Episodes from January 1, 2021 through June 30, 2021 and RO episodes from July 1, 2021 through December 31, 2021 determine eligibility for the low volume opt-out for PY3.

(4) *PY4.* RO episodes from January 1, 2022 through December 31, 2022 determine low volume opt-out eligibility for PY4.

(5) *PY5.* RO episodes from January 1, 2023 through December 31, 2023 determine low volume opt-out eligibility for PY5.

* * * * *

■ 27. Section 512.217 is amended, effective December 4, 2021, by revising paragraph (c)(3) introductory text to read as follows:

§ 512.217 Identification of individual practitioners.

* * * * *

(c) * * *

(3) If the RO participant does not certify the individual practitioner list in PY2 through PY5:

* * * * *

■ 28. Section 512.220 is amended, effective December 4, 2021, by revising paragraph (b) to read as follows:

§ 512.220 RO participant compliance with RO Model requirements.

* * * * *

(b) *CEHRT.* Each RO participant must use CEHRT, and ensure that its individual practitioners use CEHRT, in a manner sufficient to meet the

applicable requirements of the Advanced APM criteria codified in § 414.1415(a)(1)(i) of this chapter. Within 30 days of the start of PY2 and each subsequent PY, each RO participant must certify in the form and manner, and by a deadline specified by CMS, that it uses CEHRT throughout such PY in a manner sufficient to meet the requirements set forth in § 414.1415(a)(1)(i) of this chapter.

■ 29. Section 512.245 is amended, effective December 4, 2021, by revising paragraph (a) to read as follows:

§ 512.245 Included RO episodes.

(a) *General.* Any RO episode that begins on or after July 1, 2021, and ends on or before December 31, 2025, is included in the Model performance period.

* * * * *

■ 30. Section 512.255 is amended, effective December 4, 2021, by revising paragraph (c)(10) to read as follows:

§ 512.255 Determination of participant-specific professional episode payment and participant-specific technical episode payment amounts.

* * * * *

(c) * * *

(10) *Quality withhold.* In accordance with § 414.1415(b)(1) of this chapter, CMS withholds 2 percent from each professional episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, and discount factor to the national base rate starting in PY2. RO participants may earn back this withhold, in part or in full, based on their AQS.

* * * * *

■ 31. Section 512.285 is amended, effective December 4, 2021, by revising paragraph (d) to read as follows:

§ 512.285 Reconciliation process.

* * * * *

(d) *Quality reconciliation payment amount.* For Professional participants and Dual participants, CMS determines the quality reconciliation payment amount for PY2 through PY5 by multiplying the participant's AQS (as a percentage) by the total quality withhold amount for all RO episodes initiated during the PY. There is no quality reconciliation payment amount for PY1.

* * * * *

Dated: November 19, 2020.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: November 23, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–26819 Filed 12–4–20; 8:45 am]

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Part III

Bureau of Consumer Financial Protection

12 CFR Part 1026

Qualified Mortgage Definition Under the Truth in Lending Act (Regulation Z): General QM Loan Definition; Final Rule

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1026

[Docket No. CFPB–2020–0020]

RIN 3170–AA98

Qualified Mortgage Definition Under the Truth in Lending Act (Regulation Z): General QM Loan Definition

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Final rule; official interpretation.

SUMMARY: With certain exceptions, Regulation Z requires creditors to make a reasonable, good faith determination of a consumer's ability to repay any residential mortgage loan, and loans that meet Regulation Z's requirements for ''qualified mortgages'' (QMs) obtain certain protections from liability. One category of QMs is the General QM category. For General QMs, the ratio of the consumer's total monthly debt to total monthly income (DTI or DTI ratio) must not exceed 43 percent. This final rule amends the General QM loan definition in Regulation Z. Among other things, the final rule removes the General QM loan definition's 43 percent DTI limit and replaces it with price-based thresholds. Another category of QMs consists of loans that are eligible for purchase or guarantee by either the Federal National Mortgage Association (Fannie Mae) or the Federal Home Loan Mortgage Corporation (Freddie Mac) (government-sponsored enterprises or GSEs), while operating under the conservatorship or receivership of the Federal Housing Finance Agency (FHFA). The GSEs are currently under Federal conservatorship. In 2013, the Bureau established this category of QMs (Temporary GSE QMs) as a temporary measure that would expire no later than January 10, 2021 or when the GSEs cease to operate under conservatorship. In a final rule released on October 20, 2020, the Bureau extended the Temporary GSE QM loan definition to expire on the mandatory compliance date of final amendments to the General QM loan definition in Regulation Z (or when the GSEs cease to operate under the conservatorship of the FHFA, if that happens earlier). In this final rule, the Bureau adopts the amendments to the General QM loan definition that are referenced in that separate final rule.

DATES: This final rule is effective on March 1, 2021. However, the mandatory compliance date is July 1, 2021. For additional discussion of these dates, see part VII of the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: Waeiz Syed, Counsel, or Ben Cady, Pedro De Oliveira, Sarita Frattaroli, David Friend, Mark Morelli, Marta Tanenhaus, Priscilla Walton-Fein, or Steve Wrone, Senior Counsels, Office of Regulations, at 202–435–7700. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

SUPPLEMENTARY INFORMATION:

I. Summary of the Final Rule

The Ability-to-Repay/Qualified Mortgage Rule (ATR/QM Rule) requires a creditor to make a reasonable, good faith determination of a consumer's ability to repay a residential mortgage loan according to its terms. Loans that meet the ATR/QM Rule's requirements for QMs obtain certain protections from liability. The ATR/QM Rule defines several categories of QMs.

One QM category defined in the ATR/QM Rule is the General QM category. General QMs must comply with the ATR/QM Rule's prohibitions on certain loan features, its points-and-fees limits, and its underwriting requirements. For General QMs, the consumer's DTI ratio must not exceed 43 percent. The ATR/QM Rule requires that creditors must calculate, consider, and verify debt and income for purposes of determining the consumer's DTI ratio using the standards contained in appendix Q of Regulation Z.

A second, temporary category of QMs defined in the ATR/QM Rule consists of mortgages that (1) comply with the same loan-feature prohibitions and points-and-fees limits as General QMs and (2) are eligible to be purchased or guaranteed by the GSEs while under the conservatorship of the FHFA. This final rule refers to these loans as Temporary GSE QMs, and the provision that created this loan category is commonly known as the GSE Patch. Unlike for General QMs, the ATR/QM Rule does not prescribe a DTI limit for Temporary GSE QMs. Thus, a loan can qualify as a Temporary GSE QM even if the consumer's DTI ratio exceeds 43 percent, as long as the loan is eligible to be purchased or guaranteed by either of the GSEs and satisfies the other Temporary GSE QM requirements. In addition, for Temporary GSE QMs, the ATR/QM Rule does not require creditors to use appendix Q to determine the consumer's income, debt, or DTI ratio.

In 2013, the Bureau provided in the ATR/QM Rule that the Temporary GSE QM loan definition would expire with respect to each GSE when that GSE ceases to operate under Federal conservatorship or on January 10, 2021, whichever comes first. The GSEs are currently under Federal conservatorship. Despite the Bureau's expectations when the ATR/QM Rule was published in 2013, Temporary GSE QM originations continue to represent a large and persistent share of the residential mortgage loan market. Without changes to the General QM loan definition, a significant number of Temporary GSE QMs would not be made or would be made at higher prices when the Temporary GSE QM loan definition expires. The affected loans would include loans for which the consumer's DTI ratio is above 43 percent or the creditor's method of documenting and verifying income or debt is incompatible with appendix Q. Based on 2018 data, the Bureau estimates that, as a result of the General QM loan definition's 43 percent DTI limit, approximately 957,000 loans—16 percent of all closed-end first-lien residential mortgage originations in 2018—would be affected by the expiration of the Temporary GSE QM loan definition. These loans are currently originated as QMs due to the Temporary GSE QM loan definition but would not be originated under the current General QM loan definition, and might not be originated at all, if the Temporary GSE QM loan definition were to expire.

On June 22, 2020, the Bureau released two proposed rules concerning the ATR/QM Rule; these proposed rules were published in the **Federal Register** on July 10, 2020. In one of the proposals—referred to in this final rule as the Extension Proposal—the Bureau proposed to extend the Temporary GSE QM loan definition until the effective date of a final rule issued by the Bureau amending the General QM loan definition.[1] The other proposal concerned the issues addressed in this final rule. In that proposal—referred to in this final rule as the General QM Proposal or as the proposal—the Bureau proposed amendments to the General QM loan definition.[2] In the General QM Proposal, the Bureau proposed, among other things, to remove the General QM loan definition's DTI limit and replace it with a limit based on the loan's pricing. The Bureau stated that it expected such amendments would allow most loans that currently could receive QM status under the Temporary GSE QM loan definition to receive QM status under the General QM loan definition if they are made after the

[1] 85 FR 41448 (July 10, 2020).

[2] 85 FR 41716 (July 10, 2020).

Temporary GSE QM loan definition expires. Based on 2018 data, the Bureau estimated in the General QM Proposal that 943,000 conventional loans with DTI ratios above 43 percent would fall outside the QM definitions if there are no changes to the General QM loan definition before the expiration of the Temporary GSE QM loan definition but would fall within the General QM loan definition if it were amended as the Bureau proposed. The Bureau stated that, as a result, the General QM Proposal would help to facilitate a smooth and orderly transition away from the Temporary GSE QM loan definition.

On August 18, 2020, the Bureau issued a third proposal concerning the ATR/QM Rule. In that proposal—referred to in this final rule as the Seasoned QM Proposal—the Bureau proposed to create a new category of QMs (Seasoned QMs) for first-lien, fixed-rate covered transactions that meet certain performance requirements over a 36-month seasoning period, are held in portfolio until the end of the seasoning period, comply with general restrictions on product features and points and fees, and meet certain underwriting requirements.[3]

In a final rule released on October 20, 2020 (the Extension Final Rule), the Bureau amended Regulation Z to replace the January 10, 2021 sunset date of the Temporary GSE QM loan definition with a provision stating that the Temporary GSE QM loan definition will be available only for covered transactions for which the creditor receives the consumer's application before the mandatory compliance date of final amendments to the General QM loan definition in Regulation Z. The Extension Final Rule did not amend the provision stating that the Temporary GSE QM loan definition expires with respect to a GSE when that GSE ceases to operate under conservatorship (the conservatorship clause). The Extension Final Rule did not affect the QM definitions that apply to Federal Housing Administration (FHA), U.S. Department of Veterans Affairs (VA), U.S. Department of Agriculture (USDA), or Rural Housing Service (RHS) loans.

In this final rule, the Bureau amends Regulation Z to replace the existing General QM loan definition with its 43 percent DTI limit with a price-based General QM loan definition. Under the final rule, a loan meets the General QM loan definition in § 1026.43(e)(2) only if the annual percentage rate (APR) exceeds the average prime offer rate (APOR) for a comparable transaction by less than 2.25 percentage points as of the date the interest rate is set. The final rule provides higher thresholds for loans with smaller loan amounts, for certain manufactured housing loans, and for subordinate-lien transactions. The final rule retains the existing product-feature and underwriting requirements and limits on points and fees. Although the final rule removes the 43 percent DTI limit from the General QM loan definition, the final rule requires that the creditor consider the consumer's current or reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan, debt obligations, alimony, child support, and DTI ratio or residual income and verify the consumer's current or reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan and the consumer's current debt obligations, alimony, and child support. The final rule removes appendix Q. To prevent uncertainty that may result from appendix Q's removal, the final rule clarifies the consider and verify requirements. The final rule preserves the current threshold separating safe harbor from rebuttable presumption QMs, under which a loan is a safe harbor QM if its APR does not exceed APOR for a comparable transaction by 1.5 percentage points or more as of the date the interest rate is set (or by 3.5 percentage points or more for subordinate-lien transactions).

The effective date of this final rule is March 1, 2021, and the mandatory compliance date is July 1, 2021. Creditors will have the option of complying with the revised General QM loan definition for covered transactions for which creditors receive an application on or after March 1, 2021, and before July 1, 2021. The revised regulations apply to covered transactions for which creditors receive an application on or after July 1, 2021.

II. Background

A. Dodd-Frank Act Amendments to the Truth in Lending Act

The Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act)[4] amended the Truth in Lending Act (TILA)[5] to establish, among other things, ability-to-repay (ATR) requirements in connection with the origination of most residential mortgage loans.[6] The amendments were intended ''to assure that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loans and that are understandable and not unfair, deceptive or abusive.''[7] As amended, TILA prohibits a creditor from making a residential mortgage loan unless the creditor makes a reasonable and good faith determination based on verified and documented information that the consumer has a reasonable ability to repay the loan.[8]

TILA identifies the factors a creditor must consider in making a reasonable and good faith assessment of a consumer's ability to repay. These factors are the consumer's credit history, current and expected income, current obligations, DTI ratio or residual income after paying non-mortgage debt and mortgage-related obligations, employment status, and other financial resources other than equity in the dwelling or real property that secures repayment of the loan.[9] A creditor, however, may not be certain whether its ATR determination is reasonable in a particular case.

TILA addresses this potential uncertainty by defining a category of loans—called QMs—for which a creditor ''may presume that the loan has met'' the ATR requirements.[10] The statute generally defines a QM to mean any residential mortgage loan for which:

- The loan does not have negative amortization, interest-only payments, or balloon payments;
- The loan term does not exceed 30 years;
- The total points and fees generally do not exceed 3 percent of the loan amount;
- The income and assets relied upon for repayment are verified and documented;
- The underwriting uses a monthly payment based on the maximum rate during the first five years, uses a payment schedule that fully amortizes the loan over the loan term, and takes

[3] 85 FR 53568 (Aug. 28, 2020).

[4] Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 124 Stat. 1376 (2010).

[5] 15 U.S.C. 1601 *et seq.*

[6] Dodd-Frank Act sections 1411–12, 1414, 124 Stat. 2142–48, 2149; 15 U.S.C. 1639c.

[7] 15 U.S.C. 1639b(a)(2).

[8] 15 U.S.C. 1639c(a)(1). TILA section 103 defines ''residential mortgage loan'' to mean, with some exceptions including open-end credit plans, ''any consumer credit transaction that is secured by a mortgage, deed of trust, or other equivalent consensual security interest on a dwelling or on residential real property that includes a dwelling.'' 15 U.S.C. 1602(dd)(5). TILA section 129C also exempts certain residential mortgage loans from the ATR requirements. *See, e.g.,* 15 U.S.C. 1639c(a)(8) (exempting reverse mortgages and temporary or bridge loans with a term of 12 months or less).

[9] 15 U.S.C. 1639c(a)(3).

[10] 15 U.S.C. 1639c(b)(1).

into account all mortgage-related obligations; and

• The loan complies with any guidelines or regulations established by the Bureau relating to the ratio of total monthly debt to monthly income or alternative measures of ability to pay regular expenses after payment of total monthly debt.[11]

B. The ATR/QM Rule

In January 2013, the Bureau issued a final rule amending Regulation Z to implement TILA's ATR requirements (January 2013 Final Rule).[12] The January 2013 Final Rule became effective on January 10, 2014, and the Bureau has amended it several times since January 2013.[13] This final rule refers to the January 2013 Final Rule and later amendments to it collectively as the ATR/QM Rule or the Rule. The ATR/QM Rule implements the statutory ATR provisions discussed above and defines several categories of QMs.[14]

1. General QMs

One category of QMs defined by the ATR/QM Rule consists of General QMs.[15] A loan is a General QM if:

• The loan does not have negative-amortization, interest-only, or balloon-payment features, a term that exceeds 30 years, or points and fees that exceed specified limits;[16]

• The creditor underwrites the loan based on a fully amortizing schedule using the maximum rate permitted during the first five years;[17]

• The creditor considers and verifies the consumer's income and debt obligations in accordance with appendix Q;[18] and

• The consumer's DTI ratio is no more than 43 percent, determined in accordance with appendix Q.[19]

Appendix Q contains standards for calculating and verifying debt and income for purposes of determining whether a mortgage satisfies the 43 percent DTI limit for General QMs. The standards in appendix Q were adapted from guidelines maintained by FHA when the January 2013 Final Rule was issued.[20] Appendix Q addresses how to determine a consumer's employment-related income (*e.g.,* income from wages, commissions, and retirement plans); non-employment related income (*e.g.,* income from alimony and child support payments, investments, and property rentals); and liabilities, including recurring and contingent liabilities and projected obligations.[21]

2. Temporary GSE QMs

A second, temporary category of QMs defined by the ATR/QM Rule, Temporary GSE QMs, consists of mortgages that (1) comply with the ATR/QM Rule's prohibitions on certain loan features and its limitations on points and fees[22] and (2) are eligible to be purchased or guaranteed by either GSE while under the conservatorship of the FHFA.[23] Unlike for General QMs, Regulation Z does not prescribe a DTI limit for Temporary GSE QMs. Thus, a loan can qualify as a Temporary GSE QM even if the DTI ratio exceeds 43 percent, as long as the DTI ratio meets the applicable GSE's DTI requirements and other underwriting criteria, and the loan satisfies the other Temporary GSE QM requirements. In addition, income, debt, and DTI ratios for such loans generally are verified and calculated using GSE standards, rather than appendix Q. The January 2013 Final Rule provided that the Temporary GSE QM loan definition—also known as the GSE Patch—would expire with respect to each GSE when that GSE ceases to operate under conservatorship or on January 10, 2021, whichever comes first.[24]

In the January 2013 Final Rule, the Bureau explained why it created the Temporary GSE QM loan definition. The Bureau observed that it did not believe that a 43 percent DTI ratio ''represents the outer boundary of responsible lending'' and acknowledged that historically, and even after the financial crisis, over 20 percent of mortgages exceeded that threshold.[25] However, the Bureau stated that, as DTI ratios increase, the general ATR procedures, rather than the QM framework, are ''better suited for consideration of all relevant factors that go to a consumer's ability to repay a mortgage loan'' and that ''[o]ver the long term . . . there will be a robust and sizable market for prudent loans beyond the 43 percent threshold even without the benefit of the presumption of compliance that applies to qualified mortgages.''[26]

At the same time, the Bureau noted that the mortgage market was especially fragile following the financial crisis, and GSE-eligible loans and federally insured or guaranteed loans made up a significant majority of the market.[27] The Bureau believed that it was appropriate to consider for a period of time, and while the GSEs were under Federal conservatorship, that GSE-eligible loans

[11] 15 U.S.C. 1639c(b)(2)(A).

[12] 78 FR 6408 (Jan. 30, 2013).

[13] *See* 78 FR 35429 (June 12, 2013); 78 FR 44686 (July 24, 2013); 78 FR 60382 (Oct. 1, 2013); 79 FR 65300 (Nov. 3, 2014); 80 FR 59944 (Oct. 2, 2015); 81 FR 16074 (Mar. 25, 2016); 85 FR 67938 (Oct. 26, 2020).

[14] 12 CFR 1026.43(c), (e).

[15] The QM definition is related to the definition of Qualified Residential Mortgage (QRM). Section 15G of the Securities Exchange Act of 1934, added by section 941(b) of the Dodd-Frank Act, generally requires the securitizer of asset-backed securities (ABS) to retain not less than 5 percent of the credit risk of the assets collateralizing the ABS. 15 U.S.C. 78o–11. Six Federal agencies (not including the Bureau) are tasked with implementing this requirement. Those agencies are the Board of Governors of the Federal Reserve System (Board), the Office of the Comptroller of the Currency (OCC), the Federal Deposit Insurance Corporation (FDIC), the Securities and Exchange Commission, the FHFA, and the U.S. Department of Housing and Urban Development (HUD) (collectively, the QRM agencies). Section 15G of the Securities Exchange Act of 1934 provides that the credit risk retention requirements shall not apply to an issuance of ABS if all of the assets that collateralize the ABS are QRMs. *See* 15 U.S.C. 78o–11(c)(1)(C)(iii), (4)(A) and (B). Section 15G requires the QRM agencies to jointly define what constitutes a QRM, taking into consideration underwriting and product features that historical loan performance data indicate result in a lower risk of default. *See* 15 U.S.C. 78o–11(e)(4). Section 15G also provides that the definition of a QRM shall be ''no broader than'' the definition of a ''qualified mortgage,'' as the term is defined under TILA section 129C(b)(2), as amended by the Dodd-Frank Act, and regulations adopted thereunder. 15 U.S.C. 78o–11(e)(4)(C). In 2014, the QRM agencies issued a final rule adopting the risk retention requirements. 79 FR 77601 (Dec. 24, 2014). That final rule aligns the QRM definition with the QM definition defined by the Bureau in the ATR/QM Rule, effectively exempting securities comprised of loans that meet the QM definition from the risk retention requirement. That final rule also requires the agencies to review the definition of QRM no later than four years after the effective date of the final risk retention rules. In 2019, the QRM agencies initiated a review of certain provisions of the risk retention rule, including the QRM definition. 84 FR 70073 (Dec. 20, 2019). Among other things, the review allows the QRM agencies to consider the QRM definition in light of any changes to the QM definition adopted by the Bureau.

[16] 12 CFR 1026.43(e)(2)(i) through (iii).

[17] 12 CFR 1026.43(e)(2)(iv).

[18] 12 CFR 1026.43(e)(2)(v).

[19] 12 CFR 1026.43(e)(2)(vi).

[20] 78 FR 6408, 6527–28 (Jan. 30, 2013) (noting that appendix Q incorporates, with certain modifications, the definitions and standards in HUD Handbook 4155.1, Mortgage Credit Analysis for Mortgage Insurance on One-to-Four-Unit Mortgage Loans).

[21] 12 CFR 1026, appendix Q.

[22] 12 CFR 1026.43(e)(2)(i) through (iii).

[23] 12 CFR 1026.43(e)(4).

[24] 12 CFR 1026.43(e)(4)(iii)(B). The ATR/QM Rule created several additional categories of QMs. The first additional category consisted of mortgages eligible to be insured or guaranteed (as applicable) by HUD (FHA loans), the U.S. Department of Veterans Affairs (VA loans), the U.S. Department of Agriculture (USDA loans), and the Rural Housing Service (RHS loans). 12 CFR 1026.43(e)(4)(ii)(B) through (E). This temporary category of QMs no longer exists because the relevant Federal agencies have since issued their own QM rules. *See, e.g.,* 24 CFR 203.19 (HUD rule). Other categories of QMs provide more flexible standards for certain loans originated by certain small creditors. 12 CFR 1026.43(e)(5), (f); *cf.* 12 CFR 1026.43(e)(6) (applicable only to covered transactions for which the application was received before Apr. 1, 2016).

[25] 78 FR 6408, 6527 (Jan. 30, 2013).

[26] *Id.* at 6527–28.

[27] *Id.* at 6533–34.

were originated with an appropriate assessment of the consumer's ability to repay and therefore warranted being treated as QMs.[28] The Bureau believed in 2013 that this temporary category of QMs would, in the near term, help to ensure access to responsible, affordable credit for consumers with DTI ratios above 43 percent, as well as facilitate compliance by creditors by promoting the use of widely recognized, federally related underwriting standards.[29]

In making the Temporary GSE QM loan definition temporary, the Bureau sought to ''provide an adequate period for economic, market, and regulatory conditions to stabilize'' and ''a reasonable transition period to the general qualified mortgage definition.'' [30] The Bureau believed that the Temporary GSE QM loan definition would benefit consumers by preserving access to credit while the mortgage industry adjusted to the ATR/QM Rule.[31] The Bureau also explained that it structured the Temporary GSE QM loan definition to cover loans eligible to be purchased or guaranteed by either of the GSEs—regardless of whether the loans are actually purchased or guaranteed—to leave room for non-GSE private investors to return to the market and secure the same legal protections as the GSEs.[32] The Bureau believed that, as the market recovered, the GSEs and the Federal agencies would be able to reduce their market presence, the percentage of Temporary GSE QMs would decrease, and the market would shift toward General QMs and non-QM loans above a 43 percent DTI ratio.[33] The Bureau's view was that a shift towards non-QM loans could be supported by the non-GSE private market—*i.e.,* by institutions holding such loans in portfolio, selling them in whole, or securitizing them in a rejuvenated private-label securities (PLS) market. The Bureau noted that, pursuant to its statutory obligations under the Dodd-Frank Act, it would assess the impact of the ATR/QM Rule five years after the ATR/QM Rule's effective date, and the assessment would provide an opportunity to analyze the Temporary GSE QM loan definition.[34]

3. Presumption of Compliance for QMs

In the January 2013 Final Rule, the Bureau considered whether QMs should receive a conclusive presumption (*i.e.,* a safe harbor) or a rebuttable presumption of compliance with the ATR requirements. The Bureau concluded that the statute is ambiguous as to whether a creditor originating a QM receives a safe harbor or a rebuttable presumption that it has complied with the ATR requirements.[35] The Bureau noted that its analysis of the statutory construction and policy implications demonstrated that there are sound reasons for adopting either interpretation.[36] The Bureau concluded that the statutory language does not mandate either interpretation and that the presumptions should be tailored to promote the policy goals of the statute.[37] The Bureau ultimately interpreted the statute to provide for a rebuttable presumption of compliance with the ATR requirements but used its adjustment authority to establish a conclusive presumption of compliance for loans that are not ''higher-priced.'' [38]

Under the ATR/QM Rule, a creditor that makes a QM is protected from liability presumptively or conclusively, depending on whether the loan is ''higher-priced.'' The ATR/QM Rule generally defines a ''higher-priced'' loan to mean a first-lien mortgage with an APR that exceeded APOR for a comparable transaction as of the date the interest rate was set by 1.5 or more percentage points; or a subordinate-lien mortgage with an APR that exceeded APOR for a comparable transaction as of the date the interest rate was set by 3.5 or more percentage points.[39] A creditor that makes a QM that is not ''higher-priced'' is entitled to a conclusive presumption that it has complied with the ATR/QM Rule—*i.e.,* the creditor receives a safe harbor from liability.[40] A creditor that makes a loan that meets the standards for a QM but is ''higher-priced'' is entitled to a rebuttable presumption that it has complied with the ATR/QM Rule.[41]

The Bureau explained in the January 2013 Final Rule why it was adopting different presumptions of compliance based on the pricing of QMs.[42] The Bureau noted that the line it was drawing is one that has long been recognized as a rule of thumb to separate prime loans from subprime loans.[43] The Bureau noted that loan pricing is calibrated to the risk of the loan and that the historical performance of prime and subprime loans indicates greater risk for subprime loans.[44] The Bureau also noted that consumers taking out subprime loans tend to be less sophisticated and have fewer options and that the most abuses prior to the financial crisis occurred in the subprime market.[45] The Bureau concluded that these factors warrant imposing heightened standards for higher-priced loans.[46] For prime loans, however, the Bureau found that lower rates are indicative of ability to repay and noted that prime loans have performed significantly better than subprime loans.[47] The Bureau concluded that if a loan met the product and underwriting requirements for QMs and was not a higher-priced loan, there are sufficient grounds for concluding that the creditor satisfied the ATR requirements.[48] The Bureau noted that the conclusive presumption may reduce uncertainty and litigation risk and may promote enhanced competition in the prime market.[49] The Bureau also noted that the litigation risk for rebuttable presumption QMs likely would be quite modest and would have a limited impact on access to credit.[50]

The Bureau also noted in the January 2013 Final Rule that policymakers have long relied on pricing to determine which loans should be subject to additional regulatory requirements.[51] That history of reliance on pricing continues to provide support for a price-based approach to the General QM loan definition. For example, in 1994 Congress amended TILA by enacting the Home Ownership and Equity Protection Act (HOEPA) as part of the Riegle Community Development and Regulatory Improvement Act of 1994.[52] HOEPA was enacted as an amendment to TILA to address abusive practices in refinancing and home-equity mortgage loans with high interest rates or high fees.[53] The statute applied generally to closed-end mortgage credit but excluded

[28] *Id.* at 6534.
[29] *Id.* at 6533.
[30] *Id.* at 6534.
[31] *Id.* at 6536.
[32] *Id.* at 6534.
[33] *Id.*
[34] *Id.*
[35] *Id.* at 6511.
[36] *Id.* at 6507.
[37] *Id.* at 6511.
[38] *Id.* at 6514.
[39] 12 CFR 1026.43(b)(4).
[40] 12 CFR 1026.43(e)(1)(i).
[41] 12 CFR 1026.43(e)(1)(ii).
[42] 78 FR 6408 at 6506, 6510–14 (Jan. 30, 2013).
[43] *Id.* at 6408.
[44] *Id.* at 6511.
[45] *Id.*
[46] *Id.*
[47] *Id.*
[48] *Id.*
[49] *Id.*
[50] *Id.* at 6511–12.
[51] *Id.* at 6413–14, 6510–11.
[52] Riegle Community Development and Regulatory Improvement Act of 1994, Public Law 103–325, 108 Stat. 2160 (1994).
[53] As originally enacted, HOEPA defined a class of ''high-cost mortgages,'' which were generally closed-end home-equity loans (excluding home-purchase loans) with APRs or total points and fees exceeding prescribed thresholds. Mortgages covered by HOEPA have been referred to as ''HOEPA loans,'' ''Section 32 loans,'' or ''high-cost mortgages.''

purchase money mortgage loans and reverse mortgages. Coverage was triggered if a loan's APR exceeded comparable Treasury securities by specified thresholds for particular loan types, or if points and fees exceeded 8 percent of the total loan amount or a dollar threshold.[54] For high-cost loans meeting either of those thresholds, HOEPA required creditors to provide special pre-closing disclosures, restricted prepayment penalties and certain other loan terms, and regulated various creditor practices, such as extending credit without regard to a consumer's ability to repay the loan. HOEPA also created special substantive protections for high-cost mortgages, such as prohibiting a creditor from engaging in a pattern or practice of extending a high-cost mortgage to a consumer based on the consumer's collateral without regard to the consumer's repayment ability, including the consumer's current and expected income, current obligations, and employment.[55] The Board implemented the HOEPA amendments at §§ 226.31, 226.32, and 226.33 [56] of Regulation Z (12 CFR part 226).[57]

In 2001, the Board issued rules expanding HOEPA's protections to more loans by revising the APR threshold for first-lien mortgage loans and revising the ATR provisions to provide for a presumption of a violation of the rule if the creditor engages in a pattern or practice of making high-cost mortgages without verifying and documenting the consumer's repayment ability.

In 2008, the Board exercised its authority under HOEPA to extend certain protections concerning a consumer's ability to repay and prepayment penalties to a new category of ''higher-priced mortgage loans'' (HPMLs) [58] with APRs that are lower than those prescribed for high-cost loans but that nevertheless exceed the APOR by prescribed amounts. This new category of loans was designed to include subprime credit, including subprime purchase money mortgage loans. Specifically, the Board exercised its authority to revise HOEPA's restrictions on high-cost loans based on its conclusion that the revisions were necessary to prevent unfair and deceptive acts or practices in connection with mortgage loans.[59] The Board concluded that a prohibition on making individual loans without regard to repayment ability was necessary to ensure a remedy for consumers who are given unaffordable loans and to deter irresponsible lending. The 2008 HOEPA Final Rule provided a presumption of compliance with the higher-priced mortgage ability-to-repay requirements if the creditor follows certain procedures regarding underwriting the loan payment, assessing the DTI ratio or residual income, and limiting the features of the loan, in addition to following certain procedures mandated for all creditors.[60] However, the 2008 HOEPA Final Rule made clear that even if the creditor follows the required and optional criteria, the creditor obtained a presumption (not a safe harbor) of compliance with the repayment ability requirement. The consumer therefore could still rebut or overcome that presumption by showing that, despite following the required and optional procedures, the creditor nonetheless disregarded the consumer's ability to repay the loan.

C. The Bureau's Assessment of the ATR/QM Rule

Section 1022(d) of the Dodd-Frank Act requires the Bureau to assess each of its significant rules and orders and to publish a report of each assessment within five years of the effective date of the rule or order.[61] In June 2017, the Bureau published a request for information in connection with its assessment of the ATR/QM Rule (Assessment RFI).[62] These comments are summarized in general terms in part III below.

In January 2019, the Bureau published its ATR/QM Rule Assessment Report.[63] The Assessment Report included findings about the effects of the ATR/QM Rule on the mortgage market generally, as well as specific findings about Temporary GSE QM originations.

The Assessment Report found that loans with higher DTI ratios have been associated with higher levels of ''early delinquency'' (*i.e.,* delinquency within two years of origination), which the Bureau used as a proxy for measuring consumer repayment ability at consummation across a wide pool of loans.[64] The Assessment Report also found that the ATR/QM Rule did not eliminate access to credit for consumers with DTI ratios above 43 percent who qualify for Temporary GSE QMs.[65] On the other hand, based on application-level data obtained from nine large lenders, the Assessment Report found that the ATR/QM Rule eliminated between 63 and 70 percent of home purchase loans with DTI ratios above 43 percent that were not Temporary GSE QMs.[66]

One main finding about Temporary GSE QMs was that such loans continued to represent a ''large and persistent'' share of originations in the conforming segment of the mortgage market.[67] As discussed, the GSEs' share of the conventional, conforming purchase-mortgage market was large before the ATR/QM Rule, and the Assessment found a small increase in that share since the ATR/QM Rule's effective date, reaching 71 percent in 2017.[68] The Assessment Report noted that, at least for loans intended for sale in the secondary market, creditors generally offer a Temporary GSE QM even if a General QM could be originated.[69]

The continued prevalence of Temporary GSE QM originations is contrary to the Bureau's expectation at the time it issued the ATR/QM Rule in 2013.[70] The Assessment Report discussed several possible reasons for the continued prevalence of Temporary GSE QM originations. The Assessment Report first highlighted commenters' concerns with the perceived lack of clarity in appendix Q and found that such concerns ''may have contributed to investors'—and at least derivatively, creditors'—preference'' for Temporary GSE QMs instead of originating loans

[54] The Dodd-Frank Act adjusted the baseline for the APR comparison, lowered the points-and-fees threshold, and added a prepayment trigger.

[55] TILA section 129(h); 15 U.S.C. 1639(h). In addition to the disclosures and limitations specified in the statute, HOEPA expanded the Board's rulemaking authority, among other things, to prohibit acts or practices the Board found to be unfair and deceptive in connection with mortgage loans.

[56] Subsequently renumbered as sections 1026.31, 1026.32, and 1026.33 of Regulation Z.

[57] *See* 60 FR 15463 (Mar. 24, 1995).

[58] Under the Board's 2008 HOEPA Final Rule, an HPML is a consumer credit transaction secured by the consumer's principal dwelling with an APR that exceeds APOR for a comparable transaction, as of the date the interest rate is set, by 1.5 or more percentage points for loans secured by a first lien on the dwelling, or by 3.5 or more percentage points for loans secured by a subordinate lien on the dwelling. 73 FR 44522 (July 30, 2008) (2008 HOEPA Final Rule). The definition of an HPML includes practically all ''high-cost mortgages'' because the latter transactions are determined by higher loan pricing threshold tests. *See* 12 CFR 226.35(a)(1).

[59] 73 FR 44522 (July 30, 2008).

[60] *See* 12 CFR 1026.34(a)(4)(iii), (iv).

[61] 12 U.S.C. 5512(d).

[62] 82 FR 25246 (June 1, 2017).

[63] *See generally* Bureau of Consumer Fin. Prot., *Ability to Repay and Qualified Mortgage Assessment Report* (Jan. 2019), *https://files.consumerfinance.gov/f/documents/cfpb_ability-to-repay-qualified-mortgage_assessment-report.pdf* (Assessment Report).

[64] *See, e.g., id.* at 83–84, 100–05.

[65] *See, e.g., id.* at 10, 194–96.

[66] *See, e.g., id.* at 10–11, 117, 131–47.

[67] *Id.* at 188. Because the Temporary GSE QM loan definition generally affects only loans that conform to the GSEs' guidelines, the Assessment Report's discussion of the Temporary GSE QM loan definition focused on the conforming segment of the market, not on non-conforming (*e.g.,* jumbo) loans.

[68] *Id.* at 191.

[69] *Id.* at 192.

[70] *Id.* at 13, 190, 238.

under the General QM loan definition.[71] In addition, the Bureau has not revised appendix Q since 2013, while other standards for calculating and verifying debt and income have been updated more frequently.[72]

The Assessment Report noted that a second possible reason for the continued prevalence of Temporary GSE QMs is that the GSEs were able to accommodate the demand for mortgages above the General QM loan definition's DTI limit of 43 percent as the DTI ratio distribution in the market shifted upward.[73] According to the Assessment Report, in the years since the ATR/QM Rule took effect, house prices have increased and consumers hold more mortgage and other debt (including student loan debt), all of which have caused the DTI ratio distribution to shift upward.[74] The Assessment Report noted that the share of GSE home purchase loans with DTI ratios above 43 percent has increased since the ATR/QM Rule took effect in 2014.[75] The available data suggest that the share of loans with DTI ratios above 43 percent has declined in the non-GSE market relative to the GSE market.[76] The non-GSE market has constricted even with respect to highly qualified consumers; those with higher incomes and higher credit scores represent a greater share of denials.[77]

The Assessment Report found that a third possible reason for the persistence of Temporary GSE QMs is the structure of the secondary market.[78] If creditors adhere to the GSEs' guidelines, they gain access to a robust, highly liquid secondary market.[79] In contrast, the Assessment Report noted that while private market securitizations had grown somewhat in recent years, their volume was still a fraction of their pre-crisis levels.[80] There were less than $20 billion in new origination PLS issuances in 2017, compared with $1 trillion in 2005,[81] and only 21 percent of new origination PLS issuances in 2017 were non-QM issuances.[82] To the extent that private securitizations have occurred since the ATR/QM Rule took effect in 2014, the majority of new origination PLS issuances have consisted of prime jumbo loans made to consumers with strong credit characteristics, and these securities include a small share of non-QM loans.[83] The Assessment Report noted that the Temporary GSE QM loan definition may itself be inhibiting the growth of the non-QM market.[84] However, the Assessment Report also noted that it is possible that this market might not exist even with a narrower Temporary GSE QM loan definition, if consumers were unwilling to pay the premium charged to cover the potential litigation risk associated with non-QM loan (which do not have a presumption of compliance with the ATR requirements) or if creditors were unwilling or lack the funding to make the loans.[85]

D. Effects of the COVID–19 Pandemic on Mortgage Markets

The COVID–19 pandemic has had a significant effect on the U.S. economy. In the early months of the pandemic, economic activity contracted, millions of workers became unemployed, and mortgage markets were affected. In recent months, the unemployment rate has declined and there has been a significant rebound in mortgage-origination activity, buoyed by historically low interest rates and by an increasingly large share of government and GSE-backed loans. However, origination activity outside the government and GSE-backed origination channels has declined, and mortgage-credit availability for many consumers—including those who would be dependent on the non-QM market for financing—remains tight. The pandemic's impact on both the secondary market for new originations and on the servicing of existing mortgages is described below.

1. Secondary Market Impacts and Implications for Mortgage Origination Markets

The early economic disruptions associated with the COVID–19 pandemic restricted the flow of credit in the U.S. economy, particularly as uncertainty rose in mid-March 2020, and investors moved rapidly towards cash and government securities.[86] The lack of investor demand to purchase mortgages, combined with a large supply of agency mortgage-backed securities (MBS) entering the market,[87] resulted in widening spreads between the rates on a 10-year Treasury note and mortgage interest rates.[88] This dynamic made it difficult for creditors to originate loans, as many creditors rely on the ability to profitably sell loans in the secondary market to generate the liquidity to originate new loans. This resulted in mortgages becoming more expensive for both homebuyers and homeowners looking to refinance. After the actions taken by the Board in March 2020 to purchase agency MBS ''in the amounts needed to support smooth market functioning and effective transmission of monetary policy to broader financial conditions and the economy,'' [89] market conditions have improved substantially.[90] This has helped to tighten interest rate spreads, which stabilizes mortgage rates, resulting in a decline in mortgage rates since the Board's intervention and in a significant increase in refinance activity.

However, non-agency MBS [91] are generally perceived by investors as riskier than agency MBS. As a result, private capital has remained tight and non-agency mortgage credit, including non-QM lending, has declined. Issuance of non-agency MBS declined by 8.2 percent in the first quarter of 2020, with nearly all the transactions completed in January and February before the COVID–19 pandemic began to affect the economy significantly.[92] Nearly all major non-QM creditors ceased making loans in March and April 2020. Beginning in May 2020, issuers of non-agency MBS began to test the market with deals collateralized by non-QM loans largely originated prior to the pandemic, and investor demand for these securitizations has begun to recover. However, no securitization has been completed that is predominantly collateralized by non-QM loans

[71] *Id.* at 193.
[72] *Id.* at 193–94.
[73] *Id.* at 194.
[74] *Id.*
[75] *Id.* at 194–95.
[76] *Id.* at 119–20.
[77] *Id.* at 153.
[78] *Id.* at 196.
[79] *Id.*
[80] *Id.*
[81] *Id.*
[82] *Id.* at 197.
[83] *Id.* at 196.
[84] *Id.* at 205.
[85] *Id.*
[86] *The Quarterly CARES Act Report to Congress: Hearing Before the S. Comm. on Banking, Housing, and Urban Affairs,* 116th Cong. 2–3 (2020) (statement of Jerome H. Powell, Chairman, Board of Governors of the Federal Reserve System).
[87] Agency MBS are backed by loans guaranteed by Fannie Mae, Freddie Mac, and the Government National Mortgage Association (Ginnie Mae).
[88] Laurie Goodman *et al.,* Urban Inst., *Housing Finance at a Glance, Monthly Chartbook* (Mar. 26, 2020), *https://www.urban.org/sites/default/files/publication/101926/housing-finance-at-a-glance-a-monthly-chartbook-march-2020.pdf.*
[89] Press Release, Bd. of Governors of the Fed. Reserve Sys., *Federal Reserve announces extensive new measures to support the economy* (Mar. 23, 2020), *https://www.federalreserve.gov/newsevents/pressreleases/monetary20200323b.htm.*
[90] *The Quarterly CARES Act Report to Congress: Hearing Before the S. Comm. on Banking, Housing, and Urban Affairs,* 116th Cong. 3 (2020) (statement of Jerome H. Powell, Chairman, Board of Governors of the Federal Reserve System).
[91] Non-agency MBS are not backed by loans guaranteed by Fannie Mae, Freddie Mac or Ginnie Mae. This includes securities collateralized by non-QM loans.
[92] Brandon Ivey, *Non-Agency MBS Issuance Slowed in First Quarter,* Inside Mortg. Fin. (Apr. 3, 2020), *https://www.insidemortgagefinance.com/articles/217623-non-agency-mbs-issuance-slowed-in-first-quarter.*

originated since the pandemic began.[93] Many non-QM creditors—which largely depend on the ability to sell loans in the secondary market in order to fund new loans—have begun to resume originations, albeit with tighter underwriting requirements.[94] Prime jumbo financing also dropped nearly 22 percent in the first quarter of 2020.[95] Banks increased interest rates and narrowed the product offerings such that only consumers with pristine credit profiles were eligible, as these loans must be held in portfolio when the secondary market for non-agency MBS contracts, and volume remains flat.[96]

Despite the recent gains in both the agency and the non-agency mortgage sectors, the GSEs continue to play a dominant role in the market recovery, with the GSE share of first-lien mortgage originations at 61.9 percent in the third quarter of 2020, up from 45.3 percent in the third quarter of 2019. The FHA and VA share declined slightly to 17.4 percent from 19.5 percent a year prior, according to an analysis by the Urban Institute. Portfolio lending declined to 19.6 percent in the third quarter of 2020, down from 33.3 percent in the third quarter of 2019, and private label securitizations declined to 1 percent from 1.8 percent a year prior.[97]

2. Servicing Market Impacts and Implications for Origination Markets

In addition to the direct impact on origination volume and composition, the pandemic's impact on the mortgage servicing market has downstream effects on mortgage originations as many of the same entities both originate and service mortgages. Anticipating that a number of homeowners would struggle to pay their mortgages due to the pandemic and related economic impacts, Congress passed and the President signed into law the Coronavirus Aid, Relief, and Economic Security Act (CARES Act)[98] in March 2020. The CARES Act provides additional protections for borrowers with federally backed mortgages, such as those whose mortgages are purchased or securitized by a GSE or insured or guaranteed by the FHA, VA or USDA. The CARES Act mandated a 60-day foreclosure moratorium for such mortgages, which has since been extended by the agencies until the end of 2020 or January 31, 2021 in the case of the GSEs.[99] The CARES Act also allows borrowers with federally backed mortgages to request up to 180 days of forbearance due to a COVID–19-related financial hardship, with an option to extend the forbearance period for an additional 180 days.

Following the passage of the CARES Act, some mortgage servicers remain obligated to make some principal and interest payments to investors in GSE and Ginnie Mae securities, even if consumers are not making payments.[100] Servicers also remain obligated to make escrowed real estate tax and insurance payments to local taxing authorities and insurance companies. While servicers are required to hold liquid reserves to cover anticipated advances, early in the pandemic there were significant concerns that higher-than-expected forbearance rates over an extended period of time could lead to liquidity shortages, particularly among many non-bank servicers. However, while forbearance rates remain elevated at 5.54 percent for the week ending November 22, 2020, they have decreased since reaching their high of 8.55 percent on June 7, 2020.[101]

Because many mortgage servicers also originate the loans they service, many creditors, as well as several warehouse providers,[102] initially responded to the risk of elevated forbearances and higher-than-expected monthly advances by imposing credit overlays—*i.e.,* additional underwriting standards—for new originations. These new underwriting standards include more stringent requirements for non-QM, jumbo, and government loans.[103] An ''adverse market fee'' of 50 basis points on most refinances became effective for new originations delivered to the GSEs on or after December 1, 2020, to cover projected losses due to forbearances, the foreclosure moratoriums, and other default servicing expenses.[104] However, due to refinance origination profits resulting from historically low interest rates, the leveling off in forbearance rates, and actions taken at the Federal level to alleviate servicer liquidity pressure,[105] concerns over non-bank liquidity and related credit overlays have begun to ease, though Federal

[93] Brandon Ivey, *Non-Agency MBS Issuance Slow in Mid-August,* Inside Mortg. Fin. (Aug. 21, 2020), *https://www.insidemortgagefinance.com/articles/218973-non-agency-mbs-issuance-slow-in-mid-august.*

[94] Brandon Ivey, *Expanded-Credit Lending Inches Up in Third Quarter,* Inside Mortg. Fin. (Nov. 25, 2020), *https://www.insidemortgagefinance.com/articles/219861-expanded-credit-lending-ticks-up-in-3q-amid-slow-recovery.*

[95] Brandon Ivey, *Jumbo Originations Drop Nearly 22% in First Quarter,* Inside Mortg. Fin. (May 15, 2020) *https://www.insidemortgagefinance.com/articles/218028-jumbo-originations-drop-nearly-22-in-first-quarter.*

[96] Brandon Ivey, *Jumbo Lending Flat in 3Q, Wide Variation Among Lenders,* Inside Mortg. Fin. (Nov. 13, 2020) *https://www.insidemortgagefinance.com/articles/219738-jumbo-lending-level-in-3q-wide-variation-among-lenders.*

[97] Laurie Goodman *et al.,* Urban Inst., *Housing Finance at a Glance, Monthly Chartbook,* Inside Mortg. Fin. (Nov. 24, 2020), *https://www.urban.org/sites/default/files/publication/103273/housing-finance-at-a-glance-a-monthly-chartbook-november-2020_0.pdf.*

[98] Public Law 116–136, 134 Stat. 281 (2020) (includes loans backed by HUD, USDA, VA, Fannie Mae, and Freddie Mac).

[99] *See, e.g.,* Fed. Hous. Fin. Agency, *FHFA Extends Foreclosure and REO Eviction Moratoriums* (Dec. 2, 2020), *https://www.fhfa.gov/Media/PublicAffairs/Pages/FHFA-Extends-Foreclosure-and-REO-Eviction-Moratoriums-12022020.aspx;* Press Release, U.S. Dep't of Hous. & Urban Dev., *FHA Extends Foreclosure And Eviction Moratorium For Homeowners Through Year End* (Aug. 27, 2020), *https://www.hud.gov/press/press_releases_media_advisories/HUD_No_20_134;* Veterans Benefits Admin., *Extended Foreclosure Moratorium for Borrowers Affected by COVID–19* (Aug. 24, 2020), *https://www.benefits.va.gov/HOMELOANS/documents/circulars/26-20-30.pdf;* Rural Dev., U.S. Dep't of Agric., *Extension of Foreclosure and Eviction Moratorium for Single Family Housing Direct Loans* (Aug. 28, 2020), *https://content.govdelivery.com/accounts/USDARD/bulletins/29c3a9e.*

[100] The GSEs typically repurchase loans out of the trust after they fall 120 days delinquent, after which the servicer is no longer required to advance principal and interest, but Ginnie Mae requires servicers to advance principal and interest until the default is resolved. On April 21, 2020, the FHFA confirmed that servicers of GSE loans will only be required to advance four months of mortgage payments, regardless of whether the GSEs repurchase the loans from the trust after 120 days of delinquency. Fed. Hous. Fin. Agency, *FHFA Addresses Servicer Liquidity Concerns, Announces Four Month Advance Obligation Limit for Loans in Forbearance* (Apr. 21, 2020), *https://www.fhfa.gov/Media/PublicAffairs/Pages/FHFA-Addresses-Servicer-Liquidity-Concerns-Announces-Four-Month-Advance-Obligation-Limit-for-Loans-in-Forbearance.aspx.*

[101] Press Release, Mortg. Bankers Ass'n, *Share of Mortgage Loans in Forbearance Increases to 5.54%* (Dec. 1, 2020), *https://www.mba.org/2020-press-releases/december/share-of-mortgage-loans-in-forbearance-increases-to-554-percent.*

[102] Warehouse providers are creditors that provide financing to mortgage originators and servicers to fund and service loans.

[103] Maria Volkova, *FHA/VA Lenders Raise Credit Score Requirements,* Inside Mortg. Fin. (Apr. 3, 2020), *https://www.insidemortgagefinance.com/articles/217636-fhava-lenders-raise-fico-credit-score-requirements.*

[104] Press Release, Fed. Hous. Fin. Agency, *Adverse Market Refinance Fee Implementation now December 1* (Aug. 25, 2020), *https://www.fhfa.gov/Media/PublicAffairs/Pages/Adverse-Market-Refinance-Fee-Implementation-Now-December-1.aspx.*

[105] On April 10, 2020, Ginnie Mae released guidance on a Pass-Through Assistance Program whereby Ginnie Mae will provide financial assistance at a fixed interest rate to servicers facing a principal and interest shortfall as a last resort. Ginnie Mae, *All Participant Memorandum (APM) 20–03: Availability of Pass-Through Assistance Program for Participants in Ginnie Mae's Single-Family MBS Program* (Apr. 10, 2020), *https://www.ginniemae.gov/issuers/program_guidelines/Pages/mbsguideapms libdisppage.aspx?ParamID=105.* On April 7, 2020, Ginnie Mae also announced approval of a servicing advance financing facility, whereby mortgage servicing rights are securitized and sold to private investors. Press Release, *Ginnie Mae, Ginnie Mae approves private market servicer liquidity facility* (Apr. 7, 2020), *https://www.ginniemae.gov/newsroom/Pages/PressReleaseDispPage.aspx?ParamID=194.*

regulators continue to monitor the situation.[106] While the non-QM market has begun to recover, it is unclear how quickly non-banks that originate non-QM loans will fully return to their pre-pandemic level of operations and loan production.

III. Summary of the Rulemaking Process

The Bureau has solicited and received substantial public and stakeholder input on issues related to this final rule. In addition to the Bureau's discussions with and communications from industry stakeholders, consumer advocates, other Federal agencies,[107] and members of Congress, the Bureau issued requests for information (RFIs) in 2017 and 2018 and in July 2019 issued an advance notice of proposed rulemaking regarding the ATR/QM Rule (ANPR). The Bureau released the Extension Proposal and the General QM Proposal on June 22, 2020, and the Seasoned QM Proposal on August 18, 2020. The Bureau issued the Extension Final Rule on October 20, 2020.

A. The Requests for Information

In June 2017, the Bureau published the Assessment RFI to gather information for its assessment of the ATR/QM Rule.[108] In response to the Assessment RFI, the Bureau received approximately 480 comments from creditors, industry groups, consumer advocates, and individuals.[109] The comments addressed a variety of topics, including the General QM loan definition and the 43 percent DTI limit; perceived problems with, and potential changes and alternatives to, appendix Q; and how the Bureau should address the expiration of the Temporary GSE QM loan definition. The comments expressed a range of ideas for addressing the expiration of the Temporary GSE QM loan definition. Some commenters recommended making the definition permanent or extending it for various periods of time. Other comments stated that the Temporary GSE QM loan definition should be eliminated or permitted to expire.

Beginning in January 2018, the Bureau issued a general call for evidence seeking comment on its enforcement, supervision, rulemaking, market monitoring, and financial education activities.[110] As part of the call for evidence, the Bureau published requests for information relating to, among other things, the Bureau's rulemaking process,[111] the Bureau's adopted regulations and new rulemaking authorities,[112] and the Bureau's inherited regulations and inherited rulemaking authorities.[113] In response to the call for evidence, the Bureau received comments on the ATR/QM Rule from stakeholders, including consumer advocates and industry groups. The comments addressed a variety of topics, including the General QM loan definition, appendix Q, and the Temporary GSE QM loan definition. The comments also raised concerns about, among other things, the risks of allowing the Temporary GSE QM loan definition to expire without any changes to the General QM loan definition or appendix Q. The concerns raised in these comments were similar to those raised in response to the Assessment RFI, discussed above.

B. The ANPR

On July 25, 2019, the Bureau issued the ANPR. The ANPR stated the Bureau's tentative plans to allow the Temporary GSE QM loan definition to expire in January 2021 or after a short extension, if necessary, to facilitate a smooth and orderly transition away from the Temporary GSE QM loan definition. The Bureau also stated that it was considering whether to propose revisions to the General QM loan definition in light of the potential expiration of the Temporary GSE QM loan definition and requested comments on several topics related to the General QM loan definition, including whether and how the Bureau should revise the DTI limit in the General QM loan definition; whether the Bureau should supplement or replace the DTI limit with another method for directly measuring a consumer's personal finances; whether the Bureau should revise appendix Q or replace it with other standards for calculating and verifying a consumer's debt and income; and whether, instead of a DTI limit, the Bureau should adopt standards that do not directly measure a consumer's personal finances.[114] The Bureau requested comment on how much time industry would need to change its practices in response to any changes the Bureau might make to the General QM loan definition.[115] The Bureau received approximately 85 comments on the ANPR from businesses in the mortgage industry (including creditors), consumer advocates, elected officials, individuals, and research centers. The General QM Proposal provided a summary of these comments, and the Bureau considered these comments in developing the proposal.

C. The Extension Proposal, General QM Proposal, and Seasoned QM Proposal

The Bureau issued the Extension Proposal and the General QM Proposal on June 22, 2020, and those proposals were published in the **Federal Register** on July 10, 2020. In the Extension Proposal, the Bureau proposed to replace the January 10, 2021 sunset date of the Temporary GSE QM loan definition with a provision that extends the Temporary GSE QM loan definition until the effective date of final amendments to the General QM loan definition in Regulation Z (*i.e.,* a final rule relating to the General QM Proposal). The Bureau did not propose to amend the conservatorship clause. The comment period for the Extension Proposal ended on August 10, 2020.

In the General QM Proposal, the Bureau proposed, among other things, to remove the General QM loan definition's DTI limit and replace it with a limit based on the loan's pricing. Under the proposal, a loan would have met the General QM loan definition in § 1026.43(e)(2) only if the APR exceeds APOR for a comparable transaction by less than 2 percentage points as of the date the interest rate is set. The Bureau proposed higher thresholds for loans with smaller loan amounts and subordinate-lien transactions. The Bureau also proposed to retain the existing product-feature and underwriting requirements and limits on points and fees. Although the Bureau proposed to remove the 43 percent DTI limit from the General QM loan definition, the General QM Proposal would have required that the creditor consider the consumer's DTI ratio or

[106] Brandon Ivey, *Non-QM Lenders Regaining Footing,* Inside Mortg. Fin. (July 24, 2020), *https://www.insidemortgagefinance.com/articles/218696-non-qm-lenders-regaining-footing-with-a-positive-outlook* (on file).

[107] The Bureau has consulted with agencies including the FHFA, the Board, FHA, the FDIC, the OCC, the Federal Trade Commission, the National Credit Union Administration, HUD, and the Department of the Treasury.

[108] 82 FR 25246 (June 1, 2017).

[109] *See* Assessment Report, *supra* note 63, appendix B (summarizing comments received in response to the Assessment RFI).

[110] *See* Bureau of Consumer Fin. Prot., *Call for Evidence, https://www.consumerfinance.gov/policy-compliance/notice-opportunities-comment/archive-closed/call-for-evidence* (last updated Apr. 17, 2018).

[111] 83 FR 10437 (Mar. 9, 2018).

[112] 83 FR 12286 (Mar. 21, 2018).

[113] 83 FR 12881 (Mar. 26, 2018).

[114] 84 FR 37155, 37160–62 (July 31, 2019).

[115] The Bureau stated that if the amount of time industry would need to change its practices in response to the rule depends on how the Bureau revises the General QM loan definition, the Bureau requested time estimates based on alternative possible definitions.

residual income, income or assets other than the value of the dwelling, and debts and verify the consumer's income or assets other than the value of the dwelling and the consumer's debts. The Bureau proposed to remove appendix Q. To mitigate the uncertainty that may result from appendix Q's removal, the General QM Proposal would have clarified the consider and verify requirements. The Bureau proposed to preserve the current threshold separating safe harbor from rebuttable presumption QMs, under which a loan is a safe harbor QM if its APR does not exceed APOR for a comparable transaction by 1.5 percentage points or more as of the date the interest rate is set (or by 3.5 percentage points or more for subordinate-lien transactions).

Although the Bureau proposed to remove the 43 percent DTI limit and adopt a price-based approach for the General QM loan definition, the Bureau also requested comment on two alternative approaches: (1) Retaining the DTI limit and increasing it to a Specific threshold between 45 percent and 48 percent or (2) using a hybrid approach involving both pricing and a DTI limit, such as applying a DTI limit to loans that are above specified rate spreads. Under these alternative approaches, creditors would not have been required to verify debt and income using appendix Q.

The Bureau stated in the General QM Proposal that the proposed amendments would allow most loans that currently could receive QM status under the Temporary GSE QM loan definition to receive QM status under the General QM loan definition.[116] The Bureau stated that, as a result, the General QM Proposal would help to facilitate a smooth and orderly transition away from the Temporary GSE QM loan definition. The Bureau proposed that the effective date of a final rule relating to the General QM Proposal would be six months after publication of the final rule in the **Federal Register**. The revised regulations would have applied to covered transactions for which creditors receive an application on or after this effective date. The comment period for the General QM Proposal ended on September 8, 2020. The Bureau received approximately 75 comments in response to the General QM Proposal from industry, consumer advocates, and others. The Bureau summarizes and responds to these comments in parts V through VIII below.

On August 18, 2020, the Bureau issued the Seasoned QM Proposal, which was published in the **Federal Register** on August 28, 2020. The Bureau proposed to create a new category of QMs for first-lien, fixed-rate covered transactions that have met certain performance requirements over a 36-month seasoning period, are held in portfolio until the end of the seasoning period, comply with general restrictions on product features and points and fees, and meet certain underwriting requirements.[117] The Bureau stated that the primary objective of the Seasoned QM Proposal was to ensure access to responsible, affordable mortgage credit by adding a Seasoned QM definition to the existing QM definitions. The Bureau proposed that a final rule relating to the Seasoned QM Proposal would take effect on the same date as a final rule relating to the General QM Proposal. Under the Seasoned QM Proposal—as under the General QM Proposal—the revised regulations would apply to covered transactions for which creditors receive an application on or after this effective date. Thus, due to the 36-month seasoning period, no loan would be eligible to become a Seasoned QM until at least 36 months after the effective date of a final rule relating to the Seasoned QM Proposal. The comment period for the Seasoned QM Proposal ended on October 1, 2020.[118] The Bureau is issuing the Seasoned QM Final Rule concurrently with this final rule.

D. The Extension Final Rule

The Bureau issued the Extension Final Rule on October 20, 2020. It was published in the **Federal Register** on October 26, 2020. The Extension Final Rule amended Regulation Z to replace the January 10, 2021 sunset date of the Temporary GSE QM loan definition with a provision stating that the Temporary GSE QM loan definition will be available only for covered transactions for which the creditor receives the consumer's application before the mandatory compliance date of final amendments to the General QM loan definition in Regulation Z. The Extension Final Rule did not amend the conservatorship clause.[119]

IV. Legal Authority

The Bureau is issuing this final rule pursuant to its authority under TILA and the Dodd-Frank Act. Section 1061 of the Dodd-Frank Act transferred to the Bureau the ''consumer financial protection functions'' previously vested in certain other Federal agencies, including the Board. The Dodd-Frank Act defines the term ''consumer financial protection function'' to include ''all authority to prescribe rules or issue orders or guidelines pursuant to any Federal consumer financial law, including performing appropriate functions to promulgate and review such rules, orders, and guidelines.'' [120] Title X of the Dodd-Frank Act (including section 1061), along with TILA and certain subtitles and provisions of title XIV of the Dodd-Frank Act, are Federal consumer financial laws.[121]

A. TILA

TILA section 105(a). Section 105(a) of TILA directs the Bureau to prescribe regulations to carry out the purposes of TILA and states that such regulations may contain such additional requirements, classifications, differentiations, or other provisions and may further provide for such adjustments and exceptions for all or any class of transactions that the Bureau judges are necessary or proper to effectuate the purposes of TILA, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.[122] A purpose of TILA is ''to assure a meaningful disclosure of credit terms so that the consumer will be able to compare more readily the various credit terms available to him and avoid the uninformed use of credit.'' [123] Additionally, a purpose of TILA sections 129B and 129C is to assure that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loans and that are understandable and not unfair, deceptive, or abusive.[124] As discussed in the section-by-section analysis below, the Bureau is issuing certain provisions of this final rule pursuant to its rulemaking, adjustment,

[116] Based on 2018 data, the Bureau estimated in the General QM Proposal that 943,000 High-DTI conventional loans would fall outside the QM definitions if there are no changes to the General QM loan definition prior to the expiration of the Temporary GSE QM loan definition but would fall within the General QM loan definition if amended as the Bureau proposed.

[117] 85 FR 53568 (Aug. 28, 2020).

[118] 85 FR 60096 (Sept. 24, 2020).

[119] The Extension Final Rule also did not affect the QM definitions that apply to FHA, VA, USDA, or RHS loans.

[120] 12 U.S.C. 5581(a)(1)(A).

[121] Dodd-Frank Act section 1002(14), 12 U.S.C. 5481(14) (defining ''Federal consumer financial law'' to include the ''enumerated consumer laws'' and the provisions of title X of the Dodd-Frank Act), Dodd-Frank Act section 1002(12)(O), 12 U.S.C. 5481(12)(O) (defining ''enumerated consumer laws'' to include TILA).

[122] 15 U.S.C. 1604(a).

[123] 15 U.S.C. 1601(a).

[124] 15 U.S.C. 1639b(a)(2).

and exception authority under TILA section 105(a).

TILA section 129C(b)(2)(A). TILA section 129C(b)(2)(A)(vi) provides the Bureau with authority to establish guidelines or regulations relating to ratios of total monthly debt to monthly income or alternative measures of ability to pay regular expenses after payment of total monthly debt, taking into account the income levels of the borrower and such other factors as the Bureau may determine relevant and consistent with the purposes described in TILA section 129C(b)(3)(B)(i).[125] As discussed in the section-by-section analysis below, the Bureau is issuing certain provisions of this final rule pursuant to its authority under TILA section 129C(b)(2)(A)(vi).

TILA section 129C(b)(3)(A), (B)(i). TILA section 129C(b)(3)(B)(i) authorizes the Bureau to prescribe regulations that revise, add to, or subtract from the criteria that define a QM upon a finding that such regulations are necessary or proper to ensure that responsible, affordable mortgage credit remains available to consumers in a manner consistent with the purposes of TILA section 129C; or are necessary and appropriate to effectuate the purposes of TILA sections 129B and 129C, to prevent circumvention or evasion thereof, or to facilitate compliance with such sections.[126] In addition, TILA section 129C(b)(3)(A) directs the Bureau to prescribe regulations to carry out the purposes of section 129C.[127] As discussed in the section-by-section analysis below, the Bureau is issuing certain provisions of this final rule pursuant to its authority under TILA section 129C(b)(3)(B)(i).

B. Dodd-Frank Act

Dodd-Frank Act section 1022(b). Section 1022(b)(1) of the Dodd-Frank Act authorizes the Bureau to prescribe rules to enable the Bureau to administer and carry out the purposes and objectives of the Federal consumer financial laws, and to prevent evasions thereof.[128] TILA and title X of the Dodd-Frank Act are Federal consumer financial laws. Accordingly, the Bureau is exercising its authority under Dodd-Frank Act section 1022(b) to prescribe rules that carry out the purposes and objectives of TILA and title X and prevent evasion of those laws.

[125] 15 U.S.C. 1639c(b)(2)(A).

[126] 15 U.S.C. 1639c(b)(3)(B)(i).

[127] 15 U.S.C. 1639c(b)(3)(A).

[128] 12 U.S.C. 5512(b)(1).

V. Why the Bureau Is Issuing This Final Rule

The Bureau concludes that this final rule's bright-line pricing thresholds strike the best balance between ensuring consumers' ability to repay and ensuring access to responsible, affordable mortgage credit. The Bureau is amending the General QM loan definition because retaining the existing 43 percent DTI limit would reduce the size of the QM market and likely would lead to a significant reduction in access to responsible, affordable credit when the Temporary GSE QM definition expires. The Bureau continues to believe that General QM status should be determined by a simple, bright-line rule to provide certainty of QM status, and the Bureau concludes that pricing achieves this objective. Furthermore, the Bureau concludes that pricing, rather than a DTI limit, is a more appropriate standard for the General QM loan definition. While not a direct measure of financial capacity, loan pricing is strongly correlated with early delinquency rates, which the Bureau uses as a proxy for repayment ability. The Bureau concludes that conditioning QM status on a specific DTI limit would likely impair access to credit for some consumers for whom it is appropriate to presume their ability to repay their loans at consummation. Although a pricing limit that is set too low could also have this effect, compared to DTI, loan pricing is a more flexible metric because it can incorporate other factors that may also be relevant to determining ability to repay, including credit scores, cash reserves, or residual income. The Bureau concludes that a price-based General QM loan definition is better than the alternatives because a loan's price, as measured by comparing a loan's APR to APOR for a comparable transaction, is a strong indicator of a consumer's ability to repay and is a more holistic and flexible measure of a consumer's ability to repay than DTI alone.

A loan's price is not a direct measure of ability to repay, but the Bureau concludes that it is an effective indirect measure of ability to repay. The final rule amends Regulation Z to provide that a loan would meet the General QM loan definition in § 1026.43(e)(2) only if the APR exceeds APOR for a comparable transaction by less than 2.25 percentage points as of the date the interest rate is set. The Bureau is finalizing a threshold of 2.25 percentage points, an increase from the proposed threshold of 2 percentage points. The Bureau concludes that, for most first-lien covered transactions, a 2.25-percentage-point pricing threshold strikes the best balance between ensuring consumers' ability to repay and ensuring continued access to responsible, affordable mortgage credit. The final rule provides higher thresholds for loans with smaller loan amounts and for subordinate-lien transactions. As described below, the final rule provides an increase from the proposed thresholds for some small manufactured housing loans to ensure consumers have continued access to responsible, affordable credit.

Consistent with the proposal, the Bureau is not amending the existing General QM loan product-feature and underwriting requirements and limits on points and fees. Under the final rule, creditors are required to consider the consumer's DTI ratio or residual income, income or assets other than the value of the dwelling, and debts and verify the consumer's income or assets other than the value of the dwelling and the consumer's debts. The final rule removes the 43 percent DTI ratio limit and appendix Q and clarifies the consider and verify requirements for purposes of the General QM loan definition.

The Bureau is preserving the current threshold separating safe harbor from rebuttable presumption QMs, under which a loan is a safe harbor QM if its APR exceeds APOR for a comparable transaction by less than 1.5 percentage points as of the date the interest rate is set (or by less than 3.5 percentage points for subordinate-lien transactions).

A. Overview of the Existing General QM Loan Definition and the DTI Requirement

TILA section 129C(b)(2) defines QM by limiting certain loan terms and features. The statute generally prohibits a QM from permitting an increase of the principal balance on the loan (negative amortization), interest-only payments, most balloon payments, a term greater than 30 years, and points and fees that exceed a specified threshold. In addition, the statute incorporates limited underwriting criteria that overlap with some elements of the general ATR standard, including prohibiting ''no-doc'' loans where the creditor does not verify income or assets. TILA does not require DTI ratios to be included in the definition of a QM. Rather, the statute authorizes, but does not require, the Bureau to establish additional criteria relating to monthly DTI ratios, or alternative measures of ability to pay regular expenses after payment of total monthly debt, taking into account the income levels of the consumer and other factors the Bureau

determines relevant and consistent with the purposes described in TILA section 129C(b)(3)(B)(i).

In 2011, the Board proposed two alternative approaches to the General QM loan definition to implement the statutory QM requirements.[129] Proposed Alternative 1 would have included only the statutory QM requirements and would not have incorporated the consumer's DTI ratio, residual income, or other factors from the general ATR standard.[130] Proposed Alternative 2 would have included the statutory QM requirements and additional factors from the general ATR standard, including a requirement to consider and verify the consumer's DTI ratio or residual income.[131]

In the January 2013 Final Rule, the Bureau adopted the General QM loan definition in § 1026.43(e)(2). The existing General QM loan definition includes the statutory QM factors and additional factors from the general ATR standard. The existing General QM loan definition also contains a DTI limit of 43 percent. In adopting this approach in the January 2013 Final Rule, the Bureau explained that it believed the General QM loan definition should include a standard for evaluating the consumer's ability to repay, in addition to the product feature restrictions and other requirements that are specified in TILA.[132]

With respect to DTI, the January 2013 Final Rule noted that DTI ratios are widely used for evaluating a consumer's ability to repay over time because, as the available data showed, DTI ratio correlates with loan performance as measured by delinquency rate.[133] The January 2013 Final Rule noted that, at a basic level, the lower the DTI ratio, the greater the consumer's ability to pay back a mortgage loan.[134] The Bureau believed this relationship between the DTI ratio and the consumer's ability to repay applied both under conditions as they exist at consummation and under future changed circumstances, such as increases in payments for adjustable-rate mortgages (ARMs), future reductions in income, and unanticipated expenses and new debts.[135]

To provide certainty for creditors regarding the loan's QM status, the January 2013 Final Rule contained a specific DTI limit of 43 percent as part of the General QM loan definition. The Bureau stated that a specific DTI limit also provides certainty to assignees and investors in the secondary market, which the Bureau believed would help reduce concerns regarding legal risk and promote credit availability.[136] The Bureau noted that numerous commenters had highlighted the value of providing objective requirements determined based on information contained in loan files.[137] To address concerns that creditors may not have adequate certainty about whether a particular loan satisfies the requirements of the General QM loan definition, the Bureau provided definitions of debt and income for purposes of the General QM loan definition in appendix Q.[138]

The Bureau selected 43 percent as the DTI limit for the General QM loan definition. Based on analysis of data available at the time and comments, the Bureau believed that the 43 percent limit would advance TILA's goals of creditors not extending credit that consumers cannot repay while still preserving consumers' access to credit.[139] The Bureau acknowledged that there is no specific threshold that separates affordable from unaffordable mortgages; rather, there is a gradual increase in delinquency rates as DTI ratios increase.[140] Additionally, the Bureau noted that a 43 percent DTI ratio was within the range used by many creditors, generally comported with industry standards and practices for prudent underwriting, and was the threshold used by FHA as its general boundary at the time the Bureau issued the January 2013 Final Rule.[141] The Bureau noted concerns about setting a higher DTI limit, including concerns that it could allow QM status for mortgages for which there is not a sound reason to presume that the creditor had a reasonable belief in the consumer's ability to repay.[142] The Bureau was especially concerned about setting a DTI limit higher than 43 percent in the context of QMs that receive a safe harbor from the ATR requirements.[143] The Bureau was also concerned that a higher DTI limit would result in a QM boundary that substantially covered the entire mortgage market. If that were the case, creditors might be unwilling to make non-QM loans, and the Bureau was concerned that the QM rule would define the limit of credit availability.[144] The Bureau also suggested that a higher DTI limit might require a corresponding weakening of the strength of the presumption of compliance, which the Bureau believed would largely defeat the point of adopting a higher DTI limit.[145]

The January 2013 Final Rule also acknowledged concerns about imposing a DTI limit. The Bureau acknowledged that the Board, in issuing the 2011 ATR/QM Proposal, found that DTI ratios may not have significant predictive power, once the effects of credit history, loan type, and loan-to-value (LTV) ratio are considered.[146] Similarly, the Bureau noted that some commenters responding to the 2011 ATR/QM Proposal suggested that the Bureau should include compensating factors in addition to a specific DTI limit due to concerns about restricting access to credit.[147] The Bureau acknowledged that a standard that takes into account multiple factors may produce more accurate ability-to-repay determinations, at least in specific cases, but was concerned that incorporating a multi-factor test or compensating factors into the General QM loan definition would undermine the certainty for creditors and the secondary market of whether loans were eligible for QM status.[148] The Bureau also acknowledged arguments that residual income—generally defined as the monthly income that remains after a consumer pays all personal debts and obligations, including the prospective mortgage—may be a better measure of repayment ability.[149] However, the Bureau noted that it lacked sufficient data to mandate a bright-line rule based on residual income.[150] The Bureau anticipated further study of the issue as part of the five-year assessment of the Rule.[151]

The Bureau acknowledged in the January 2013 Final Rule that the 43 percent DTI limit in the General QM loan definition could restrict access to credit based on market conditions. Among other things, the Bureau expressed concern that, as the mortgage market recovered from the financial crisis, there could be a limited non-QM market, which, in conjunction with the 43 percent DTI limit, could impair access to credit for consumers with DTI

[129] 76 FR 27390, 27453 (May 11, 2011) (2011 ATR/QM Proposal).

[130] *Id.* at 27453.

[131] *Id.*

[132] 78 FR 6408, 6516 (Jan. 30, 2013).

[133] *Id.* at 6526–27.

[134] *Id.* at 6526.

[135] *Id.* at 6526–27.

[136] *Id.*

[137] *Id.*

[138] *Id.*

[139] *Id.*

[140] *Id.*

[141] *Id.*

[142] *Id.* at 6528.

[143] *Id.*

[144] *Id.*

[145] *Id.*

[146] *Id.* at 6527.

[147] *Id.*

[148] *Id.*

[149] *Id.* at 6528.

[150] *Id.*

[151] *Id.*

ratios over 43 percent.[152] To preserve access to credit for such consumers while the market recovered, the Bureau adopted the Temporary GSE QM loan definition, which did not include a specific DTI limit. As discussed below, the Temporary GSE QM loan definition continues to play a significant role in ensuring access to credit for consumers.

B. Why the Bureau Is Adopting a Price-Based QM Definition To Replace the General QM Loan Definition's DTI Limit

The Bureau concludes that this final rule's price-based approach best balances consumers' ability to repay with ensuring access to responsible, affordable mortgage credit. The Bureau is amending the General QM definition because retaining the existing 43 percent DTI limit would reduce the size of the QM market and likely would lead to a significant reduction in access to responsible, affordable credit when the Temporary GSE QM definition expires. The Bureau continues to believe that General QM status should be determined by a simple, bright-line rule to provide certainty of QM status, and the Bureau concludes that pricing achieves this objective. The Bureau concludes that a price-based General QM loan definition is better than the alternatives because a loan's price, as measured by comparing a loan's APR to APOR for a comparable transaction, is a strong indicator of a consumer's ability to repay and is a more holistic and flexible measure of a consumer's ability to repay than DTI alone.

1. Considerations Related to the General QM Loan Definition's DTI Limit

The proposal described the Bureau's concerns about the 43 percent DTI limit and its potentially negative effect on access to credit. In particular, the Bureau is concerned that imposing a DTI limit under the General QM loan definition would deny QM status for loans to some consumers for whom it is appropriate to presume ability to repay at consummation and that denying QM status to such loans risks denying consumers access to responsible, affordable credit. The Bureau is concerned that the current approach to DTI ratios as part of the General QM loan definition is not the best approach because it would likely impair some consumers' ability to access responsible and affordable credit. These access-to-credit concerns are especially acute for lower-income and minority consumers.

The proposal noted that a DTI limit may unduly restrict access to credit because it provides an incomplete picture of the consumer's financial capacity. While the Bureau acknowledges that DTI ratios generally correlate with loan performance, as the Bureau found in the January 2013 Final Rule and as shown in recent Bureau analysis described below, the proposal noted that a consumer's DTI ratio is only one way to measure financial capacity and is not necessarily a holistic measure of the consumer's ability to repay. The proposal also noted that the Bureau's own experience and the feedback it has received from stakeholders since issuing the January 2013 Final Rule suggest that imposing a DTI limit as a condition for QM status under the General QM loan definition may be overly burdensome and complex in practice.

As described in the proposal, the Bureau's Assessment Report highlights the tradeoffs of conditioning the General QM loan definition on a DTI limit. The Assessment Report included specific findings about the General QM loan definition's DTI limit, including certain findings related to DTI ratios as probative of a consumer's ability to repay. The Assessment Report found that loans with higher DTI ratios have been associated with higher levels of ''early delinquency'' (*i.e.,* delinquency within two years of origination), which, as explained below, may serve as a proxy for measuring whether a consumer had a reasonable ability to repay at the time the loan was consummated.[153] For example, the Assessment Report notes that for all periods and samples studied, a positive relationship between DTI ratios and early delinquency is present and economically meaningful.[154] The Assessment Report states that higher DTI ratios independently increase expected early delinquency, regardless of other underwriting criteria.[155]

At the same time, findings from the Assessment Report indicate that the specific 43 percent DTI limit in the current rule has restricted access to credit, particularly in the absence of a robust non-QM market. The report found that, for consumers with DTI ratios above 43 percent who qualify for loans eligible for purchase or guarantee by the GSEs, the Rule has not decreased access to credit.[156] However, the Assessment Report attributes the fact that the 43 percent DTI limit has not reduced access to credit for such consumers to the existence of the Temporary GSE QM loan definition. The findings in the Assessment Report indicate that there would be some reduction in access to credit for consumers with DTI ratios above 43 percent when the Temporary GSE QM loan definition expires, absent changes to the General QM loan definition. For example, based on application-level data obtained from nine large lenders, the Assessment Report found that the January 2013 Final Rule eliminated between 63 and 70 percent of non-GSE eligible home purchase loans with DTI ratios above 43 percent.[157] The proposal noted the Bureau's concern about a similar effect for loans with DTI ratios above 43 percent when the Temporary GSE QM loan definition expires. The proposal acknowledged that the Assessment Report's finding, without other information, does not prove or disprove the effectiveness of the DTI limit in achieving the purposes of the January 2013 Final Rule in ensuring consumers' ability to repay the loan. If the denied applicants in fact lacked the ability to repay, then the reduction in approval rates is a consequence consistent with the purposes of the Rule. However, if the denied applicants did have the ability to repay, then these data suggest an unintended consequence of the Rule. This possibility is supported by the fact that other findings in the Assessment Report suggest that applicants for non-GSE eligible loans with DTI ratios above 43 percent are being denied, even though other compensating factors indicate that some of them may have the ability to repay their loans.[158]

The current condition of the non-QM market heightens the access-to-credit concerns related to the specific 43 percent DTI limit, particularly if such conditions persist after the expiration of the Temporary GSE QM loan definition. The Bureau stated in the January 2013 Final Rule that it believed mortgages that could be responsibly originated with DTI ratios that exceed 43 percent, which historically includes over 20 percent of mortgages, would be made under the general ATR standard.[159] However, the Assessment Report found that a robust market for non-QM loans above the 43 percent DTI limit has not materialized as the Bureau had

[152] *Id.* at 6533.

[153] *See* Assessment Report, *supra* note 63, at 83–84, 100–05.

[154] *Id.* at 104–05.

[155] *Id.* at 105.

[156] *See, e.g., id.* at 10, 194–96.

[157] *See, e.g., id.* at 10–11, 117, 131–47.

[158] *See, e.g.,* Assessment Report *supra* note 63, at 150, 153, Table 20. Table 20 illustrates how the pool of denied non-GSE eligible applicants with DTI ratios above 43 percent has changed between 2013 and 2014. After the introduction of the Rule, the pool of denied applicants contains more consumers with higher incomes, higher FICO scores, and higher down payments.

[159] 78 FR 6408, 6527 (Jan. 30, 2013).

predicted. Therefore, there is limited capacity in the non-QM market to provide access to credit after the expiration of the Temporary GSE QM loan definition.[160] As described above, the non-QM market has been further reduced by the recent economic disruptions associated with the COVID–19 pandemic, with most mortgage credit now available in the QM lending space. The Bureau acknowledges the slow development of the non-QM market since the January 2013 Final Rule took effect and further acknowledges that the recent economic disruptions associated with the COVID–19 pandemic may significantly hinder its development in the near term.

At the time of the January 2013 Final Rule, the Bureau adopted the Temporary GSE loan definition to provide a period for economic, market, and regulatory conditions to stabilize and for a reasonable transition period to the General QM loan definition and non-QM loans above a 43 percent DTI ratio. However, contrary to the Bureau's expectations, lending largely has remained in the Temporary GSE QM space, and a sizable market to support non-QM lending has not yet emerged.[161] As noted above, the Bureau acknowledges that the recent economic disruptions associated with the COVID–19 pandemic may further hinder the development of the non-QM market, at least in the near term. As noted in the proposal, the Bureau expects that a significant number of Temporary GSE QMs would not qualify as General QMs under the current rule after the Temporary GSE QM loan definition expires, either because they have DTI ratios above 43 percent or because their method of documenting and verifying income or debt is incompatible with appendix Q. Some alternative loan options would still be available to many consumers after the expiration of the Temporary GSE QM loan definition. The proposal, however, emphasized the Bureau's expectation that, with respect to loans that are currently Temporary GSE QMs and would not otherwise qualify as General QMs under the current definition, some would cost materially more for consumers and some would not be made at all.

Based on 2018 data, the Bureau estimated in the proposal that, as a result of the General QM loan definition's 43 percent DTI limit, approximately 957,000 loans—16 percent of all closed-end first-lien residential mortgage originations in 2018—would be affected by the expiration of the Temporary GSE QM loan definition.[162] These loans are currently originated as QMs due to the Temporary GSE QM loan definition but would not be originated under the current General QM loan definition, and might not be originated at all, if the Temporary GSE QM loan definition were to expire. An additional, smaller number of loans that currently qualify as Temporary GSE QMs may not fall within the General QM loan definition after the expiration of the Temporary GSE QM loan definition because the method used for verifying income or debt would not comply with appendix Q.[163] As explained in the Extension Final Rule, the Temporary GSE QM loan definition will expire on the mandatory compliance date of this final rule or when GSE conservatorship ends.

As explained in the proposal, the Bureau believes that many loans currently originated under the Temporary GSE QM loan definition would cost materially more or may not be made at all, absent changes to the General QM loan definition. After the Temporary GSE QM loan definition expires, the Bureau expects that many consumers with DTI ratios above 43 percent who would have received a Temporary GSE QM would instead obtain FHA-insured loans since FHA currently insures loans with DTI ratios up to 57 percent.[164] The number of loans that move to FHA would depend on FHA's willingness and ability to insure such loans, whether FHA continues to treat all loans that it insures as QMs under its own QM rule, and how many loans that would have been originated as Temporary GSE QMs with DTI ratios above 43 percent exceed FHA's loan-amount limit.[165] For example, the Bureau estimated in the proposal that, in 2018, 11 percent of Temporary GSE QM loans with DTI ratios above 43 percent exceeded FHA's loan-amount limit.[166] Thus, the Bureau considers that at most 89 percent of loans that would have been Temporary GSE QMs with DTI ratios above 43 percent could move to FHA.[167] The Bureau expects that loans that would be originated as FHA loans instead of under the Temporary GSE QM loan definition generally would cost materially more for many consumers.[168] The Bureau expects that some consumers offered FHA loans might choose not to take out a mortgage because of these higher costs.

The proposal explained that it is also possible that some consumers with DTI ratios above 43 percent would be able to obtain loans in the private market.[169] The number of loans absorbed by the private market would likely depend, in part, on whether actors in the private market would be willing to assume the legal or credit risk associated with funding loans—as non-QM loans or small-creditor portfolio QMs—that would have been Temporary GSE QMs (with DTI ratios above 43 percent)[170] and, if so, whether actors in the private market would offer lower prices or better terms.[171] For example, the Bureau estimated that 55 percent of loans that would have been Temporary GSE QMs (with DTI ratios above 43 percent) in 2018 had credit scores at or above 680 and LTV ratios at or below 80 percent—credit characteristics traditionally considered attractive to actors in the private market.[172] At the same time, the Assessment Report found there has been limited momentum toward a greater role for private market non-QM loans. It is uncertain how great this role will be in the future,[173] particularly in the short term due to the economic effects of the COVID–19 pandemic. Finally, the proposal noted that some consumers

[160] Assessment Report, *supra* note 63, at 198.

[161] *Id.* at 198.

[162] Proposed Rule's Dodd-Frank Act section 1022(b) analysis (citing the Bureau's prior estimate of affected loans in the ANPR); *see* 84 FR 37155, 37159 (July 31, 2019).

[163] *Id.* at 37159 n.58.

[164] In fiscal year 2019, approximately 57 percent of FHA-insured purchase mortgages had a DTI ratio above 43 percent. U.S. Dep't of Hous. & Urban Dev., *Annual Report to Congress Regarding the Financial Status of the FHA Mutual Mortgage Insurance Fund, Fiscal Year 2019,* at 33 (using data from App. B Tbl. B9) (Nov. 14, 2018), *https://www.hud.gov/sites/dfiles/Housing/documents/2019FHAAnnualReportMMIFund.pdf.*

[165] 84 FR 37155, 37159 (July 31, 2019).

[166] *Id.* In 2018, FHA's county-level maximum loan limits ranged from $294,515 to $679,650 in the continental United States. *See* U.S. Dep't of Hous. & Urban Dev., *FHA Mortgage Limits, https://entp.hud.gov/idapp/html/hicostlook.cfm* (last visited Dec. 8, 2020).

[167] 84 FR 37155, 37159 (July 31, 2019).

[168] Interest rates and insurance premiums on FHA loans generally feature less risk-based pricing than conventional loans, charging more similar rates and premiums to all consumers. As a result, they are likely to cost more than conventional loans for consumers with stronger credit scores and larger down payments. Consistent with this pricing differential, consumers with higher credit scores and larger down payments chose FHA loans relatively rarely in 2018 HMDA data on mortgage originations. *See* Bureau of Consumer Fin. Prot., *Introducing New and Revised Data Points in HMDA* (Aug. 2019), *https://files.consumerfinance.gov/f/documents/cfpb_new-revised-data-points-in-hmda_report.pdf.*

[169] 84 FR 37155, 37159 (July 31, 2019).

[170] *See* 12 CFR 1026.43(e)(5) (extending QM status to certain portfolio loans originated by certain small creditors). In addition, section 101 of the Economic Growth, Regulatory Relief, and Consumer Protection Act, Public Law 115–174, 132 Stat. 1296 (2018), amended TILA to add a safe harbor for small creditor portfolio loans. *See* 15 U.S.C. 1639c(b)(2)(F).

[171] 84 FR 37155, 37159 (July 31, 2019).

[172] *Id.*

[173] *Id.*

with DTI ratios above 43 percent who would have sought Temporary GSE QM loans may adapt to changing options and make different choices, such as adjusting their borrowing to result in a lower DTI ratio.[174] However, some consumers who would have sought Temporary GSE QMs (with DTI ratios above 43 percent) may not obtain loans at all.[175] For example, based on application-level data obtained from nine large lenders, the Assessment Report found that the January 2013 Final Rule eliminated between 63 and 70 percent of non-GSE-eligible home purchase loans with DTI ratios above 43 percent.[176]

As noted in the proposal, the Bureau also has particular concerns about the effects of the appendix Q definitions of debt and income on access to credit. The Bureau intended for appendix Q to provide creditors with certainty about the DTI ratio calculation to foster compliance with the General QM loan definition. However, based on extensive stakeholder feedback and the Bureau's own experience, the proposal recognized that appendix Q's definitions of debt and income are rigid and difficult to apply and do not provide the level of compliance certainty that the Bureau anticipated. Stakeholders have reported that these concerns are particularly acute for transactions involving self-employed consumers, consumers with part-time employment, and consumers with irregular or unusual income streams. The proposal expressed concern that the standards in appendix Q could negatively impact access to credit for these consumers, particularly after expiration of the Temporary GSE QM loan definition. The Assessment Report also noted concerns with the perceived lack of clarity in appendix Q and found that such concerns ''may have contributed to investors'—and at least derivatively, creditors'—preference'' for Temporary GSE QMs.[177] Appendix Q, unlike other standards for calculating and verifying debt and income, has not been revised since 2013.[178] The current definitions of debt and income in appendix Q have proven to be complex in practice. In the proposal, the Bureau expressed concerns about other potential approaches to defining debt and income in connection with conditioning QM status on a specific DTI limit.

The current approach to DTI ratios under the General QM loan definition may also stifle innovation in underwriting because it focuses on a single metric, with strict verification standards under appendix Q, which may constrain new approaches to assessing repayment ability. Such innovations include certain new uses of cash flow data and analytics to underwrite mortgage applicants. This emerging technology has the potential to accurately assess consumers' ability to repay using, for example, bank account data that can identify the source and frequency of recurring deposits and payments and identify remaining disposable income. Identifying the remaining disposable income could be a method of assessing the sufficiency of a consumer's residual income and could potentially satisfy a requirement to consider either DTI or residual income. This innovation could potentially expand access to responsible, affordable mortgage credit, particularly for applicants with non-traditional income and limited credit history. The proposal expressed concern that the potential negative effect of the current General QM loan definition on innovation in underwriting may be heightened while the market is largely concentrated in the QM lending space and may limit access to credit for some consumers with DTI ratios above 43 percent.

2. The Proposed Price-Based General QM Loan Definition

In light of these concerns, the Bureau proposed to remove the 43 percent DTI limit from the General QM loan definition in § 1026.43(e)(2)(vi) and replace it with a requirement based on the price of the loan. In issuing the proposal, the Bureau acknowledged the significant debate[179] over whether loan pricing, a consumer's DTI ratio, or another direct or indirect measure of a consumer's personal finances is a better predictor of loan performance, particularly when analyzed across various points in the economic cycle. In seeking comments on the proposal, the Bureau noted that it was not making a determination as to whether DTI ratios, a loan's price, or some other measure is the best predictor of loan performance. Rather, the analyses provided by stakeholders and the Bureau's own analysis show that pricing is strongly correlated with loan performance, based on early delinquency rates, across a variety of loans and economic conditions. The Bureau acknowledged that DTI is also predictive of loan performance and that other direct and indirect measures of consumer finances may also be predictive of loan performance. However, the Bureau weighed several policy considerations in selecting an approach for the proposal based on the purposes of the ATR/QM provisions of TILA.

In proposing a price-based General QM loan definition, the Bureau sought to balance considerations related to ensuring consumers' ability to repay and maintaining access to credit. As noted in the proposal, the Bureau views the relevant provisions of TILA as fundamentally about assuring that consumers receive mortgage credit that they can repay. However, the Bureau also stated its concern about maintaining access to responsible, affordable mortgage credit. The proposal noted the Bureau's concern that the current General QM loan definition, with a 43 percent DTI limit, would result in a significant reduction in the scope of the QM market and could reduce access to responsible, affordable mortgage credit after the Temporary GSE QM loan definition expires. The lack of a robust non-QM market enhances those concerns. Although it remains possible that, over time, a substantial market for non-QM loans will emerge, that market has developed slowly, and the recent economic disruptions associated with the COVID–19 pandemic may significantly hinder its development, at least in the near term.

With respect to ability to repay, the proposal focused on analysis of early delinquency rates to evaluate whether a loan's price, as measured by the spread of APR over APOR (herein referred to as the loan's rate spread), is an appropriate measure of whether a loan should be presumed to comply with the ATR provisions. The proposal noted that, because the affordability of a given mortgage will vary from consumer to

[174] *Id.*

[175] *Id.*

[176] *See* Assessment Report, *supra* note 63, at 10–11, 117, 131–47.

[177] *Id.* at 193.

[178] *Id.* at 193–94.

[179] *See, e.g.,* Norbert Michel, *The Best Housing Finance Reform Options for the Trump Administration,* Forbes (July 15, 2019), *https://www.forbes.com/sites/norbertmichel/2019/07/15/the-best-housing-finance-reform-options-for-the-trump-administration/#4f5640de7d3f;* Eric Kaplan *et al.,* Milken Institute, *A Blueprint for Administrative Reform of the Housing Finance System,* at 17 (2019), *https://assets1b.milkeninstitute.org/assets/Publication/Viewpoint/PDF/Blueprint-Admin-Reform-HF-System-1.7.2019-v2.pdf* (suggesting that the Bureau both (1) expand the 43 percent DTI limit to 45 percent to move market share of higher-DTI loans from the GSEs and FHA to the non-agency market, and (2) establish a residual income test to protect against the risk of higher DTI loans); Morris Davis *et al., A Quarter Century of Mortgage Risk* (FHFA, Working Paper 19–02, 2019), *https://www.fhfa.gov/PolicyProgramsResearch/Research/Pages/wp1902.aspx* (examining various loan characteristics and a summary measure of risk—the stressed default rate—for predictiveness of loan performance).

consumer based upon a range of factors, there is no single recognized metric, or set of metrics, that can directly measure whether the terms of mortgage loans are reasonably within consumers' ability to repay. As such, consistent with the Bureau's prior analyses in the Assessment Report, the Bureau's analysis in the proposal used early distress as a proxy for the lack of the consumer's ability to repay at consummation across a wide pool of loans. Specifically, and consistent with the Assessment Report,[180] the proposal measured early distress as whether a consumer was ever 60 or more days past due within the first two years after origination (referred to herein as the early delinquency rate). The Bureau's analysis focused on early delinquency rates to capture consumers' difficulties in making payments soon after consummation of the loan (*i.e.,* within the first two years), even if these delinquencies do not lead to consumers potentially losing their homes (*i.e.,* 60 or more days past due, as opposed to 90 or more days or in foreclosure), as early difficulties in making payments indicate a higher likelihood that the consumer may have lacked ability to repay at consummation. As in the Assessment Report, the Bureau assumed that the average early delinquency rate across a wide pool of mortgages—whether safe harbor QM, rebuttable presumption QM, or non-QM—is probative of whether such loans are reasonably within consumers' repayment ability. The Bureau acknowledged that alternative measures of delinquency, including those used in analyses submitted as comments on the ANPR, may also be probative of repayment ability.

In issuing the proposal, the Bureau reviewed available evidence to assess whether rate spreads can distinguish loans that are likely to have low early delinquency rates, and thus may be presumed to comply with the ATR requirements, from loans that are likely to have higher rates of early delinquency, for which a presumption of compliance with the ATR requirements would not be warranted. The proposal stated that the Bureau's own analysis and analyses published in response to the Bureau's ANPR and RFIs provide strong evidence of increasing early delinquency rates with higher rate spreads across a range of datasets, time periods, loan types, measures of rate spread, and measures of delinquency. The Bureau's delinquency analysis used data from the National Mortgage Database (NMDB),[181] including a matched sample of NMDB and HMDA loans.[182] As noted in the proposal, the analysis shows that delinquency rates rise with rate spread. The Bureau's delinquency analysis is described below. Table numbers in part V match those from the Bureau's proposal, except that Tables 7A and 8A in part V.B.5, below, did not appear in the proposal.

Table 1 shows early delinquency rates for 2002–2008 first-lien purchase originations in the NMDB, with loans categorized according to their approximate rate spread. The Bureau analyzed 2002 through 2008 origination years because the relatively fixed private mortgage insurance (PMI) pricing during these years allows for reliable approximation of this important component of rate spreads.[183] The sample is restricted to loans without product features that would make them non-QM loans under the current rule. Table 1 shows that early delinquency rates increase consistently with rate spreads, from a low of 2 percent among loans with rate spreads below or near zero, up to 14 percent for loans with rate spreads of 2.25 percentage points or more over APOR.[184] This sample includes loans originated during the peak of the housing boom and delinquencies that occurred during the ensuing recession, contributing to the high overall levels of early delinquency.

TABLE 1—2002–2008 ORIGINATIONS, EARLY DELINQUENCY RATE BY RATE SPREAD

Rate spread (interest rate + PMI approximation − PMMS [185]) in percentage points	Early delinquency rate (%)
<0	2
0–0.24	2
0.25–0.49	4
0.50–0.74	5
0.75–0.99	6
1.00–1.24	8
1.25–1.49	10
1.50–1.74	12
1.75–1.99	13
2.00–2.24	14
2.25 and above	14

The proposal noted that analysis of additional data, as reflected in Table 2, also shows early delinquency rates rising with rate spread. Table 2 shows early delinquency statistics for 2018 NMDB first-lien purchase originations that have been matched to 2018 HMDA data, enabling the Bureau to use actual rate spreads over APOR rather than approximated rate spreads in its analysis.[186] As with the data reflected in Table 1, loans with product features that would make them non-QM under the current rule are excluded from Table 2. However, only delinquencies occurring through December 2019 are observed in Table 2, meaning most loans are not observed for a full two years after origination. This more recent sample provides insight into early delinquency rates under post-crisis lending standards, and for an origination cohort that had not undergone (as of December 2019) a large economic downturn. The 2018 data are divided into wider bins (as compared to Table 1) to ensure

[180] *See* Assessment Report, *supra* note 63, at 83.

[181] The NMDB, jointly developed by the FHFA and the Bureau, provides de-identified loan characteristics and performance information for a 5 percent sample of all mortgage originations from 1998 to the present, supplemented by de-identified loan and borrower characteristics from Federal administrative sources and credit reporting data. *See* Bureau of Consumer Fin. Prot., *Sources and Uses of Data at the Bureau of Consumer Financial Protection,* at 55–56 (Sept. 2018), *https://www.consumerfinance.gov/documents/6850/bcfp_sources-uses-of-data.pdf.*

[182] HMDA was originally enacted by Congress in 1975 and is implemented by Regulation C, 12 CFR part 1003. *See* Bureau of Consumer Fin. Prot., *Mortgage data (HMDA), https://www.consumerfinance.gov/data-research/hmda/* (last visited Dec. 8, 2020). HMDA requires many financial institutions to maintain, report, and publicly disclose loan-level information about mortgages. These data are housed here to help show whether lenders are serving the housing needs of their communities; they give public officials information that helps them make decisions and policies; and they shed light on lending patterns that could be discriminatory. The public data are modified to protect applicant and borrower privacy.

[183] *See* Neil Bhutta and Benjamin J. Keys, *Eyes Wide Shut? The Moral Hazard of Mortgage Insurers during the Housing Boom,* (NBER Working Paper No. 24844, 2018), *https://www.nber.org/papers/w24844.pdf.* APOR is approximated with weekly Freddie Mac Primary Mortgage Market Survey (PMMS) data, retrieved from Fed. Reserve Bank of St. Louis, Fed. Reserve Econ. Data, *https://fred.stlouisfed.org/* (Mar. 4, 2020). Each loan's APR is approximated by the sum of the interest rate in the NMDB data and an assumed PMI payment of 0.32, 0.52, or 0.78 percentage points for loans with LTVs above 80 but at or below 85, above 85 but at or below 90, and above 90, respectively. These PMI are based on standard industry rates during this time period. The 30-year Fixed Rate PMMS average is used for fixed-rate loans with terms over 15 years, and 15-year Fixed Rate PMMS is used for loans with terms of 15 years or less. The 5/1-year Adjustable-Rate PMMS average is used (for available years) for ARMs with a first interest rate reset occurring 5 or more years after origination, while the 1-year adjustable-rate PMMS average is used for all other ARMs.

[184] Loans with rate spreads of 2.25 percentage points or more are grouped in Tables 1 and 5 to ensure sufficient sample size for reliable analysis of the 2002–2008 data. This grouping ensures that all cells shown in Table 5 contain at least 500 loans.

[185] Freddie Mac's PMMS is the source of data underlying APOR for most mortgages. See *supra* note 183 for additional details.

[186] Where possible, the FHFA provided an anonymized match of HMDA loan identifiers for 2018 NMDB originations, allowing the Bureau to analyze more detailed HMDA loan characteristics (*e.g.,* rate spread over APOR) for approximately half of 2018 NMDB originations.

enough loans per bin. As with Table 1, the proposal noted that Table 2 shows that early delinquency rates increase consistently with rate spreads, from a low of 0.2 percent for loans with rate spreads near APOR or below APOR, up to 4.2 percent for loans with rate spreads of 2 percentage points or more over APOR.[187]

TABLE 2—2018 ORIGINATIONS, EARLY DELINQUENCY RATE BY RATE SPREAD

Rate spread over APOR in percentage points	Early delinquency rate (as of Dec. 2019) (%)
<0	0.2
0–0.49	0.2
0.50–0.99	0.6
1.00–1.49	1.7
1.50–1.99	2.7
2.00 and above	4.2

Given the specific DTI limit under the current rule, the Bureau also analyzed the relationship between DTI ratios and early delinquency for the same samples of loans in Tables 3 and 4. As described in the proposal, the Bureau's analyses show that early delinquency rates increase consistently with DTI ratio in both samples. In the 2002–2008 sample, early delinquency rates increase from a low of 3 percent among loans with DTI ratios at or below 25 percent, up to 9 percent for loans with DTI ratios between 61 and 70 percent.[188] In the 2018 sample, early delinquency rates increase from 0.4 percent among loans with DTI ratios at or below 25 percent, up to 0.9 percent among loans with DTI ratios between 44 and 50.[189] The difference in early delinquency rates between loans with the highest and lowest DTI ratios is smaller than the difference in early delinquency rates between the highest and lowest rate spreads during both periods. The proposal explained that, for these samples and bins of rate spread and DTI ratios, this pattern is consistent with a stronger correlation between rate spread and early delinquency than between DTI ratios and early delinquency.

TABLE 3—2002–2008 ORIGINATIONS, EARLY DELINQUENCY RATE BY DTI RATIO

DTI	Early delinquency rate (%)
0–20	3
21–25	3
26–30	4
31–35	5
36–40	6
41–43	6
44–45	7
46–48	7
49–50	8
51–60	8
61–70	9

TABLE 4—2018 ORIGINATIONS, EARLY DELINQUENCY RATE BY DTI

DTI	Early delinquency rate (as of Dec. 2019) (%)
0–25	0.4
26–35	0.5
36–43	0.7
44–48	0.9
49–50	0.9

The proposal further analyzed the strengths of DTI ratios and pricing in predicting early delinquency rates in Tables 5 and 6, which show the early delinquency rates of these same samples categorized according to both their DTI ratios and their rate spreads. Table 5 shows early delinquency rates for 2002–2008 first-lien purchase originations in the NMDB, with loans categorized according to both their DTI ratio and their approximate rate spread. For loans within a given DTI ratio range, those with higher rate spreads consistently had higher early delinquency rates. Loans with low rate spreads had relatively low early delinquency rates even at high DTI ratio levels, as seen in the 2 percent early delinquency rate for loans priced below APOR but with DTI ratios of 46 to 48 percent, 51 to 60 percent, and 61 to 70 percent. However, the highest early delinquency rates occurred for loans with high rate spreads and high DTI ratios, reaching 26 percent for loans priced 2 to 2.24 percentage points above APOR with DTI ratios of 61 to 70 percent. Across DTI bins, loans priced significantly above APOR had early delinquency rates much higher than loans priced below APOR.

TABLE 5—2002–2008 ORIGINATIONS, EARLY DELINQUENCY RATE BY RATE SPREAD AND DTI RATIO

Rate spread (interest rate + PMI approx. − PMMS) in percentage points	DTI 0–20 (%)	DTI 21–25 (%)	DTI 26–30 (%)	DTI 31–35 (%)	DTI 36–40 (%)	DTI 41–43 (%)	DTI 44–45 (%)	DTI 46–48 (%)	DTI 49–50 (%)	DTI 51–60 (%)	DTI 61–70 (%)
<0	2	1	1	2	2	2	2	2	3	2	2
0–0.24	2	2	2	2	2	3	3	3	3	3	3
0.25–0.49	3	3	3	3	4	5	4	5	5	5	5
0.50–0.74	4	4	4	4	5	6	6	6	7	7	7
0.75–0.99	4	5	5	6	6	7	7	7	8	8	10
1.00–1.24	6	6	6	7	7	9	9	9	10	11	13
1.25–1.49	6	7	8	8	10	11	12	12	12	14	15
1.50–1.74	7	8	9	10	13	13	15	14	16	15	20
1.75–1.99	7	8	10	12	14	15	16	16	16	18	22
2.00–2.24	6	10	10	12	15	15	17	19	18	20	26
2.25 and above	7	9	10	13	15	16	16	18	19	20	25

[187] Loans with rate spreads of 2 percentage points or more are grouped in Tables 2 and 6 to ensure sufficient sample size for reliable analysis of the 2018 data. This grouping ensures that all cells shown in Table 6 contain at least 500 loans.

[188] Fewer than 0.7 percent of loans have reported DTI ratios over 70 percent in the 2002–2008 data. These loans are excluded from Tables 3 and 5 due to reliability concerns (including outliers which may reflect reporting errors) and to ensure that all cells shown in Table 5 contain at least 500 loans.

[189] Fewer than 0.5 percent of loans have reported DTI ratios over 50 percent in the 2018 data. These loans are excluded from Tables 4 and 6 due to reliability concerns (including outliers which may reflect reporting errors) and to ensure that all cells shown in Table 6 contain at least 500 loans.

Similarly, Table 6 shows average early delinquency statistics, with loans categorized according to both DTI and rate spread, for the sample of 2018 NMDB first-lien purchase originations that have been matched to 2018 HMDA data.[190] For Table 6, the higher early delinquency rate for loans with higher rate spreads over APOR matches the pattern shown in the data from Table 5. Overall early delinquency rates are substantially lower, reflecting the importance of economic conditions in the likelihood of delinquency for any given consumer. However, the 2018 loans priced significantly above APOR also had early delinquency rates much higher than loans priced below APOR.

TABLE 6—2018 ORIGINATIONS, EARLY DELINQUENCY RATE BY RATE SPREAD AND DTI RATIO

Rate spread over APOR in percentage points	DTI 0–25 (%)	DTI 26–35 (%)	DTI 36–43 (%)	DTI 44–50 (%)
<0	0.1	0.1	0.2	0.3
0–0.49	0.2	0.1	0.3	0.3
0.50–0.99	0.1	0.4	0.8	0.8
1.00–1.49	1.0	1.4	1.5	2.3
1.50–1.99	.....	3.2	2.5	2.3
2.00 and above	.....	4.4	3.9	4.2

The proposal noted that the high relative risk of early delinquency for higher-priced loans holds across samples, demonstrating that rate spreads distinguish early delinquency risk under a range of economic conditions and creditor practices. The proposal also highlighted that analyses published in response to the Bureau's ANPR and RFIs are consistent with the Bureau's analysis showing that early delinquency rates rise consistently with rate spread. For example, CoreLogic analyzed a set of 2018 HMDA conventional mortgage originations merged to loan performance data collected from mortgage servicers.[191] The CoreLogic analysis found: (1) The lowest delinquency rates among loans with rate spreads that are below APOR, and (2) increased early delinquency rates for each sequentially higher bin of rate spreads up to 2 percentage points over APOR. In assessing the CoreLogic analysis, the Bureau noted that loans priced at or above 2 percentage points over APOR in the 2018 HMDA data are relatively rare and are disproportionately made for manufactured housing and smaller loan amounts and therefore may not be well represented in mortgage servicing datasets. However, the proposal noted that these loans also have relatively high rates of delinquency.[192] CoreLogic found a similar, but more variable, positive relationship between rate spreads over APOR and delinquency in earlier cohorts (2010–2017) of merged HMDA-CoreLogic originations, a period in which rate spreads were only reported for loans priced at least 1.5 percentage points over APOR.[193] The proposal also noted that analyses by the Urban Institute (using loan performance data from Black Knight) show a comparable positive relationship between rate spreads—measured there as the note rate over PMMS—and delinquency.[194] The analysis found that the relationship holds across a range of loan types (conventional loans held in portfolio, in GSE securitizations, and in private securitizations; FHA loans; VA loans) and years (1995–2018). Additional analyses by the Urban Institute show the same positive relationship between rate spread and loan performance in Fannie Mae loan-level performance data.[195]

The proposal stated that, collectively, this evidence suggests that higher rate spreads—including the specific measure of APR over APOR—are strongly correlated with early delinquency rates. Given that early delinquency captures consumers' difficulty making required payments, the proposal preliminarily concluded that rate spreads provide a strong indicator of ability to repay.

The proposal acknowledged that a test that combines rate spread and DTI may better predict early delinquency rates than either metric on its own. However, the proposal also noted that any rule with a specific DTI limit would need to provide standards for calculating the income that may be counted and the debt that must be counted so that creditors and investors can ensure with reasonable certainty that they have accurately calculated DTI within the specific DTI limit. As noted above, the current definitions of debt and income in appendix Q have proven to be complex in practice and may unduly restrict access to credit. The proposal expressed concerns about whether other potential approaches could define debt and income with sufficient clarity while at the same time providing flexibility to accommodate new approaches to verification and underwriting.

In addition to strongly correlating with loan performance, the proposal tentatively concluded that a price-based General QM loan definition is a more holistic and flexible measure of a consumer's ability to repay than DTI alone. The proposal explained that mortgage underwriting, and by extension, a loan's price, generally includes consideration of a consumer's DTI. However, the proposal explained that loan pricing also includes an assessment of additional factors that might compensate for a higher DTI ratio and that might also be probative of a consumer's ability to repay. One of the primary criticisms of the current 43 percent DTI ratio is that it is too limited

[190] As in Tables 2 and 4, above, the 2018 data are divided into larger bins to ensure enough loans per bin. Loans with a DTI ratio greater than 50 percent are excluded, as well as loans with a DTI ratio at or below 25 percent and rate spreads of 1.5 percentage points and above, because these bins contained fewer than 500 loans in the matched 2018 NMDB–HMDA sample.

[191] *See* Archana Pradhan & Pete Carroll, *Expiration of the CFPB's Qualified Mortgage (QM) GSE Patch—Part V,* CoreLogic Insights Blog (Jan. 13, 2020), *https://www.corelogic.com/blog/2020/1/expiration-of-the-cfpbs-qualified-mortgage-qm-gse-patch-part-v.aspx.* Delinquency was measured as of October 2019, so loans do not have two full years of payment history.

[192] The Bureau analyzes the performance and pricing for smaller loans in the section-by-section analysis for § 1026.43(e)(2)(vi).

[193] *See* Archana Pradhan & Pete Carroll, *Expiration of the CFPB's Qualified Mortgage (QM) GSE Patch—Part IV,* CoreLogic Insights Blog (Jan. 11, 2020), *https://www.corelogic.com/blog/2020/1/expiration-of-the-cfpbs-qualified-mortgage-qm-gse-patch-part-iv.aspx.* (Delinquency measured as of October 2019.)

[194] *See* Karan Kaul & Laurie Goodman, Urban Inst., *Updated: What, If Anything, Should Replace QM GSE Patch,* at 9 (Oct. 2020), *https://www.urban.org/sites/default/files/publication/99268/2018_10_30_qualified_mortgage_rule_update_finalized_4.pdf.*

[195] *See* Karan Kaul *et al.,* Urban Inst., *Comment Letter to the Consumer Financial Protection Bureau on the Qualified Mortgage Rule,* at 9–10 (Sept. 2019), *https://www.urban.org/sites/default/files/publication/101048/comment_letter_to_the_consumer_financial_protection_bureau_0.pdf.*

in assessing a consumer's finances and, as such, may unduly restrict access to credit. Therefore, the proposal noted that a potential benefit of a price-based General QM loan definition is that a mortgage loan's price reflects credit risk based on many factors, including DTI ratios, and may be a more holistic measure of ability to repay than DTI ratios alone. Further, there is inherent flexibility for creditors in a rate-spread-based General QM loan definition, which could facilitate innovation in underwriting, including the use of emerging research into alternative mechanisms to assess a consumer's ability to repay. Such innovations include certain new uses of cash flow data and analytics to underwrite mortgage applicants. This emerging technology has the potential to accurately assess consumers' ability to repay using, for example, bank account data that can identify the source and frequency of recurring deposits and payments and identify remaining disposable income. Identifying the remaining disposable income could be a method of assessing the consumer's residual income and could potentially satisfy a requirement to consider either DTI or residual income, absent a specific DTI limit.

The proposal also noted that there is significant precedent for using the price of a mortgage loan to determine whether to apply additional consumer protections, in recognition of the lower risk generally posed by lower-priced mortgages. A price-based General QM loan definition would be consistent with these existing provisions that provide greater protections to consumers with more expensive loans. For example, TILA and Regulation Z use a loan's APR in comparison to APOR and as one trigger for heightened consumer protections for certain ''high-cost mortgages'' pursuant to HOEPA.[196] Loans that meet HOEPA's high-cost trigger are subject to special disclosure requirements and restrictions on loan terms, and consumers with high-cost mortgages have enhanced remedies for violations of the law. Further, in 2008, the Board exercised its authority under HOEPA to require certain consumer protections concerning a consumer's ability to repay, prepayment penalties, and escrow accounts for taxes and insurance for HPMLs, which have APR spreads lower than those prescribed for high-cost mortgages but that nevertheless exceed APOR by a specified threshold.[197] Although the ATR/QM Rule replaced the ability-to-repay requirements promulgated pursuant to HOEPA and the Board's 2008 rule,[198] HPMLs remain subject to additional requirements related to escrow accounts for taxes and homeowners insurance and to appraisal requirements.[199] The proposal also noted that the ATR/QM Rule itself provides additional protection to QMs that are higher-priced covered transactions, as defined in § 1026.43(b)(4), in the form of a rebuttable presumption of compliance with the ATR provisions, instead of a conclusive safe harbor.

Finally, the proposal preliminarily concluded that a price-based General QM loan definition would provide compliance certainty to creditors because creditors would be able to readily determine whether a loan is a General QM. Creditors have experience with APR calculations due to the existing price-based regulatory requirements described above, and for various other disclosure and compliance reasons under Regulation Z. Creditors also have experience determining the appropriate APOR for use in calculating rate spreads. As such, the proposal stated that the approach should provide certainty to creditors regarding a loan's status as a QM.[200]

Although the proposal would have required creditors to consider the consumer's DTI ratio or residual income, income or assets other than the value of the dwelling, and debts, the proposal would not have mandated a specific DTI limit. The proposal would have removed appendix Q and instead would have provided creditors additional flexibility for defining income or assets other than the value of the dwelling and debts. The Bureau did not propose a single, specific set of standards equivalent to appendix Q for what must be counted as income or assets and what may be counted as debts. For purposes of the proposed requirement, income or assets and debts would be determined in accordance with proposed § 1026.43(e)(2)(v)(B), which would have required the creditor to verify the consumer's current or reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan and the consumer's current debt obligations, alimony, and child support. The proposed rule would have provided a safe harbor to creditors using verification standards the Bureau specifies. The proposal noted that this could potentially include relevant provisions from Fannie Mae's Single Family Selling Guide, Freddie Mac's Single-Family Seller/Servicer Guide, FHA's Single Family Housing Policy Handbook, the VA's Lenders Handbook, and the Field Office Handbook for the Direct Single Family Housing Program and Handbook for the Single Family Guaranteed Loan Program of the USDA, current as of the proposal's public release. However, under the proposal, creditors would not have been required to verify income and debt according to the standards the Bureau specifies. Rather, the proposal would have provided creditors with the flexibility to develop other methods of compliance with the verification requirements.

[196] *See* TILA section 103(aa)(i); Regulation Z § 1026.32(a)(1)(i). TILA and Regulation Z also provide a separate price-based coverage trigger based on the points and fees charged on a loan. *See* TILA section 130(aa)(ii); Regulation Z § 1026.32(a)(1)(ii).

[197] *See generally* 73 FR 44522 (July 30, 2008).

[198] The Board's 2008 rule was superseded by the January 2013 Final Rule, which imposed ability-to-repay requirements on a broader range of closed-end consumer credit transactions secured by a dwelling. *See generally* 78 FR 6408 (Jan. 30, 2013).

[199] *See* § 1026.35(b) and (c).

[200] The Bureau understands from feedback that creditors are concerned about errors in DTI calculations and have previously requested that the Bureau permit a cure of DTI overages that are discovered after consummation. *See* 79 FR 25730, 25743–45 (May 6, 2014) (requesting comment on potential cure or correction provisions for DTI overages).

The proposal would have provided that a loan meets the General QM loan definition in § 1026.43(e)(2) only if the APR exceeds APOR for a comparable transaction by less than 2 percentage points as of the date the interest rate is set. In proposing this threshold, the Bureau tentatively concluded that it would strike an appropriate balance between ensuring that loans receiving QM status may be presumed to comply with the ATR provisions and ensuring that access to responsible, affordable mortgage credit remains available to consumers. For these same reasons, the Bureau proposed higher thresholds for smaller loans and subordinate-lien transactions, as the Bureau was concerned that loans with lower loan amounts may be priced higher than larger loans, even if the consumers have similar credit characteristics and a similar ability to repay. For all loans, regardless of loan size, the Bureau did not propose to alter the current threshold separating safe harbor from rebuttable presumption QMs in § 1026.43(b)(4), under which a loan is a safe harbor QM if its APR exceeds APOR for a comparable transaction by less than 1.5 percentage points as of the date the interest rate is set (or 3.5 percentage points for subordinate-lien transactions). As such, under the proposal, first-lien loans that otherwise meet the General QM loan definition and for which the APR exceeds APOR by 1.5 or more percentage points (but by less than 2 percentage points) as of the date the interest rate is set would have received a rebuttable presumption of compliance with the ATR provisions.

Finally, the proposal provided analysis of the potential effects on access to credit of a price-based approach to defining a General QM. As indicated by the various combinations in Table 7 below, the proposal analyzed 2018 HMDA data and found that under the current rule—including the Temporary GSE QM loan definition, the General QM loan definition with a 43 percent DTI limit, and the Small Creditor QM loan definition in § 1026.43(e)(5)—90.6 percent of conventional purchase loans were safe harbor QMs and 95.8 percent were safe harbor QMs or rebuttable presumption QMs. Under the proposed General QM loan definition's rate-spread thresholds of 1.5 (safe harbor) and 2.0 (rebuttable presumption) percentage points over APOR, the proposal stated that 91.6 percent of conventional purchase loans would have been safe harbor QMs and 96.1 percent would have been safe harbor QM or rebuttable presumption QMs.[201] Based on these 2018 data, the proposal stated that rate-spread thresholds of 1.0–2.0 percentage points over APOR for safe harbor QMs would have covered 83.3 to 94.1 percent of the conventional purchase market (as safe harbor QMs), while rate-spread thresholds of 1.5–2.5 percentage points over APOR for rebuttable presumption QMs would have covered 94.3 to 96.8 percent of the conventional purchase market (as safe harbor and rebuttable presumption QMs). As explained further in part V.B.5, the Bureau is providing in Table 7A revised estimates for the size of the QM market based on the higher thresholds for small loans and manufactured housing loans as adopted by this final rule and also to reflect a revised methodology to identify creditors eligible to originate loans as small creditors under § 1026.43(e)(5).

TABLE 7—PROPOSAL'S ESTIMATED SHARE OF 2018 CONVENTIONAL FIRST-LIEN PURCHASE LOANS WITHIN VARIOUS PRICE-BASED SAFE HARBOR (SH) QM AND REBUTTABLE PRESUMPTION (RP) QM DEFINITIONS

[HMDA data]

Approach	Safe harbor QM (share of conventional purchase market)	QM overall (share of conventional purchase market)
Temporary GSE QM + DTI 43	90.6	95.8
Proposal (SH 1.50, RP 2.00)	91.6	96.1
SH 0.75, RP 1.50	74.6	94.3
SH 1.00, RP 1.50	83.3	94.3
SH 1.25, RP 1.75	88.4	95.3
SH 1.35, RP 2.00	89.8	96.1
SH 1.40, RP 2.00	90.5	96.1
SH 1.75, RP 2.25	93.1	96.6
SH 2.00, RP 2.50	94.1	96.8

Despite the expected benefits of a price-based General QM loan definition, the proposal noted concerns about the definition. In particular, the Bureau acknowledged that while the Bureau believes a loan's price may be a more holistic and flexible measure of a consumer's ability to repay than DTI alone, the Bureau recognized that there is a distinction between credit risk, which largely determines pricing relative to the prime rate, and a particular consumer's ability to repay, which is one component of credit risk. The Bureau also acknowledged that factors unrelated to the individual loan (*e.g.,* institutional factors such as the competing policy considerations inherent in setting guarantee fees on GSE loans) can influence its price and that a price-based approach would incentivize some creditors to price some loans just below the threshold so that the loans will receive the presumption

[201] All estimates in Table 7 included loans that meet the Small Creditor QM loan definition in § 1026.43(e)(5). In particular, loans originated by small creditors that meet the criteria in § 1026.43(e)(5) are safe harbor QMs if priced below 3.5 percentage points over APOR or are rebuttable presumption QMs if priced 3.5 percentage points or more over APOR. The Bureau has provided revised analysis in part V.B.5 to reflect a revised methodology to identify creditors eligible to originate loans as small creditors under § 1026.43(e)(5).

of compliance that comes with QM status. The proposal also acknowledged concerns about the sensitivity of a price-based General QM loan definition to macroeconomic cycles and that a price-based approach would likely be pro-cyclical, with a more expansive QM market when the economy is expanding, and a more restrictive QM market when credit is tight. The Bureau discusses these concerns below in part V.B.5.

As noted above, stakeholders providing feedback prior to the General QM Proposal suggested a range of options the Bureau should consider to replace the 43 percent DTI limit in the General QM loan definition. These options are discussed at length in the proposal.[202] The Bureau considered these options in developing the proposal, but preliminarily concluded that the price-based approach in proposed § 1026.43(e)(2) would best achieve the statutory goals of ensuring consumers' ability to repay and maintaining access to responsible, affordable, mortgage credit. However, as explained in part V.B.3, below, the Bureau requested comment on whether an alternative approach that adopts a higher DTI limit or a hybrid approach that combines pricing and a DTI limit, along with a more flexible standard for defining income or assets and debts, could provide a superior alternative to the price-based approach.

The proposal also acknowledged that some stakeholders requested that the Bureau make the Temporary GSE QM loan definition permanent. The Bureau did not propose this alternative because of its concern that there is not a basis to presume for an indefinite period that loans eligible to be purchased or guaranteed by the GSEs—whether or not the GSEs are under conservatorship—have been originated with appropriate consideration of consumers' ability to repay.[203] The Bureau also expressed concern that making the Temporary GSE QM loan definition permanent could stifle innovation and competition in private-sector approaches to underwriting. The Bureau also expressed concern that, as long as the Temporary GSE QM loan definition continues in effect, the non-GSE private market is less likely to rebound and that the existence of the Temporary GSE QM loan definition may be contributing to the limited non-GSE private market. As explained above, the Extension Final Rule extended the Temporary GSE QM loan definition to expire on the mandatory compliance date of this final rule or when GSE conservatorship ends.

3. Alternative to the Proposed Price-Based General QM Loan Definition: Retaining a DTI Limit

Although the Bureau proposed to remove the 43 percent DTI limit and adopt a price-based approach for the General QM loan definition, the Bureau requested comment on an alternative approach that would retain a DTI limit, but raise it above the current limit of 43 percent, and provide a more flexible set of standards for verifying income or assets and debts in place of appendix Q. The Bureau requested comment on this alternative proposal because of concerns about the price-based approach. In particular, the Bureau acknowledged the sensitivity of a price-based QM definition to macroeconomic cycles, including concerns that the price-based approach could be pro-cyclical, with a more expansive QM market when the economy is expanding, and a more restrictive QM market when credit is tight. The Bureau was especially concerned about these potential effects given the recent economic disruptions associated with the COVID–19 pandemic. The Bureau also acknowledged that a small share of loans that satisfy the current General QM loan definition would lose QM status under the proposed price-based approach due to the loans' rate spread exceeding the applicable threshold. Further, and as described above, the Bureau analyzed the relationship between DTI ratios and early delinquency, using data on first-lien conventional purchase originations from the NMDB, including a matched sample of NMDB and HMDA loans. That analysis, as shown in Tables 3 and 4 above, shows that early delinquency rates increase consistently with DTI ratio. For these reasons, the Bureau requested comment on whether an approach that increases the DTI limit to a specific threshold within a range of 45 to 48 percent and that includes more flexible definitions of debt and income would be a superior alternative to a price-based approach.[204]

The Bureau also analyzed the potential effects of a DTI-based approach on the size of the QM market and on access to credit. As indicated in the proposal's Table 8, the proposal found that 2018 HMDA data show that with the Temporary GSE QM loan definition and the General QM loan definition with a 43 percent DTI limit, 90.6 percent of conventional purchase loans were safe harbor QMs and 95.8 percent were safe harbor QM or rebuttable presumption QMs. If, instead, the Temporary GSE QM loan definition were not in place along with the General QM loan definition (with the 43 percent DTI limit), and assuming no change in consumer or creditor behavior from the 2018 HMDA data, then the proposal found that only 69.3 percent of loans would have been safe harbor QMs and 73.6 percent of loans would have been safe harbor QMs or rebuttable presumption QMs. The proposal also noted that raising the DTI limit above 43 percent would increase the size of the QM market and, as a result, potentially increase access to credit relative to the General QM loan definition with a DTI limit of 43 percent. The proposal noted that the magnitude of the increase in the size of the QM market and potential increase in access to credit would depend on the selected DTI limit. A DTI limit in the range of 45 to 48 percent would likely result in a QM market that is larger than one with a DTI limit of 43 percent but smaller than the status quo (*i.e.,* Temporary GSE QM loan definition and DTI limit of 43 percent). However, the proposal noted the Bureau's expectation that consumers and creditors would respond to changes in the General QM loan definition, potentially allowing additional loans to be made as safe harbor QMs or rebuttable presumption QMs. As explained further in part V.B.5, the Bureau is providing in Table 8A revised analysis of the size of the QM market to reflect a revised methodology to identify creditors eligible to originate loans as small creditors under § 1026.43(e)(5).

[202] 85 FR 41716, 41736–37 (July 10, 2020).

[203] *Id.* at 41737. *See also* 78 FR 6408, 6534 (Jan. 13, 2013) (stating that the Bureau believed it was appropriate to presume that loans that are eligible to be purchased or guaranteed by the GSEs ''while under conservatorship'' have been originated with appropriate consideration of consumers' ability to repay ''in light of this significant Federal role and the government's focus on affordability in the wake of the mortgage crisis'').

[204] The Bureau acknowledged that some loans currently originated as Temporary GSE QMs have higher DTI ratios. However, the proposal expressed concern about adopting a DTI limit above a range of 45 to 48 percent without a requirement to consider compensating factors.

TABLE 8—PROPOSAL'S ESTIMATED SHARE OF 2018 CONVENTIONAL PURCHASE LOANS WITHIN VARIOUS SAFE HARBOR QM AND REBUTTABLE PRESUMPTION QM DEFINITIONS

[HMDA data]

Approach	Safe harbor QM (share of conventional market)	QM overall (share of conventional market)
Temporary GSE QM + DTI 43	90.6	95.8
Proposal (Pricing at 2.0)	91.6	96.1
DTI limit 43	69.3	73.6
DTI limit 45	76.1	80.9
DTI limit 46	78.8	83.8
DTI limit 47	81.4	86.6
DTI limit 48	84.1	89.4
DTI limit 49	87.0	92.4
DTI limit 50	90.8	96.4

The Bureau specifically requested comment on a specific DTI limit between 45 and 48 percent. The Bureau requested comment and data on whether increasing the DTI limit to a specific percentage between 45 and 48 percent would be a superior alternative to the proposed price-based approach, and, if so, on what specific DTI percentage the Bureau should include in the General QM loan definition. The Bureau requested comment and data as to how specific DTI percentages would be expected to affect access to credit and would be expected to affect the risk that the General QM loan definition would include loans that should not receive a presumption of compliance with TILA's ATR requirements. The Bureau also requested comment on whether increasing the DTI limit to a specific percentage between 45 to 48 percent would better balance the goals of ensuring access to responsible, affordable credit and ensuring that QM status is limited to loans for which it is appropriate to presume that consumers have the ability to repay. The Bureau also requested comment on the macroeconomic effects of a DTI-based approach, as well as whether and how the Bureau should weigh such effects in amending the General QM loan definition. In addition, the Bureau requested comment on whether, if the Bureau adopts a higher specific DTI limit as part of the General QM loan definition, the Bureau should retain the price-based threshold of 1.5 percentage points over APOR to separate safe harbor QMs from rebuttable presumption QMs for first-lien transactions.

The Bureau also requested comment on whether to adopt a hybrid approach in which a combination of a DTI limit and a price-based threshold would be used in the General QM loan definition. The proposal noted that one such approach could impose a DTI limit only for loans above a certain pricing threshold. Such an approach would be intended to reduce the likelihood that loans for which the consumer lacks ability to repay would receive a presumption of compliance with the ATR requirements, while avoiding the potential burden and complexity of a DTI limit for many lower-priced loans. The proposal explained that a similar approach might impose a DTI limit above a certain pricing threshold and also tailor the presumption of compliance with the ATR requirements based on DTI. For example, the proposal noted that the rule could provide that (1) for loans with rate spreads under 1 percentage point, the loan is a safe harbor QM regardless of the consumer's DTI ratio; (2) for loans with rate spreads at or above 1 but less than 1.5 percentage points, a loan is a safe harbor QM if the consumer's DTI ratio does not exceed 50 percent and a rebuttable presumption QM if the consumer's DTI is above 50 percent; and (3) if the rate spread is at or above 1.5 but less than 2 percentage points, the loan would be rebuttable presumption QM if the consumer's DTI ratio does not exceed 50 percent and a non-QM loan if the DTI ratio is above 50 percent.

The proposal explained another hybrid approach that would impose a DTI limit on all General QMs but would allow higher DTI ratios for loans below a set pricing threshold. For example, the rule could generally impose a DTI limit of 47 percent but could permit a loan with a DTI ratio up to 50 percent to be eligible for QM status under the General QM loan definition if the APR is less than 2 percentage points over APOR. This approach might limit the likelihood of providing QM status to loans for which the consumer lacks ability to repay, but also would permit some lower-priced loans with higher DTI ratios to achieve QM status.

With respect to the Bureau's concerns about appendix Q, the Bureau requested comment on an alternative method of defining debt and income to replace appendix Q in conjunction with a specific DTI limit. The Bureau expressed concern that the appendix Q definitions of debt and income are rigid and difficult to apply and do not provide the level of compliance certainty that the Bureau anticipated at the time of the January 2013 Final Rule. The proposal further noted that, under the current rule, some loans that would otherwise have DTI ratios below 43 percent do not satisfy the General QM loan definition because their method of documenting and verifying income or debt is incompatible with appendix Q. In particular, the Bureau requested comment on whether the approach in proposed § 1026.43(e)(2)(v) could be applied with a General QM loan definition that includes a specific DTI limit. As discussed in more detail in the section-by-section discussion of § 1026.43(e)(2)(v), proposed § 1026.43(e)(2)(v)(A) would have required creditors to consider the consumer's monthly DTI ratio or residual income; current or reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan; and debt obligations, alimony, and child support. Proposed § 1026.43(e)(2)(v)(B) and the associated commentary would have explained how creditors must verify and count the consumer's current or reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan and the consumer's current debt obligations, alimony, and child support, relying on the standards set forth in the ATR

requirements in § 1026.43(c). Proposed § 1026.43(e)(2)(v)(B) would have further provided creditors a safe harbor with standards the Bureau may specify for verifying debt and income, potentially including relevant provisions from the Fannie Mae Single Family Selling Guide, the Freddie Mac Single-Family Seller/Servicer Guide, FHA's Single Family Housing Policy Handbook, the VA's Lenders Handbook, and USDA's Field Office Handbook for the Direct Single Family Housing Program and Handbook for the Single Family Guaranteed Loan Program, current as of the proposal's public release. The Bureau also requested comments on potentially adding to the safe harbor other standards that external stakeholders develop.

The Bureau requested comment on whether the alternative method of defining debt and income in proposed § 1026.43(e)(2)(v)(B) could replace appendix Q in conjunction with a specific DTI limit. As noted above, the proposal expressed concern that this approach, which combines a general standard with safe harbors, may not be appropriate for a General QM loan definition with a specific DTI limit. The Bureau requested comment on whether the approach in proposed § 1026.43(e)(2)(v)(B) would address the problems associated with appendix Q and would provide an alternative method of defining debt and income that would be workable with a specific DTI limit. The Bureau requested comment on whether allowing creditors to use standards the Bureau may specify to verify debt and income—as would be permitted under proposed § 1026.43(e)(2)(v)(B)—as well as potentially other standards external stakeholders develop and the Bureau adopts, would provide adequate clarity and flexibility while also ensuring that DTI calculations across creditors and consumers are sufficiently consistent to provide meaningful comparison of a consumer's calculated DTI ratio to any DTI ratio threshold specified in the rule.

The Bureau also requested comment on what changes, if any, would need to be made to proposed § 1026.43(e)(2)(v)(B) to accommodate a specific DTI limit. For example, the Bureau requested comment on whether creditors that comply with manuals that have been revised but are substantially similar to the manuals specified above should receive a safe harbor, as the Bureau proposed. The Bureau also requested comment on its proposal to allow creditors to ''mix and match'' verification standards, including whether the Bureau should instead limit or prohibit such ''mixing and matching'' under an approach that incorporates a specific DTI limit. The Bureau requested comment on whether these aspects of the approach in proposed § 1026.43(e)(2)(v)(B), if used in conjunction with a specific DTI limit, would provide sufficient certainty to creditors, investors, and assignees regarding a loan's QM status and whether it would result in potentially inconsistent application of the General QM loan definition.

4. Comments on the Price-Based General QM Loan Definition

Numerous commenters supported the Bureau's proposal to move from a DTI-based General QM loan definition to one based on pricing. Commenters that supported the proposal included industry commenters, consumer advocate commenters, a research center commenter, joint industry and consumer advocate commenters, and two GSE commenters. Commenters who supported the proposed price-based approach generally supported the Bureau's rationale for the proposal, described in part V.B.2 above. With respect to measuring consumers' ability to repay, commenters supporting the proposal generally agreed with the Bureau's analysis showing that the price of a loan is strongly associated with its performance, measured by whether a consumer was 60 days or more past due during the first two years of the loan, and also agreed that price is a strong indicator of consumers' ability to repay.

A joint consumer advocate and industry comment letter generally supporting the proposal described its analysis of the relationship between delinquency rates and rate spread. The commenter's analysis used Fannie Mae Single-Family Loan Performance data and, like the Bureau's 2002–2008 delinquency analysis, approximated rate spreads using the sum of the mortgage interest rate and an estimated PMI premium, minus APOR. Unlike the Bureau's analysis, however, the commenter used a risk-based estimated PMI premium to approximate current PMI pricing practices. The commenter noted that using risk-based PMI pricing increases the variance of rate spread estimates for loans with PMI, such that low-risk consumers have lower premiums and high-risk borrowers have higher premiums. Like the Bureau's delinquency analysis, the joint commenter defined early delinquency as whether the consumer was ever 60 days delinquent during the first two years of the loan. The joint commenter's analysis looks at loans by rate spread, ranging from less than a 0.5 percentage point rate spread, up to 3.0 or more percentage points, in increments of 0.5 percentage points. The commenter provided results of this analysis for loans originated between 1999–2019, and also provided results for loans originated between 2013–2018. For both sets of loans, the analysis shows early delinquency rates rising with rate spread. For the 1999–2019 dataset, loans with rate spreads of less than 0.5 percentage points had an early delinquency rate of 1.0 percent, rising to 14.3 percent for rate spreads of 3 percentage points or more. For the 2013–2018 dataset, loans with rate spreads of less than 0.5 percentage points had an early delinquency rate of 0.5 percent, rising to 10.5 percent for rate spreads of 3 percentage points or more.

Similarly, a research center commenter generally supporting the proposal also provided analysis of loan performance by rate spread. The commenter looked at Fannie Mae Single-Family Loan Performance data and portfolio loans and loans in PLS channels in the Black Knight McDash database. The commenter measured loan performance by whether the consumer was ever 60 days or more delinquent, rather than by whether the consumer was 60 days or more delinquent in the first two years of the loan as in the Bureau's delinquency analysis. The commenter stated that its measure is more conservative in that it produces higher default rates. The commenter noted that its analysis found all measures of default to be highly correlated with rate spreads but also noted that defaults on loans originated after the financial crisis (defined by the commenter as 2013 to 2018 originations) are lower than for any other period in recent history. The commenter attributes this to improvements in mortgage underwriting. This commenter's analysis is discussed further below in the section-by-section analysis of § 1026.43(e)(2)(vi).

Some commenters supporting the proposal, including a research center and a joint consumer advocate and industry comment, argued that pricing is a stronger predictor of default than DTI. The joint consumer advocate and industry commenter noted that DTI is a particularly weak predictor of loan performance for near-prime loans. In support of that assertion, the commenter cited analysis finding that, for a thousand consumers with DTI ratios between 45 and 50 percent, only two additional consumers default compared to consumers with DTI ratios between 40 and 45 percent. That commenter also cited analysis showing that, for each year since 2011, the 90-day delinquency

rate for loans with DTI ratios over 45 percent is less than that for loans with DTI ratios between 30 percent and 45 percent. The commenter asserts that this is counterintuitive to the idea that higher DTI ratios are a sound predictor of default.

Some commenters supporting the proposed price-based approach, including several industry commenters, specifically agreed with the Bureau's observation that pricing is a more holistic measure of a consumer's financial capacity than DTI alone. Generally, these commenters agreed with the Bureau's observation that pricing considers a broader set of factors, which results in a strong measure of ability to repay that is more complete than a DTI-based definition. A joint consumer advocate and industry commenter asserted that a DTI limit would curtail access to credit for creditworthy consumers, such as those who have demonstrated the ability to handle debt by regularly paying rent or who have compensating factors permitting them to exceed a particular DTI cutoff. That commenter also asserted that there are considerable challenges to the measurement of DTI, especially the income component, which are accentuated for non-traditional and non-salary employees, including many entrepreneurs and gig workers.

Commenters supporting the price-based approach, including a GSE commenter, also agreed with the Bureau's assertion that the price-based approach would maintain access to responsible, affordable mortgage credit after the expiration of the Temporary GSE QM loan definition. A research center commenter estimated the overall effect of the proposed changes on QM lending volumes using 2019 HMDA data to determine the number of loans that would not have been QMs in 2019 under the current rule but would be QMs under the proposal (using the General QM pricing thresholds in the proposal). The commenter found that there were 346,376 such loans that would have gained QM status under the proposal. The commenter further found that 49,200 loans would have been QMs in 2019 under the current rule but would be non-QM loans under the proposal (*i.e.,* loans with DTI ratios of 43 percent or lower, but with pricing that exceeded the proposed rate-spread thresholds), resulting in a gain of approximately 297,000 QMs under the proposed thresholds. The commenter asserted that, while the creditors of these loans gaining QM status would receive legal protection due to the loans' QM status, the reduction in litigation risk would translate into better pricing for the consumer. A joint consumer advocate and industry commenter expressed concern about access to credit under a DTI-based approach, noting that ''higher DTI'' consumers above the threshold would likely pay substantially higher interest rates on potentially riskier products or may be unable to obtain financing. In support of that assertion, the commenter cited the Assessment Report findings that applicants for jumbo loans with DTI ratios above 43 percent (who were therefore ineligible for QMs under the General QM loan definition or the Temporary GSE QM loan definition) paid significantly higher interest rates and had reduced access to credit. The commenter further expressed concern that such effects would disproportionately affect low-income and low-wealth families, including families of color.

As compared to a DTI-based approach, some commenters indicated that the price-based approach would expand access to credit for certain underserved market segments, such as low-income and minority consumers. Conversely, some commenters, including a consumer advocate commenter, expressed concern that a price-based General QM loan definition would curtail access to credit to low-income and minority consumers. A research center commenter that supported the price-based approach also acknowledged that minority consumers are more likely to have higher rate spreads. This commenter stated that, for GSE loans, 6.2 percent and 5.0 percent of all purchase lending to Black and Hispanic households, respectively, had rate spreads above 1.5 percentage points, compared with 2 percent for non-Hispanic White households. The commenter stated that the disparity was wider in the non-GSE conventional channel, with 13.4 percent and 17.0 percent for Black and Hispanic households, respectively, compared with 5 percent for non-Hispanic White households. An industry commenter cited a 2019 study that found that, compared to similar borrowers, Hispanic and African-American borrowers are charged rates that are 7.9 basis points higher for purchase transactions and 3.6 basis points higher for refinance transactions by creditors using algorithmic-based pricing systems.[205] However, this commenter suggested that the Bureau address this access-to-credit concern by adjusting the rate-spread threshold. As discussed below, many commenters supporting the proposed price-based approach requested that the Bureau increase either the proposed safe harbor threshold, the threshold separating QMs from non-QM loans, or both, to further ensure continued access to credit, including for minority consumers. A consumer advocate commenter also cited the 2019 study referenced above.

Commenters supporting the proposed price-based approach also generally supported removing the 43 percent DTI limit and appendix Q. With respect to appendix Q, a consumer advocate commenter specifically asserted that, even if the Bureau retained and revised appendix Q, those revisions would quickly become antiquated. Consistent with the Bureau's rationale for the proposal, some commenters also cited the historical precedent for a price-based threshold in Regulation Z, including the existing QM safe harbor threshold. Some commenters noted that a price-based approach would be simple to implement because rate spreads are already required to be calculated for other regulatory purposes.

Although many commenters supported the overall shift from a DTI-based General QM loan definition to one based on pricing, numerous commenters opposed the price-based approach. These commenters include individual commenters, an academic commenter, a research center commenter, industry commenters, and some consumer advocate commenters. Some commenters asserted that a loan's price is not an adequate indicator of a consumer's ability to repay. For example, some commenters that opposed the price-based approach argued that creditors do not necessarily consider individual ability-to-repay factors in deciding on the price of loans they offer to the consumer, that price may vary across creditors for reasons unrelated to the consumer, and that the price-based approach may favor some creditors or business models over others. Some commenters critical of the proposal noted that a loan's price is set by reference to factors that are not specific to the consumer, in some instances including prohibited factors such as race, and therefore is an inappropriate basis for the General QM loan definition. Similarly, some commenters argued that price is an inadequate indicator of a consumer's ability to repay because price is based on credit risk (*i.e.,* risk of loss to the creditor or investor) rather than risk to the consumer. Some commenters

[205] Robert Bartlett *et al.,* Haas School of Business UC Berkeley, *Consumer Lending Discrimination in the FinTech Era* (2019), *https://faculty.haas.berkeley.edu/morse/research/papers/discrim.pdf.*

asserted that creditors do not price risk accurately, with some commenters citing the experience of loans made prior to the financial crisis as support for this concern. Some commenters, including a research center commenter, asserted that creditors would use the price-based approach to manipulate APOR or adjust their prices to fit just under the rate-spread thresholds.

A consumer advocate commenter argued that LTV ratios, which may be one component of pricing, cannot form the basis of the QM definition. This commenter cited TILA section 129C(a)(3), which provides that the consumer's equity in the dwelling or real property that secures repayment of the loan cannot be considered as a financial resource of the borrower in determining a consumer's ability to repay. The commenter argued that, by extension, LTV ratios also cannot legally form any part of the basis of the QM definition. That commenter further asserted that creditors' reliance on LTV ratios in setting price does not reflect consumers' ability to repay because (1) consumers with substantial equity are likely to pay their mortgage regardless of the impact it may have on their overall finances; (2) consumers with substantial equity may have the option to refinance or sell their home and are therefore unlikely to default and allow their home to go into foreclosure; and (3) even if a consumer with substantial equity does go into foreclosure, the lower the LTV ratio, the more likely the creditor will be able to recover the unpaid principal balance from sale proceeds. The commenter contends that because pricing a loan involves consideration of the consumer's equity, a price-based approach to defining QM is impermissible.

One research center commenter asserted that the price-based approach does not capture risk accurately and criticized the Bureau's delinquency analysis, which focuses on average early delinquency rates by rate spread and DTI bins. That commenter analyzed 2018 HMDA data, which is described in the Bureau's Tables 2 and 4 provided in the proposal and above, and servicer data from CoreLogic's Loan Level Markets Analytics dataset through 2019, using a risk assessment matrix developed by the commenter that combines LTV ratios, DTI ratios, and credit scores. The commenter's analysis replicated the Bureau's definition of early delinquency of 60 days past due during the first two years of the loan. The commenter found that, for loans with identical rate spreads, early delinquency rates vary with other characteristics like LTV ratios, DTI ratios, and credit scores. Similarly, for loans with similar risk levels based on the commenters' risk assessment matrix, the rate spreads vary greatly. The commenter asserts that this is evidence that price does not capture risk accurately. The commenter further argued that the price-based approach is less accurate in predicting the likelihood of default for higher-risk loans. The commenter asserted that some higher-risk loans may be cross-subsidized, and further noted that pricing can be influenced by whether the consumer shopped for a loan and by ''random luck.'' Analyzing Optimal Blue rate data from the 2013–2018 timeframe, the research center commenter contended that the price-based approach would have signaled that market-wide risk declined, whereas other measures, including DTI and other industry risk metrics, would have signaled the opposite.

A consumer advocate commenter asserted that the price-based approach would grant QM status to loans where a sizeable percentage of consumers lack ability to repay and would create heightened risk of foreclosure. The commenter cited to the Bureau's delinquency analysis in Table 1 (provided in the proposal and above) that looked at loans originated between 2002 and 2008 and shows an early delinquency rate of 13 percent for loans priced between 1.75 and 1.99 percentage points over APOR. The commenter also cited Urban Institute analysis of loans from 2001 to 2004 and 2005 to 2008 and pointed to loans priced between 1.51 and 2.0 percentage points over APOR having 90-day delinquency rates of 20.4 percent and 29.2 percent, respectively.[206] The commenter asserted that this undercuts the Bureau's theory that creditors accurately assess and price for risk throughout the business cycle and indicates that the proposal would extend a presumption of compliance with the ATR provisions to loans that are not affordable.

That consumer advocate commenter disagreed with the Bureau's analysis using 60-day delinquency rates during the first two years of the loan as a measure of ability to repay because the commenter asserted that consumers tend to forgo other expenses[207] and take extreme measures to make timely mortgage payments, even if the loan was not affordable at consummation. This commenter argued that TILA requires assessment of a consumer's ability to repay the mortgage and still meet other obligations and cover basic living expenses. The commenter argued that the fact that a consumer was not 60 days or more past due on their mortgage does not answer the question of whether the loan was affordable at consummation. The commenter requested that the Bureau examine correlations between mortgage originations and delinquencies on other types of credit obligations that are visible in credit reporting data to assess the extent to which mortgages at various price and DTI levels are consistent with an assessment of the consumer's ability to repay. That commenter further asserted that default has more to do with macroeconomic conditions than individual ability to repay.

An industry commenter asserted that the Bureau failed to examine the effect of a DTI limit on mortgage performance by property type. The commenter asserted that community association housing[208] is unique from other housing models in that homeowners are required to pay assessments for community operations and that consumers' DTI may increase if community association costs increase. The commenter provided analysis of the percentage of loans 180 days delinquent by DTI bin, using Fannie Mae Condominium Unit Mortgages from 2002–2008 and 2015–2019. The commenter asserted that the analysis shows that, within the sample, ''high DTI'' loans have higher 180-day delinquency rates and the difference in delinquency rate is significant. The commenter asserted that this is evidence that reasonable DTI requirements are important for condominium unit mortgages and urged the Bureau to

[206] See *supra* note 194.

[207] Among other things, the commenter cited a recent Experian consumer ''payment hierarchy'' study, which used samples of consumers at various points in time and with various combinations of credit obligations and observed the relative performance of the credit obligations for two years. The commenter pointed out that, with respect to the consumers observed from February 2018 to February 2020—the most recent cohort in the study—Experian found that among those consumers with a mortgage, auto loan, retail card, and general purpose credit card, 0.81 percent became 90 days delinquent on their mortgage, whereas 4.26 percent became 90 days delinquent on their bank card. The disparities were roughly the same for consumers with a mortgage, bank card, and personal loan. *See* Experian, *Consumer payment hierarchy by trade type: Time-series analysis* (July 2020), *http://images.go.experian.com/Web/ExperianInformationSolutionsInc/%7Ba6ad2c78-e1da-46eb-b97b-bf2d953ce38d%7D_Payment_Hierarchy_Report.pdf.* The commenter stated that this suggests that originating a mortgage where the consumer lacks a reasonable ability to repay may manifest in delinquencies on credit obligations other than the mortgage itself.

[208] The commenter collectively referred to homeowners associations, condominium associations, and housing cooperatives as ''community associations.''

study the relationship between high DTI ratios, property type, and delinquency prior to issuing the final rule or to expand its analysis to include property type as a variable in testing the effectiveness of pricing as a measure of ability to repay.

Some commenters, including a research center commenter, a consumer advocate commenter, and two academic commenters, raised concerns that the price-based approach would be pro-cyclical. Some commenters that criticized the proposal as pro-cyclical expressed concern that the price-based General QM loan definition could grant QM status to loans exceeding consumers' ability to repay during periods of economic expansion, lead to increased housing prices, and create systemic risk. Similarly, some commenters that criticized the proposed approach expressed concern that removing the DTI limit would remove a constraint on housing prices. These commenters generally asserted that increased housing prices could increase consumers' mortgage payments and thereby increase the likelihood that consumers would be unable to afford their loan. These commenters further asserted that increased housing prices would prevent some consumers from obtaining loans altogether. For these reasons, these commenters asserted that the price-based approach could have a negative effect on access to credit for some consumers. These commenters also asserted that the pro-cyclical nature of the price-based approach could disproportionately affect underserved borrowers, including minority consumers.

An academic commenter expressed concern that the Bureau's delinquency analysis does not reflect the full extent of rate compression. That commenter criticized the Bureau's delinquency analysis of 2002–2008 first-lien purchase originations in the NMDB (Tables 1, 3, and 5 in the proposal and above), asserting that the analysis incorrectly assumes that rate spreads remained constant during that seven year period. The commenter stated that the Bureau should analyze rate spreads and associated default risk by vintage year, citing analysis showing that rate spreads fell significantly between 2004 and 2006 and suggesting that the Bureau's analysis therefore underestimates early delinquency rates at the height of the subprime mortgage boom. The commenter also criticized the Bureau's delinquency analysis of 2018 HMDA data (Tables 2, 4, and 6 in the proposal and above) as not informative because they do not cover two full years and are not indicative of bubble conditions. Another academic commenter analyzed a dataset of primarily subprime loans that were securitized in private-label securitizations during the housing bubble of the 2000s. The commenter stated that, in that dataset, over half of the subprime loans made between 2003 to 2005 had rate spreads that would satisfy the proposed rate-spread test for QM status. The commenter asserts that the data show that pricing as a measure of ability to repay fails when there is a credit boom due to rate spread compression and urged the Bureau to retain a DTI limit and consider an LTV ratio requirement as well as part of the General QM loan definition.

Other commenters, including commenters that supported the proposed price-based approach, expressed concerns about fluctuations in rate spreads over time. An industry commenter and a research center commenter suggested that the Bureau evaluate the rate-spread thresholds periodically and on an as-needed basis to determine if adjustments to the thresholds may be necessary to accommodate changing market and economic conditions. These commenters cited the rapidly changing market conditions at the beginning of the COVID–19 pandemic as an example of why it may be necessary to periodically adjust rate spreads. A consumer advocate commenter urged the Bureau not to adopt a mechanism that would allow the Bureau to adjust the rate-spread thresholds in emergency situations without notice and comment rulemaking.

Some commenters that did not support the price-based approach argued that the approach would not achieve the Bureau's stated goals of maintaining access to responsible, affordable mortgage credit. A research center commenter cited the January 2013 Final Rule, including the General and Temporary GSE QM loan definitions, as pro-cyclically supporting the current home price boom by providing additional leverage to consumers to bid up home prices. The commenter stated that this disproportionately affects the housing markets for low-income households and entry-level homes, where the supply is the tightest and the increase in leverage has been the greatest. The commenter disagreed with the Bureau's assertion that a DTI limit would unduly restrict access to credit, as the commenter asserts that a DTI limit would provide friction during a housing boom, which would reduce demand and slow house price appreciation. The commenter stated that the proposed price-based approach would not achieve the Bureau's goal of expanding access to credit because it would be even more pro-cyclical, resulting in higher house price appreciation. The commenter asserted that the proposed price-based approach does not provide any friction to slow house price appreciation and would boost demand more than the current rule, including the Temporary GSE QM loan definition. The commenter stated that the average rate spread for 2018 GSE purchase loans was 0.51 basis points, and asserted that creditors can therefore loosen lending standards and increase rate spreads over the foreseeable future with the resulting loans remaining below the 1.5 percentage point safe harbor threshold. The commenter also noted concern that the proposal would lower the QM standard and fuel higher risk leverage.

Some commenters specifically expressed concerns that the proposed rule would disproportionately harm minority consumers. For example, one commenter asserted that by replacing the DTI requirement with a pricing threshold, the proposed rule would subject higher percentages of Black or Hispanic borrowers to higher default rates. Another commenter stated that the proposal would burden borrowers of color with higher mortgage costs without underwriting and repayment ability assessment protections. Some commenters suggested that the proposed rule is fundamentally flawed because it may subject minority borrowers to higher prices that are unrelated to their actual risk due to ongoing discrimination in the market. Commenters urged the Bureau to assess and empirically evaluate the extent to which there is fair lending risk created by and embedded in its proposed pricing thresholds for QMs before adopting any final rule. One commenter suggested the Bureau disaggregate its analysis to assess the extent to which, at any given price band (and especially at the margins), early delinquency rates are consistent for non-Hispanic White, Black, and Hispanic consumers.

Some commenters (including industry commenters, consumer advocate commenters, and two joint industry and consumer advocate commenters that supported the proposed price-based approach) expressed concern about the connection between the price-based General QM loan definition and fair lending laws, including the Equal Credit Opportunity Act [209] (ECOA) and the Fair Housing Act.[210] These commenters stated that pricing discrimination

[209] 15 U.S.C. 1691 *et seq.*

[210] 42 U.S.C. 3601 *et seq.*

contravenes the underlying tenet of the General QM Proposal that if a consumer is purely priced on the true level of risk and ability to repay, the rate charged to the consumer is an indicator of risk—in the event of discriminatory pricing on a prohibited basis, the rate charged to the consumer is not a true indicator of risk. The commenters urged the Bureau to (1) make clear that it will not tolerate pricing discrimination or other forms of bias in the lending process and (2) limit the ability of a financial institution to receive the QM safe harbor in instances where pricing discrimination has occurred. Some of these commenters asked the Bureau to articulate explicitly that the designation of a loan as a QM does not signify compliance with the Fair Housing Act, ECOA, or any other anti-discrimination law pertaining to mortgage lending. Other commenters further requested that the rule specifically condition a General QM's safe harbor status on compliance with ECOA. These commenters requested that the rule provide that a loan loses its QM safe harbor status if there is a confirmed instance of discriminatory pricing on a prohibited basis that is not self-reported and remedied by the creditor.

A research center commenter, as well as an individual commenter, argued that the proposed approach would disproportionately affect minority consumers, which the commenters asserted would be a violation of the Fair Housing Act. In particular, the commenters described analysis indicating that increased housing prices that occur during periods of economic expansion (which the commenters asserted would be exacerbated as a result of the price-based General QM loan definition) occur predominately in areas with lower-income consumers, with higher concentrations of minority consumers. The commenters further asserted that the price-based approach would stimulate greater availability of credit which, combined with increased home prices, would expose low-income households, especially minority consumers, to heightened risk of default through higher mortgage payments. The commenters asked the Bureau to implement a multi-factor approach that combines DTI ratio, LTV ratio, and credit score as the key regulatory component of the General QM loan definition. The commenters argued that this approach would narrow the differential in delinquency rates between Black or Hispanic consumers and non-Hispanic White consumers when compared to delinquency rates under the proposed price-based approach.

Most commenters that did not support the proposed price-based approach advocated for alternative approaches to the General QM loan definition, such as retaining a DTI-based definition, a hybrid approach based on DTI and pricing, or a multi-factor approach. Several commenters supported a DTI-based approach rather than an approach based on pricing. Some commenters, including an academic commenter, industry commenters, and consumer advocate commenters, asserted that DTI is more reflective of a consumer's ability to repay than a loan's price, which includes factors that are not related to the specific consumer. For example, an academic commenter argued that the rule should retain a DTI limit because a DTI limit is effective in containing default risk. This commenter asserted that the Bureau should increase the DTI limit above 43 percent, should further expand the DTI limit for GSE mortgage programs that have an established track record of safe loans, and should amend appendix Q to provide more flexible methods for determining DTI. Other commenters advocating for a DTI-based approach suggested that the Bureau raise the current 43 percent limit. An industry commenter advocating for a DTI-based approach suggested retaining the current 43 percent DTI limit. Another industry commenter suggested that the Bureau retain a DTI limit for General QMs and raise the threshold to 50 percent with compensating factors, such as allowances for lower LTV ratios and for verified assets. That commenter also suggested that residual income be permitted as a compensating factor for a high DTI ratio but did not favor allowing residual income as a substitute for a DTI determination. As described above, several commenters advocating for the price-based General QM loan definition criticized a DTI-based General QM loan definition.

Other commenters advocated for a hybrid approach to the General QM loan definition. Some commenters, including a consumer advocate commenter and industry commenters, advocated for an approach that would raise the DTI ratio limit and also would expand the General QM loan definition to include loans with higher DTI ratios if the loans are below a set pricing threshold. For example, an industry commenter suggested that the Bureau impose a DTI limit of 47 percent but allow a General QM to have a DTI ratio of up to 50 percent if the rate spread is less than 2 percentage points. Another industry commenter suggested a hybrid approach that would retain the current DTI-based approach for higher-priced loans. Commenters advocating for hybrid approaches generally asserted that such approaches would better balance ensuring consumers have the ability to repay with ensuring access to responsible, affordable mortgage credit than a General QM loan definition based on pricing alone. An industry commenter advocated for an alternative method of defining General QMs that would use a DTI limit of 45 to 48 percent, in addition to the price-based approach. As noted above, a research center commenter suggested the Bureau define General QMs by reference to a multi-factor approach that combines DTI ratio, LTV ratio, and credit score. Other commenters argued against hybrid approaches, including noting concerns about the complexity of such approaches and concerns generally related to retaining a specific DTI component to the rule.

Commenters also raised issues related to the timing of the rulemaking and the issuance of the final rule. Some consumer advocate commenters and an individual commenter requested that the Bureau pause the rulemaking in light of the COVID–19 pandemic. Consumer advocate commenters requesting the Bureau pause the rulemaking cited the turmoil and economic fallout from the pandemic and the rising calls for racial justice as reasons to pause the rulemaking. The individual commenter and consumer advocate commenters raising this issue suggested that the Bureau focus its efforts on assisting homeowners struggling due to the pandemic. An industry commenter asserted that the Bureau should extend the Temporary GSE QM loan definition while it undertakes a study of alternative measures to evaluate consumers' ability to repay, such as residual income or cash flow underwriting (*e.g.,* using bank account data that can identify the source and frequency of recurring deposits and payments and identify remaining disposable income).

An academic commenter stated that the Bureau should not address the Temporary GSE QM loan definition until the final resolution of the GSEs' status. That commenter also expressed concerns that the elimination of the Temporary GSE QM loan definition would set off a housing crisis by making homeownership unattainable for some consumers and risky for others if the GSEs respond to the elimination of the Temporary GSE QM loan definition by retreating from a substantial segment of the market. Another industry commenter expressed concern about the provision of the Temporary GSE QM

loan definition that provides that the definition expires with respect to a GSE when that GSE ceases to operate under conservatorship. The commenter recommended that the Bureau remove this conservatorship clause. The commenter noted that the status of the conservatorships is outside of the Bureau's control and stated that, if one or both conservatorships were to end on short notice, the sudden expiration of the Temporary GSE QM loan definition would create uncertainty in the market and reduce access to credit. The commenter stated that the Bureau should clarify in advance of the end of conservatorship what steps the Bureau would take with respect to the Temporary GSE QM loan definition if the conservatorships were to end.

A research center commenter suggested that the Bureau consider the proposed changes to the QM rule in conjunction with the more recent Seasoned QM Proposal. The commenter suggested that the Bureau should consider additional analysis to study the interplay between default rates, rate-spread thresholds, loan products, and seasoning periods. The commenter asserted that, to the extent the seasoning proposal has implications for the General QM loan definition (or vice versa), a combined evaluation of both proposals would be more accurate than assessing the proposals separately.

The Final Rule

The Bureau concludes that this final rule's bright-line pricing thresholds best balance consumers' ability to repay with ensuring access to responsible, affordable mortgage credit. The Bureau is amending the General QM loan definition because retaining the existing 43 percent DTI limit would reduce the size of the QM market and likely would lead to a significant reduction in access to responsible, affordable credit when the Temporary GSE QM definition expires. The Bureau continues to believe that General QM status should be determined by a simple, bright-line rule to provide certainty of QM status, and the Bureau concludes that pricing achieves this objective. Furthermore, the Bureau concludes that pricing, rather than a DTI limit, is a more appropriate standard for the General QM loan definition. While not a direct measure of financial capacity, loan pricing is strongly correlated with early delinquency rates, which the Bureau uses as a proxy for repayment ability. The Bureau concludes that conditioning QM status on a specific DTI limit would likely impair access to credit for some consumers for whom it is appropriate to presume their ability to repay their loans at consummation. Although a pricing limit that is set too low could also have this effect, compared to DTI, loan pricing is a more flexible metric because it can incorporate other factors that may also be relevant to determining ability to repay, including credit scores, cash reserves, or residual income. The Bureau concludes that a price-based General QM loan definition is better than the alternatives because a loan's price, as measured by comparing a loan's APR to APOR for a comparable transaction, is a strong indicator of a consumer's ability to repay and is a more holistic and flexible measure of a consumer's ability to repay than DTI alone.

Specifically, the final rule amends Regulation Z to remove the current 43 percent DTI limit and provides that a loan would meet the General QM loan definition in § 1026.43(e)(2) only if the APR exceeds APOR for a comparable transaction by less than 2.25 percentage points as of the date the interest rate is set. As described further below, the Bureau is finalizing a threshold of 2.25 percentage points, an increase from the proposed threshold of 2 percentage points, because the Bureau concludes that, for most first-lien covered transactions, a 2.25-percentage-point pricing threshold strikes the best balance between ensuring consumers' ability to repay and ensuring access to responsible, affordable mortgage credit. The final rule provides higher thresholds for loans with smaller loan amounts and for subordinate-lien transactions.[211] The final rule provides an increase from the proposed thresholds for some small manufactured housing loans to ensure continued access to credit.[212] The Bureau is preserving the current threshold separating safe harbor from rebuttable presumption QMs, under which a loan is a safe harbor QM if its APR exceeds APOR for a comparable transaction by less than 1.5 percentage points as of the date the interest rate is set (or by less than 3.5 percentage points for subordinate-lien transactions).

The final rule requires the creditor to consider the consumer's monthly DTI ratio or residual income. The final rule also requires the creditor to consider the consumer's current or reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan and the consumer's debt obligations, alimony, and child support, as described in the section-by-section analysis of § 1026.43(e)(2)(v)(A). The final rule removes appendix Q and, as described further below in the section-by-section analysis of § 1026.43(e)(2)(v)(B), provides creditors additional flexibility for defining the consumer's income or assets and debts. As discussed below, these amounts must be determined in accordance with § 1026.43(e)(2)(v)(B), which requires the creditor to verify the consumer's current or reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan and the consumer's current debt obligations, alimony, and child support. The final rule provides a safe harbor to creditors using verification standards the Bureau specifies. Under the final rule, this safe harbor includes relevant provisions from Fannie Mae's Single Family Selling Guide, Freddie Mac's Single-Family Seller/Servicer Guide, FHA's Single Family Housing Policy Handbook, the VA's Lenders Handbook, and the Field Office Handbook for the Direct Single Family Housing Program and Handbook for the Single Family Guaranteed Loan Program of the USDA, current as of the proposal's public release. However, creditors are not required to verify income and debt according to the standards the Bureau specifies. The final rule provides creditors with the flexibility to develop other methods of compliance with the verification requirements.

Consistent with the proposal, the Bureau is not amending the existing product-feature and underwriting

[211] These thresholds are discussed below in the section-by-section analysis of § 1026.43(e)(2)(vi)(B)–(F). Final § 1026.43(e)(2)(vi)(B) provides that, for first-lien covered transactions with loan amounts greater than or equal to $66,156 (indexed for inflation) but less than $110,260 (indexed for inflation), the APR may not exceed APOR for a comparable transaction as of the date the interest rate is set by 3.5 or more percentage points. Section 1026.43(e)(2)(vi)(C) provides that, for first-lien covered transactions with loan amounts less than $66,156 (indexed for inflation), the APR may not exceed APOR for a comparable transaction as of the date the interest rate is set by 6.5 or more percentage points. Section 1026.43(e)(2)(vi)(E) provides that, for subordinate-lien covered transactions with loan amounts greater than or equal to $66,156 (indexed for inflation), the APR may not exceed APOR for a comparable transaction as of the date the interest rate is set by 3.5 or more percentage points. Section 1026.43(e)(2)(vi)(F) provides that, for subordinate-lien covered transactions with loan amounts less than $66,156 (indexed for inflation), the APR may not exceed APOR for a comparable transaction as of the date the interest rate is set by 6.5 or more percentage points.

[212] Final § 1026.43(e)(2)(vi)(D) provides that, for first-lien covered transactions secured by a manufactured home with loan amounts less than $110,260 (indexed for inflation), the APR may not exceed APOR for a comparable transaction as of the date the interest rate is set by 6.5 or more percentage points.

requirements and limits on points and fees. The statutory QM protections prohibit certain risky loan terms and features that could increase the risk that loans would be unaffordable and also include limited underwriting criteria that overlap with some elements of the ATR requirements. However, the Bureau concludes, as it initially concluded in the January 2013 Final Rule, that the General QM criteria should include additional assurances of a consumer's ability to repay to ensure that loans that obtain QM status warrant a presumption of compliance with the ATR requirements. The Bureau also continues to believe that creditors should be able to determine whether individual mortgage transactions will be deemed QMs through a bright-line metric.

In the January 2013 Final Rule, the Bureau exercised its authority under TILA section 129C(b)(2)(A)(vi) to impose a specific DTI limit as part of the General QM loan definition. The Bureau concludes that retaining the existing 43 percent DTI limit after the Temporary GSE QM loan definition expires would significantly reduce the size of the QM market and likely would reduce access to responsible, affordable mortgage credit. For the reasons described in part V.B.1, the Bureau believes that many loans currently originated under the Temporary GSE QM loan definition would cost materially more or may not be made at all, absent changes to the General QM loan definition. In particular, based on 2018 data, the Bureau estimated in the proposal that, as a result of the General QM loan definition's 43 percent DTI limit, approximately 957,000 loans—16 percent of all closed-end first-lien residential mortgage originations in 2018—would be affected by the expiration of the Temporary GSE QM loan definition. These loans are currently originated as QMs due to the Temporary GSE QM loan definition but would not be originated under the current General QM loan definition, and might not be originated at all, if the Temporary GSE QM loan definition were to expire. An additional, smaller number of loans that currently qualify as Temporary GSE QMs may not fall within the General QM loan definition after expiration of the Temporary GSE QM loan definition because the method used for verifying income or debt would not comply with appendix Q.

After the Temporary GSE QM loan definition expires, the Bureau expects that many consumers with DTI ratios above 43 percent who would have received a Temporary GSE QM would instead obtain FHA-insured loans if the 43 percent DTI limit remained in place. The Bureau estimated in the proposal that, in 2018, 11 percent of Temporary GSE QMs with DTI ratios above 43 percent exceeded FHA's loan-amount limit.[213] Thus, the Bureau considers that at most 89 percent of loans that would have been Temporary GSE QMs with DTI ratios above 43 percent could move to FHA.[214] The Bureau expects that loans that would be originated as FHA loans instead of under the Temporary GSE QM loan definition generally would cost materially more for many consumers, and that some consumers offered FHA loans might choose not to take out a mortgage because of these higher costs. Some consumers with DTI ratios above 43 percent would be able to obtain loans in the private market. The number of loans absorbed by the private market would likely depend, in part, on whether actors in the private market would be willing to assume the legal or credit risk associated with funding loans—as non-QM loans or small-creditor portfolio QMs—that would have been Temporary GSE QMs (with DTI ratios above 43 percent)[215] and, if so, whether actors in the private market would offer more lower prices or better terms.[216] Finally, some consumers with DTI ratios above 43 percent who would have sought Temporary GSE QMs may make different choices, such as adjusting their borrowing to result in a lower DTI ratio, if the 43 percent DTI limit remained in place.[217] However, some consumers who would have sought Temporary GSE QMs (with DTI ratios above 43 percent) may not obtain loans at all.[218] For example, based on application-level data obtained from nine large lenders, the Assessment Report found that the January 2013 Final Rule eliminated between 63 and 70 percent of non-GSE eligible home purchase loans with DTI ratios above 43 percent.[219]

As described in the proposal and above, the Bureau is now adopting a price-based approach to replace the specific DTI limit in the General QM loan definition because the Bureau concludes that a loan's price, as measured by comparing a loan's APR to APOR for a comparable transaction, is a strong indicator of a consumer's ability to repay. A loan's price is not a direct measure of ability to repay, but the Bureau concludes that it is an effective indirect indicator for ability to repay. The Bureau's delinquency analysis, analysis provided by commenters, and other analysis published in response to the Bureau's requests for comment, provide strong evidence that rate spreads distinguish loans that are likely to have low early delinquency rates, and thus should receive a presumption of compliance with the ATR requirements, from loans that are likely to have higher rates of delinquency, which should not receive that presumption. The Bureau finds this to be the case across a range of datasets, time periods, loan types, measures of rate spread, and measures of delinquency.

The Bureau acknowledged in the proposal that there is significant debate over whether a loan's price, a consumer's DTI ratio, or another direct or indirect measure of a consumer's personal finances is a better predictor of loan performance, particularly when analyzed across various points in the economic cycle. Some commenters argued that DTI ratios are a better predictor of default than a loan's price and therefore provide a better indicator of a consumer's ability to repay. However, as noted in the proposal, the Bureau is not determining whether DTI ratios, a loan's price, or some other measure is the best predictor of loan performance. Rather, the Bureau sought to balance considerations related to ensuring consumers' ability to repay and maintaining access to responsible, affordable credit in selecting the price-based approach, consistent with the purposes of the ATR/QM provisions of TILA. As noted, the Bureau's delinquency analysis, along with other available evidence, provide strong evidence that rate spreads can distinguish loans that are likely to have low early delinquency rates from loans that are likely to have higher rates of early delinquency. Further, maintaining access to responsible, affordable mortgage credit after the expiration of the Temporary GSE QM loan definition is a critical policy goal, and the Bureau finds that the price-based approach would also further this goal.

The Bureau further concludes that the price-based approach is a more holistic and flexible measure of a consumer's ability to repay than DTI alone, as

[213] In 2018, FHA's county-level maximum loan limits ranged from $294,515 to $679,650 in the continental United States. *See* U.S. Dep't of Hous. & Urban Dev., *FHA Mortgage Limits, https://entp.hud.gov/idapp/html/hicostlook.cfm* (last visited Dec. 8, 2020).

[214] 84 FR 37155, 37159 (July 31, 2019).

[215] *See* 12 CFR 1026.43(e)(5) (extending QM status to certain portfolio loans originated by certain small creditors). In addition, section 101 of the Economic Growth, Regulatory Relief, and Consumer Protection Act, Public Law 115–174, 132 Stat. 1296 (2018), amended TILA to add a safe harbor for small creditor portfolio loans. *See* 15 U.S.C. 1639c(b)(2)(F).

[216] 84 FR 37155, 37159 (July 31, 2019).

[217] *Id.*

[218] *Id.*

[219] *See* Assessment Report, *supra* note 63, at 10–11, 117, 131–47.

described above and in the proposal. Mortgage underwriting, and by extension, a loan's price, generally includes an assessment of additional factors, such as credit scores and cash reserves, that might compensate for a higher DTI ratio and that might also be probative of a consumer's ability to repay. In contrast, the Bureau finds that a DTI limit may unduly restrict access to credit because it provides an incomplete picture of the consumer's financial capacity. In particular, and as described above, the Bureau concludes that conditioning QM status on a specific DTI limit would likely impair access to credit for some consumers for whom it is appropriate to presume ability to repay their loans at consummation. Further, and as described above in part V.B.2, there is inherent flexibility for creditors in a price-based QM definition, which will facilitate innovation in underwriting, including use of emerging research into alternative mechanisms to assess a consumer's ability to repay, such as cash flow underwriting. The Bureau concludes that the price-based approach best balances ability-to-repay considerations with ensuring continued access to responsible, affordable mortgage credit.

The Bureau is also concerned that including a specific DTI limit in the General QM loan definition would be in tension with the changes to the debt and income verification requirements in this final rule. As described in the section-by-section analysis of § 1026.43(e)(2)(v)(B) below, the Bureau is finalizing a revised approach for verifying debt and income in § 1026.43(e)(2)(v)(B) that provides flexibility for creditors to adopt innovative verification methods while also providing greater certainty that a loan has QM status. The revised verification approach allows creditors flexibility to use any reasonable verification method and criteria, provided that the creditor verifies debt and income using reasonably reliable third-party records. The final rule provides a safe harbor for creditors that use specific versions of manuals listed in commentary and provides that creditors also obtain a safe harbor if they ''mix and match'' the verification standards in those manuals, or use revised versions of the manuals that are ''substantially similar'' to the versions listed in the commentary. The Bureau is concerned that this verification approach, which provides flexibility to creditors in verifying debt and income, could create uncertainty if it were used in conjunction with a specific DTI limit. In particular, the Bureau is concerned that it could lead to disagreement among market participants over whether the DTI ratio for a given loan is above or below the limit and therefore whether the loan is a QM, which could complicate the sale of loans into the secondary market and disrupt access to credit. The Bureau has not identified verification approaches that, if used in conjunction with a specific DTI limit, would provide sufficient certainty to creditors, investors, and assignees regarding a loan's QM status and also provide flexibility to creditors in order to preserve access to responsible, affordable mortgage credit.

The Bureau also concludes that the price-based approach will ensure continued access to responsible, affordable mortgage credit after the expiration of the Temporary GSE QM loan definition. As described above, the proposal provided analysis of the potential effects on access to credit of a price-based approach to defining a General QM using 2018 HMDA data to estimate the percentage of conventional first-lien purchase loans within various price-based safe harbor and General QM thresholds. The Bureau has adjusted that analysis for the final rule to account for the final rule's higher pricing threshold for some small manufactured home loans, discussed below in the section-by-section analysis of § 1026.43(e)(2)(vi). The Bureau has also adjusted its analysis to reflect a revised methodology to identify creditors eligible to originate QMs as small creditors under § 1026.43(e)(5). Specifically, the Bureau lacks data on assets for certain non-depository creditors. The revised methodology estimates that such lenders have assets over $2 billion if their volume of 2018 HMDA originations not reported as sold exceeds $400 million. This revised methodology slightly reduces the estimated number of creditors eligible to originate QMs as small creditors as compared to the proposal's estimates. Specifically, a small number of non-depository creditors who primarily report loans as not sold (*e.g.,* several creditors that specialize in manufactured home lending) are now estimated to be ineligible to originate QMs as small creditors. These adjustments are all reflected in Table 7A. Table 7A also provides an estimate of the percentage of loans under the pricing thresholds of 1.5 percent above APOR (safe harbor) and 2.25 above APOR (rebuttable presumption) adopted in this final rule.

TABLE 7A—FINAL RULE'S SHARE OF 2018 CONVENTIONAL FIRST-LIEN PURCHASE LOANS WITHIN VARIOUS PRICE-BASED SAFE HARBOR (SH) QM AND REBUTTABLE PRESUMPTION (RP) QM DEFINITIONS

[HMDA data]

Approach	Safe harbor QM (share of conventional purchase market)	QM overall (share of conventional purchase market)
Temporary GSE QM + DTI 43	89.6	94.7
Final Rule (SH 1.50, RP 2.25)	91.3	96.3
SH 0.75, RP 1.50	74.2	93.9
SH 1.00, RP 1.50	83.1	93.9
SH 1.25, RP 1.75	88.1	95.0
SH 1.35, RP 2.00	89.6	95.8
SH 1.40, RP 2.00	90.2	95.8
SH 1.50, RP 2.00	91.3	95.8
SH 1.75, RP 2.25	92.8	96.3
SH 2.00, RP 2.50	93.9	96.6

As discussed further below, the Bureau is maintaining the current safe harbor threshold for QMs, such that a loan is a safe harbor QM if its APR does not exceed APOR for a comparable transaction by 1.5 percentage points or more as of the date the interest rate is set (or by 3.5 percentage points or more for subordinate-lien transactions). As

discussed in the section-by-section analysis of § 1026.43(e)(2)(vi)(A), the Bureau is adopting a threshold of 2.25 percentage points over APOR for transactions with a loan amount greater than or equal to $110,260 (indexed for inflation).[220] As shown in Table 7A, under these thresholds and using the 2018 HMDA data, 91.3 percent of conventional purchase loans would have been safe harbor QMs and 96.3 percent would have been safe harbor QMs or rebuttable presumption QMs.

As discussed above in part V.B.3, the Bureau also analyzed the potential effects of a DTI-based approach on the size of the QM market, as reflected in Table 8 in the proposal and above. For comparison, the Bureau has also adjusted that analysis to reflect the revised methodology, discussed above, to identify creditors eligible to originate QMs as small creditors under § 1026.43(e)(5). These adjustments are reflected in Table 8A.

TABLE 8A—FINAL RULE'S SHARE OF 2018 CONVENTIONAL PURCHASE LOANS WITHIN VARIOUS SAFE HARBOR QM AND REBUTTABLE PRESUMPTION QM DEFINITIONS (HMDA DATA) UNDER THE FINAL RULE

Approach	Safe harbor QM (share of conventional market)	QM overall (share of conventional market)
Temporary GSE QM + DTI 43	89.6	94.7
Final Rule (Pricing at 2.25)	91.3	96.3
DTI limit 43	68.9	73.1
DTI limit 45	75.7	80.5
DTI limit 46	78.5	83.5
DTI limit 47	81.1	86.3
DTI limit 48	83.8	89.1
DTI limit 49	86.7	92.2
DTI limit 50	90.5	96.3

As noted above, some commenters stated that the proposed price-based approach would expand access to credit for certain underserved market segments, such as low-income and minority consumers. At the same time, some commenters, including a consumer advocate commenter, expressed concern that a price-based approach would curtail access to credit for some low-income and minority consumers because these consumers are more likely to have mortgages with higher rate spreads. The Bureau concludes that the thresholds in the final rule best balance considerations related to ability to repay while retaining access to responsible, affordable mortgage credit, including for minority consumers. In particular, using 2018 HMDA data that was used in the proposal to estimate the size of the QM market under various pricing thresholds, the Bureau estimates that 96.8 percent of conventional purchase loans to minority consumers would receive QM status under the final rule, compared to 94.9 percent under the current rule with the Temporary GSE QM loan definition and the General QM loan definition with a DTI limit of 43 percent, or 67.9 percent under only a General QM loan definition with a DTI limit of 43 percent. Under the proposed price-based thresholds, 95.5 percent of conventional purchase loans to minority consumers would have received QM status.

Finally, the Bureau concludes that a price-based General QM loan definition will provide compliance certainty to creditors because they will be able to readily determine whether a loan is a General QM. As described above, creditors have experience with APR calculations due to the existing price-based regulatory requirements and for various other disclosure and compliance reasons under Regulation Z. Creditors also have experience determining the appropriate APOR for use in calculating rate spreads. As such, the Bureau concludes that the price-based approach will provide certainty to creditors regarding a loan's status as a QM.

The Bureau acknowledges that a small percentage of loans eligible for General QM status under the current rule would be ineligible for General QM status under the final rule. Specifically, those are loans with DTI ratios below 43 percent and that otherwise satisfy the current General QM loan definition that are priced above the rate-spread thresholds established by the final rule (*e.g.,* 2.25 percentage points or higher for a first lien transaction with a loan amount greater than or equal to $110,260 (indexed for inflation)). As described below in the Dodd-Frank Act section 1022(b) analysis, the Bureau expects that creditors may adjust the price of some of these loans to meet the General QM pricing thresholds under the final rule. For other loans, creditors may instead originate those loans as non-QM loans or under other QM definitions, including as FHA loans, although the Bureau acknowledges that consumers may pay higher costs for these loans. The Bureau further acknowledges that some consumers who would be eligible for a General QM under the current rule but not under the final rule's pricing thresholds may be unable to obtain a mortgage, although the Bureau expects that the number of such consumers will be small. As shown in Table 8A and discussed further below in the section-by-section analysis of § 1026.43(e)(2)(vi), the final rule represents an overall expansion of loans eligible for General QM status relative to the current definition. Further, and as the Bureau observed in the January 2013 rule, it is not possible to define by a bright-line rule a class of mortgages for which each consumer will have ability to repay.[221] The Bureau's decision to adopt a price-based approach reflects an appropriate balance of credit access and ability-to-repay considerations, taking into account the most efficient and effective means to ensure compliance.

[220] As discussed in the section-by-section analysis of § 1026.43(e)(2)(vi)(B)–(F), the Bureau proposed a loan amount threshold of $109,898 to align with the threshold for the limits on points and fees, as updated for inflation, in § 1026.43(e)(3)(i) and the associated commentary. On August 19, 2020, the Bureau issued a final rule adjusting the loan amounts for the limits on points and fees under § 1026.43(e)(3)(i), based on the annual percentage change reflected in the CPI–U in effect on June 1, 2020. 85 FR 50944 (Aug. 19, 2020). To ensure consistency, the Bureau is finalizing a loan amount threshold of $110,260 rather than a threshold of $109,898.

[221] *See* 78 FR 6408, 6511 (Jan. 30, 2013).

The Bureau also acknowledges comments suggesting that a test that combines rate spread and DTI may better predict early delinquency rates than either metric on its own. However, the Bureau's concerns about a DTI-based approach also apply to these hybrid approaches. The Bureau agrees with commenters asserting that hybrid approaches would be unduly complex and are not necessary given that price is also strongly correlated with loan performance, as described above. The Bureau also concludes that multi-factor approaches suggested by commenters are complex and unnecessary given that price is strongly correlated with loan performance.

One commenter criticized the price-based approach based on analysis showing that for loans with identical rate spreads, default occurrences vary, and for loans with similar default occurrences, the rate spreads vary greatly. The Bureau disagrees that such a finding shows that price is not an effective indicator of a consumer's ability to repay. The commenter's analysis shows that pricing and the commenter's preferred risk metric are both correlated with early delinquency, even when holding the other metric fixed. This only demonstrates that neither metric is perfectly correlated with early delinquency and that each metric is predictive of early delinquency independently of the other. The Bureau has concluded that pricing is an effective indicator of a consumer's ability to repay in part because it is strongly correlated with early delinquency, based on the Bureau's delinquency analysis and external analysis described above, recognizing that there is not a perfect correlation between price and early delinquency. However, there also is not a perfect correlation between early delinquency and DTI, nor between early delinquency and the alternative measures proposed by commenters. Because many different factors are correlated with early delinquency, the Bureau expects that, even at a fixed level of one potential measure of a consumer's ability to repay, early delinquency rates will still vary with other factors. While multi-factor approaches that incorporate additional variables may achieve higher correlations with early delinquency, such approaches are more complex and may involve greater prescriptiveness.

As noted above, a consumer advocate commenter expressed concern about the use of 60-day early delinquency rates in the first two years of a mortgage to measure ability to repay. That commenter raised concerns that mortgage payments may not be affordable but consumers may forgo paying other expenses so that they are able to continue making timely mortgage payments. The Bureau acknowledges that this may occur for some consumers, consistent with the Experian analysis cited by the consumer advocate commenter which showed that consumers with a mortgage and other credit obligations were less likely to be delinquent on their mortgage than on their other credit obligations.[222] However, the Bureau believes that, as a general matter, 60-day early delinquencies in the first two years is an appropriate metric to measure ability to repay. Moreover, the Bureau notes that an analysis provided by a research center commenter, described above, measured loan performance by whether the consumer was ever 60 days or more delinquent, rather than by reference to the two-year period used in the Bureau's delinquency analysis. The commenter noted that its analysis also found delinquency to be highly correlated with rate spreads, when delinquency is measured over the life of the loan.

As noted above, some comments asserted that pricing is not an appropriate QM criterion because it reflects risk of loss to the creditor and not the consumer's ability to repay the loan. The proposal recognized that there is a distinction between credit risk, which largely determines pricing relative to APOR, and a particular consumer's ability to repay, which is one component of credit risk. While a consumer's ability to afford loan payments is an important component of pricing, the loan's price will reflect additional factors related to the loan that may not in all cases be probative of the consumer's repayment ability. While the Bureau recognizes these concerns about a price-based approach, the Bureau's delinquency analysis and the analyses by external parties discussed above provide evidence that rate spreads are correlated with delinquency. Further, the Bureau notes that the final rule includes a requirement to consider the consumer's DTI ratio or residual income as part of the General QM loan definition, and to verify the debt and income used to calculate DTI or residual income. These requirements are discussed further below in the section-by-section analysis of § 1026.43(e)(2)(v)(A) and are included in the General QM loan definition to further ensure that, consistent with the purposes of TILA, creditors appropriately consider consumers' financial capacity and that consumers are thus offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loan.

Similarly, some commenters raised concerns that factors unrelated to the consumer, or the individual loan, can influence the price of a loan and that a price-based approach may be more consistent with some business models than others. Some commenters also raised concerns that a price-based approach is variable and that whether a consumer receives a General QM under the price-based approach may vary by creditor. While the Bureau acknowledges these criticisms of a price-based approach, the Bureau's delinquency analysis and the analyses by external parties discussed above provide evidence that rate spreads are correlated with delinquency, across a range of datasets, time periods, loan types, measures of rate spread, and measures of delinquency.

The Bureau also recognizes concerns that a price-based approach may incentivize some creditors to price some loans just below the threshold so that the loans will receive the presumption of compliance that comes with QM status. The proposal acknowledged that creditors are likely to react to the final rule by adjusting the price of some loans they offer to fall just below the threshold separating QMs from non-QM loans. To the extent creditors offer loans at lower prices to obtain QM status under the final rule, consumers will pay less for those loans. Those loans would also be subject to the QM product-feature restrictions and limits on points and fees, which would provide a benefit to consumers who might have otherwise received a non-QM loan that included a more risky product feature or included points and fees above the QM limits. The Bureau does not expect significant changes in loan pricing as a result of the safe harbor threshold, which exists under the current ATR/QM Rule. The Bureau points to research cited by some commenters, which suggests that, while creditors reacted to the safe harbor pricing threshold in the January 2013 Final Rule by reducing the share of higher-priced mortgages that they originated, the economic significance of the response was minor and did not materially affect the mortgage market at the time the rule took effect.[223]

The Bureau disagrees with the comment asserting that the price-based

[222] *See supra* note 207.

[223] Neil Bhutta & Daniel Ringo, *Effects of the Ability to Repay and Qualified Mortgage Rules on the Mortgage Market,* FEDS Notes, Bd. of Governors of the Fed. Reserve Sys. (2015), *https://www.federalreserve.gov/econresdata/notes/feds-notes/2015/effects-of-the-ability-to-repay-and-qualified-mortgage-rules-on-the-mortgage-market-20151229.html.*

approach is inappropriate because LTV ratios are a component of pricing. Nothing in the statutory text of TILA prohibits the Bureau from adopting the price-based approach. Indeed, TILA provides the Bureau with considerable flexibility to determine the appropriate criteria to define QM and to adjust the statutory QM requirements as necessary or proper to achieve Congress's objectives. The Bureau's authority with respect to defining QMs is discussed above in part IV. TILA section 129C(b)(2)(A)(vi) provides the Bureau with authority to establish guidelines or regulations relating to ratios of total monthly debt to monthly income or alternative measures of ability to pay regular expenses after payment of total monthly debt, taking into account the income levels of the borrower and such other factors as the Bureau may determine relevant and consistent with the purposes described in TILA section 129C(b)(3)(B)(i). TILA section 129C(b)(3)(B)(i) authorizes the Bureau to prescribe regulations that revise, add to, or subtract from the criteria that define a QM upon a finding that such regulations are necessary or proper to ensure that responsible, affordable mortgage credit remains available to consumers in a manner consistent with the purposes of TILA section 129C; or are necessary and appropriate to effectuate the purposes of TILA sections 129B and 129C, to prevent circumvention or evasion thereof, or to facilitate compliance with such sections. In addition, TILA section 129C(b)(3)(A) directs the Bureau to prescribe regulations to carry out the purposes of section 129C.

The Bureau finds that the price-based approach is consistent with this authority and with the purposes of TILA and section 129C's presumption of compliance with the ATR requirements for QMs. TILA sections 129B and 129C do not suggest that, in prohibiting creditors from considering the consumers' equity in the property securing the transaction as a financial resource to repay the loan, Congress intended to limit the Bureau's authority to impose loan pricing restrictions that, if incorporated into the QM definition, would provide sufficient assurance of the consumer's ability to repay. The Dodd-Frank Act amendments to TILA rely on pricing thresholds to distinguish between and among categories of QM and non-QM loans that should receive heightened consumer protections.[224] And, as described above, Dodd-Frank amendments to TILA in part codify and expand a pre-existing HOEPA regime that relied on pricing for similar purposes. Further, the Bureau notes that under this final rule creditors must consider the consumer's monthly DTI ratio or residual income; current or reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan; and debt obligations, alimony, and child support to satisfy the General QM loan definition.[225] In light of this requirement, including the exclusion of the value of the dwelling that secures the loan from the assets the creditor may consider for purposes of this requirement,[226] the Bureau concludes that the price-based approach is consistent with TILA section 129C(a)(3). For these reasons, and consistent with the statutory text, structure and purposes of the TILA, the Bureau concludes that it is an appropriate use of its authority to include a loan's price as one criterion to define General QMs.

With respect to commenters expressing concern about the sensitivity of a price-based General QM loan definition to macroeconomic cycles, the Bureau acknowledged this concern in the proposal. The proposal noted that periods of economic expansion, increasing house prices, and strong demand from consumers with weaker credit characteristics often lead to greater availability of credit. This is because as house prices increase, home equity also increases, and secondary market investors expect fewer losses accordingly. Even if a consumer were to default, increasing collateral values make it more likely that the investors would still recover the full amount of their investment. This increased likelihood of recovery may result in an underpricing of credit risk. To the extent such underpricing occurs, rate spreads over APOR would compress and additional higher-priced, higher-risk loans would fit within the proposed General QM loan definition. Further, the proposal recognized that, during periods of economic downturn, investors' demand for mortgage credit may fall as they seek safer investments to limit losses in the event of a broader economic decline. This may result in creditors reducing the availability of mortgage credit to riskier borrowers, through credit overlays and price increases, to protect against the risk that creditors may be unable to sell the loans profitably in the secondary markets, or even sell the loans at all. The proposal recognized that, while APOR would also increase during periods of economic stress and low secondary market liquidity, consumers with riskier credit characteristics may see disproportionate pricing increases relative to the increases in a more normal economic environment. These effects would likely make price-based QM standards pro-cyclical, with a more expansive QM market when the economy is expanding, and a more restrictive QM market when credit is tight. As a result, a rate spread-based QM threshold would likely be less effective than a binding DTI limit in deterring risky loans during periods of strong housing price growth or encouraging safe loans during periods of weak housing price growth. As described above, some commenters to the proposal highlighted these concerns and argued that the Bureau should not finalize the price-based approach due to potential systemic risks. However, the Bureau notes that a binding DTI limit risks restricting access to affordable credit relative to this final rule. The Bureau concludes that the advantages of the price-based approach in providing a flexible and holistic indicator of ability to repay outweigh the macroeconomic cycle concerns as considerations toward ensuring the availability of responsible, affordable mortgage credit. In addition, the Bureau believes that the QM product feature restrictions, the consider and verify requirements, and the final rule's special rule for ARMs mitigate some concerns regarding the pro-cyclical risks during economic expansions.

As noted, a commenter expressed concern that the Bureau's delinquency analysis does not reflect the full extent of rate compression. That commenter argued that the Bureau should analyze rate spreads and associated default risk by vintage year, citing analysis showing that rate spreads fell significantly between 2004 and 2006 and suggesting that the Bureau's analysis therefore may not capture potential declines in the correlation between price and early delinquency rates at the height of the subprime mortgage boom. With respect to this comment, the Bureau recognizes, as stated above, that there is not a

[224] *See, e.g.,* TILA section 129C(b)(2)(C) (establishing distinct points-and-fees thresholds for QMs based on loan pricing); section 129C(c)(ii) (establishing price-based restrictions on QMs permitted to impose prepayment penalties).

[225] *See* section-by-section analysis of § 1026.43(e)(2)(v)(A).

[226] In the January 2013 Final Rule, the Bureau exercised its authority under TILA section 105(a) to provide, in the context of the ATR provisions in § 1026.43(c)(2)(i), that a creditor may not look to the value of the dwelling that secures the covered transaction in assessing the consumer's repayment ability, instead of providing that a creditor may not look to the consumer's equity in the dwelling, as provided in TILA section 129C(a). The Bureau adopted this approach to provide broader protections to consumers. *See* 78 FR 6408, 6463–64 (Jan. 30, 2013).

perfect correlation between pricing and early delinquency rates. However, the Bureau has concluded that pricing is strongly correlated with early delinquency, based on the Bureau's delinquency analysis, external analysis described in the proposal, and analysis provided by commenters, which cover a wide range of years and economic conditions.[227] With respect to other commenters that expressed concerns about fluctuations in rate spreads over time, the Bureau recognizes that overall market spreads expand and tighten over time, as described above.[228] The Bureau concludes the pricing thresholds in the final rule provide the best balance between ability-to-repay considerations and ensuring access to responsible, affordable mortgage credit. The Bureau further notes that it monitors changing market and economic conditions and it could consider changes to the thresholds if circumstances warrant.

With respect to commenters that expressed concern about the connection between the price-based General QM loan definition and fair lending laws, including ECOA and the Fair Housing Act, the Bureau recognizes that some creditors may violate Federal fair lending laws by charging certain borrowers higher prices on the basis of race or national origin compared to non-Hispanic White borrowers with similar credit characteristics, and the Bureau reaffirms its commitment to consistent, efficient, and effective enforcement of Federal fair lending laws.[229] The Bureau further emphasizes that the General QM loan definition, as amended by this final rule, does not create an inference or presumption that a loan satisfying the General QM loan definition is compliant with any Federal, State, or local anti-discrimination laws that pertain to lending. A creditor has an independent obligation to comply with ECOA and Regulation B, and an effective way for a creditor to minimize and evaluate fair lending risks under these laws is by monitoring their policies and practices and implementing effective compliance management systems. The Bureau declines to amend the ATR/QM Rule to provide that a loan loses its QM safe harbor status if there is a confirmed instance of discriminatory pricing on a prohibited basis that is not self-reported and remedied by the creditor.

The Bureau disagrees with commenters who assert that the price-based General QM loan definition does not advance fair lending. As noted above, the Bureau concludes that conditioning QM status on a specific DTI limit may impair access to responsible, affordable credit for some consumers for whom it might be appropriate to presume ability to repay their loans at consummation. Specifically, using a bright-line DTI ratio threshold may have an adverse impact on responsible access to credit, including for low-to-moderate-income and minority homeowners. As discussed above, a price-based General QM loan definition is better than the alternatives because a loan's price, as measured by comparing a loan's APR to APOR for a comparable transaction, is a strong indicator of a consumer's ability to repay and is a more holistic and flexible measure of a consumer's ability to repay than DTI alone. The Bureau therefore expects that this final rule will improve access to credit for low-to-moderate-income and minority homeowners, without the unnecessary complexity of hybrid or multi-factor alternatives urged by some commenters.

With respect to the comment that provided analysis of loan performance for loans secured by condominiums and urged the Bureau to study the relationship between high DTI ratios, property type, and delinquency prior to issuing the final rule or expand its delinquency analysis to include property type as a variable, the Bureau declines to undertake that further analysis at this time. As described above, the Bureau has concluded that pricing is strongly correlated with early delinquency and is concerned that a DTI limit may have an adverse impact on responsible access to credit. The Bureau also notes that fees and special assessments imposed by a condominium, cooperative, or homeowners association are mortgage-related obligations that must be included in the calculation of the consumer's debt-to-income or residual income for purposes of § 1026.43(e)(2)(v)(A) and therefore are incorporated into the General QM loan definition. Further, mortgage creditors often account for the property type when pricing a mortgage, and the rate-spread threshold would thus capture any differential risk for such loans that is reflected in their price. However, the Bureau will monitor the effects of the General QM final rule to determine if future changes are necessary to ensure continued access to responsible, affordable credit, including for particular property types such as condominiums.

The Bureau also declines to eliminate the conservatorship clause of the Temporary GSE QM loan definition. As explained in the Extension Final Rule, when the Bureau adopted the January 2013 Final Rule, the FHFA's conservatorship of the GSEs was central to its willingness to presume that loans that are eligible for purchase, guarantee, or insurance by the GSEs would be originated with appropriate consideration of consumers' ability to repay.[230] If the GSEs are not under conservatorship, the Bureau is concerned about presuming that loans eligible for purchase or guarantee by either of the GSEs have been originated with appropriate consideration of the consumer's ability to repay.

With respect to the comment that expressed concern about the expiration of the Temporary GSE QM loan definition in light of the current GSE loan market, the Bureau anticipates that the final rule will preserve access to credit relative to the status quo. In particular, the Bureau concludes the General QM loan definition's pricing thresholds included in this final rule, in conjunction with the debt and income verification provisions in § 1026.43(e)(2)(v)(B), will ensure continued access to responsible, affordable mortgage credit, including for loans that have historically been eligible for purchase by the GSEs. With respect to the comment suggesting the Bureau consider evaluating changes to the General QM loan definition and the Seasoned QM Proposal at the same time, the Bureau has considered the expected effects of both proposals and is issuing rules on both of these topics at the same time.

[227] While the Bureau's conclusion on the strong correlation between pricing and early delinquency is based on its own delinquency analysis in this final rule, an Urban Institute analysis cited by a commenter also showed a positive correlation between pricing and rate spread during the years 2005 to 2008, largely covering the market conditions present during the subprime mortgage boom. *See supra* note 194.

[228] With respect to the commenter who presented analysis of subprime loans from the 2000s housing boom and asserted that the data show that pricing as a measure of ability to repay fails when there is a credit boom due to rate spread compression, the Bureau notes that it is unclear from the analysis whether these loans would have also satisfied the QM product feature restrictions and limits on points and fees, or how the performance of the loans varied with rate spreads.

[229] *See, e.g.,* Consent Order, *U.S.* v. *Bancorpsouth Bank,* No. 1:16–cv–00118, ECF No. 8 (N.D. Miss.) (July 25, 2016), *https://files.consumerfinance.gov/f/documents/201606_cfpb_bancorpSouth-consent-order.pdf* (joint action for discriminatory mortgage lending practices including charging African-American customers for certain mortgage loans more than non-Hispanic White borrowers with similar loan qualifications).

[230] 78 FR 6408, 6534 (Jan. 13, 2013) (stating that the Bureau believed it was appropriate to presume that loans that are eligible to be purchased or guaranteed by the GSEs ''while under conservatorship'' have been originated with appropriate consideration of consumers' ability to repay ''in light of this significant Federal role and the government's focus on affordability in the wake of the mortgage crisis'').

C. The QM Presumption of Compliance Under a Price-Based General QM Loan Definition

To address potential uncertainty regarding the reasonableness of some ability-to-repay determinations, all QMs provide creditors with a presumption of compliance with the ATR requirements. Lower-priced QMs provide a conclusive presumption of compliance (*i.e.,* a safe harbor) whereas higher-priced QMs provide a rebuttable presumption of compliance.[231] The proposal would have preserved the current § 1026.43(b)(4) pricing threshold that generally separates safe harbor QMs from rebuttable presumption QMs, such that a loan is a safe harbor QM if its APR exceeds APOR for a comparable transaction by less than 1.5 percentage points as of the date the interest rate is set (or by less than 3.5 percentage points for subordinate-lien transactions).[232]

1. Considerations Related to the Safe Harbor Threshold

As stated in the proposal, in developing the approach to the presumptions of compliance for QMs in the January 2013 Final Rule, the Bureau first considered whether the statute prescribes if QMs receive a conclusive or rebuttable presumption of compliance with the ATR provisions. As discussed above in part II.A, TILA section 129C(b) provides that loans that meet certain requirements are ''qualified mortgages'' and that creditors making QMs ''may presume'' that such loans have met the ATR requirements. However, the statute does not specify whether the presumption of compliance means that the creditor receives a conclusive presumption or a rebuttable presumption of compliance with the ATR provisions. The Bureau noted that its analysis of the statutory construction and policy implications demonstrates that there are sound reasons for adopting either interpretation.[233] The Bureau concluded that the statutory language is ambiguous and does not mandate either interpretation and that the presumptions should be tailored to promote the policy goals of the statute.[234] The Bureau interpreted the statute to provide for a rebuttable presumption of compliance with the ATR provisions but used its adjustment and exception authority to establish a conclusive presumption of compliance for loans that are not ''higher-priced covered transactions.'' [235]

In the January 2013 Final Rule, the Bureau identified several reasons why loans that are not higher-priced loans (generally prime loans) should receive a safe harbor. The Bureau noted that the fact that a consumer receives a prime rate is itself indicative of the absence of any indicia that would warrant a loan-level price adjustment, and thus is suggestive of the consumer's ability to repay.[236] The Bureau noted that prime rate loans have performed significantly better historically than subprime loans and that the prime segment of the market has been subject to fewer abuses.[237] The Bureau noted that the QM requirements will ensure that the loans do not contain certain risky product features and are underwritten with careful attention to consumers' DTI ratios.[238] The Bureau also noted that a safe harbor provides greater legal certainty for creditors and secondary market participants and may promote enhanced competition and expand access to credit.[239] The Bureau determined that if a loan met the product and underwriting requirements for QM and was not a higher-priced covered transaction, there are sufficient grounds for concluding that the creditor satisfied the ATR provisions.[240]

The Bureau in the January 2013 Final Rule pointed to factors to support its decision to adopt a rebuttable presumption for QMs that are higher-priced covered transactions. The Bureau noted that QM requirements, including the restrictions on product features and the 43 percent DTI limit, would help prevent the return of the lax lending practices of some lenders in the years before the financial crisis, but that it is not possible to define by a bright-line rule a class of mortgages for which each consumer will have ability to repay, particularly for subprime loans.[241] The Bureau noted that subprime pricing is often the result of loan-level price adjustments established by the secondary market and calibrated to default risk.[242] The Bureau also noted that consumers in the subprime market tend to be less sophisticated and have fewer options and thus are more susceptible to predatory lending practices.[243] The Bureau noted that subprime loans have performed considerably worse than prime loans.[244] The Bureau therefore concluded that QMs that are higher-priced covered transactions would receive a rebuttable presumption of compliance with the ATR provisions. The Bureau recognized that this approach could increase by a modest amount the litigation risk for subprime QMs but did not expect that imposing a rebuttable presumption for higher-priced QMs would have a significant impact on access to credit.[245]

2. The Bureau's Proposal

The safe harbor threshold. The Bureau did not propose to alter the approach in the current ATR/QM Rule, under current § 1026.43(b)(4) and (e)(1)(i), of providing a conclusive presumption of compliance with the ATR requirements (*i.e.,* a safe harbor) to loans that meet the General QM requirements in § 1026.43(e)(2) and for which the APR exceeds the APOR by less than 1.5 percentage points (or by less than 3.5 percentage points for subordinate-lien loans).[246] In the proposal, when discussing the safe harbor threshold, the Bureau restated its preliminary conclusion that pricing is strongly correlated with loan performance and that pricing thresholds should be included in the General QM loan definition in § 1026.43(e)(2). The Bureau also preliminarily concluded that for prime loans, the pricing, in conjunction with the revised QM requirements in proposed § 1026.43(e)(2), provides sufficient grounds for supporting a conclusive presumption that the creditor complied with the ATR requirements. The Bureau further noted that, under the proposed price-based approach, creditors would be required to consider DTI or residual income for a loan to satisfy the requirements of the General QM loan definition. The Bureau also stated that a safe harbor for prime QMs appears to be supported by the better performance of prime loans compared to subprime loans, and by the potential benefits of greater competition and access to credit from the greater certainty and reduced litigation risk arising from a safe harbor.

[231] As discussed in the section-by-section analysis of § 1026.43(e)(2)(vi) below, this final rule provides that loans with an APR exceeding the APOR by 2.25 percentage points or more (or exceeding higher thresholds for certain small or subordinate-lien loans) are not eligible for General QM status under § 1026.43(e)(2). Unless otherwise eligible for QM status (such as under § 1026.43(e)(5) or § 1026.43(f)), for non-QM loans a creditor must make a reasonable and good faith determination of the consumer's ability to repay and does not receive a presumption of compliance.

[232] Subordinate-lien transactions are discussed below in the section-by-section analysis of § 1026.43(e)(2)(vi).

[233] 78 FR 6408, 6507 (Jan. 30, 2013).

[234] *Id.* at 6511.

[235] *Id.* at 6514.

[236] *Id.* at 6511.

[237] *Id.*

[238] *Id.*

[239] *Id.*

[240] *Id.*

[241] *Id.*

[242] *Id.*

[243] *Id.*

[244] *Id.* at 6511.

[245] *Id.* at 6511–13.

[246] Subordinate-lien transactions are discussed below in the section-by-section analysis of § 1026.43(e)(2)(vi).

The Bureau tentatively concluded that the current safe harbor threshold of 1.5 percentage points for first liens restricts safe harbor QMs to lower-priced, generally less risky, loans while ensuring that responsible, affordable credit remains available to consumers. The Bureau stated its general belief that these same considerations support not changing the current safe harbor threshold of 3.5 percentage points for subordinate-lien transactions, which generally perform better and have stronger credit characteristics than first-lien transactions. The Bureau's proposal to address subordinate-lien transactions is discussed further below in the section-by-section analysis of § 1026.43(e)(2)(vi). For the reasons discussed below, this final rule is maintaining the current safe harbor thresholds in current § 1026.43(b)(4) and (e)(1)(i).

Rebuttable Presumption QMs. The proposal generally would have maintained the current ATR/QM Rule's rebuttable presumption of compliance with the ATR requirements for loans that exceed the safe harbor threshold but that otherwise meet the General QM requirements in § 1026.43(e)(2).[247] The Bureau did not propose to revise § 1026.43(e)(1)(ii)(B), which defines the grounds on which the presumption of compliance that applies to higher-priced QMs can be rebutted. Section 1026.43(e)(1)(ii)(B) provides that a consumer may rebut the presumption by showing that, at the time the loan was originated, the consumer's income and debt obligations left insufficient residual income or assets to meet living expenses. The analysis considers the consumer's monthly payments on the loan, mortgage-related obligations, and any simultaneous loans of which the creditor was aware, as well as any recurring, material living expenses of which the creditor was aware. The Bureau stated in the January 2013 Final Rule that this standard was sufficiently broad to provide consumers a reasonable opportunity to demonstrate that the creditor did not have a good faith and reasonable belief in the consumer's repayment ability, despite meeting the prerequisites of a QM. At the same time, the Bureau stated that it believed the standard was sufficiently clear to provide certainty to creditors, investors, and regulators about the standards by which the presumption can successfully be rebutted in cases in which creditors have met the QM requirements. The Bureau also noted that the standard was consistent with the standard in the 2008 HOEPA Final Rule.[248] Commentary to that rule provides, as an example of how its presumption may be rebutted, that the consumer could show ''a very high debt-to-income ratio and a very limited residual income . . . depending on all of the facts and circumstances.''[249] The Bureau noted that, under the definition of QM that the Bureau was adopting, the creditor was generally not entitled to a presumption if the consumer's DTI ratio was ''very high.'' As a result, the Bureau focused on the standard for rebutting the presumption in the January 2013 Final Rule on whether, despite meeting a DTI test, the consumer nonetheless had insufficient residual income to cover the consumer's living expenses.[250]

The Bureau did not propose to change the standard for rebutting the presumption of compliance with the ATR requirements and stated its belief that the existing standard continues to balance consumer protection and access-to-credit considerations. For example, the Bureau did not propose amending the presumption of compliance to provide that the consumer may use the DTI ratio to rebut the presumption of compliance by establishing that the DTI ratio is very high, or by establishing that the DTI ratio is very high and that the residual income is not sufficient. First, the Bureau tentatively determined that permitting the consumer to rebut the presumption by establishing that the DTI ratio is very high is not necessary because the existing rebuttal standard already incorporates an examination of the consumer's actual income and debt obligations (*i.e.,* the components of the DTI ratio) by providing the consumer the option to show that the consumer's residual income—which is calculated using the same components—was insufficient at consummation. Accordingly, the Bureau anticipated that the addition of a DTI ratio to the rebuttal standard would not add probative value beyond the current residual income test in § 1026.43(e)(1)(ii)(B). Second, the Bureau anticipated that the addition of a DTI ratio as a ground to rebut the presumption of compliance would undermine compliance certainty to creditors and the secondary market without providing any clear benefit to consumers. The Bureau tentatively determined that the rebuttable presumption standard would continue to be sufficiently broad to provide consumers a reasonable opportunity to demonstrate that the creditor did not have a good faith and reasonable belief in the consumer's repayment ability, despite meeting QM standards. The Bureau did not receive comments regarding the grounds on which the presumption of compliance can be rebutted.

3. Comments on the Safe Harbor Threshold

The Bureau received several comments concerning the proposed 1.5-percentage-point safe harbor threshold. A joint comment from consumer advocates stated that, if the Bureau finalizes a price-based approach, the proposed threshold should not be increased. A GSE commenter supported the 1.5-percentage-point threshold and stated it would be equally supportive if the Bureau increases the threshold. Various commenters, including a research center and several consumer advocate and industry commenters, specifically recommended increasing the safe harbor threshold to 2 percentage points. Commenters generally acknowledged that delinquency rates for safe harbor QMs would increase as the pricing threshold increases but expressed differing views on whether the proposed threshold should nonetheless be increased to expand access to credit.

A joint comment from consumer advocates generally objected to a price-based approach but specifically stated that increasing the safe harbor threshold would not significantly increase access to credit. The joint comment stated that the ATR/QM Rule's 1.5-percentage-point threshold is consistent with the Board's 2008 HOEPA Final Rule, which offered only a rebuttable presumption—not a safe harbor—for loans priced 1.5 percentage points or more above APOR. The joint comment stated that in markets with less competition, including minority communities, creditors routinely face no downward pressure on prices and will charge consumers more than they would in a more competitive market. The joint comment stated that, in less competitive markets, the current 1.5-percentage-point safe harbor threshold has

[247] However, as discussed in the section-by-section analysis of § 1026.43(e)(2)(vi) below, under the proposal a loan would not have been eligible for QM status (*i.e.,* would not receive any presumption of compliance with the ATR requirements) under § 1026.43(e)(2) if the loan exceeded the separate pricing thresholds in proposed § 1026.43(e)(2)(vi).

[248] 78 FR 6408, 6512 (Jan. 30, 2013).

[249] *See* Regulation Z comment 34(a)(4)(iii)–1.

[250] 78 FR 6408, 6511–12 (Jan. 30, 2013). The Bureau in the January 2013 Final Rule stated that it interpreted TILA section 129C(b)(1) to create a rebuttable presumption of compliance with the ATR requirements, but exercised its adjustment authority under TILA section 105(a) to limit the ability to rebut the presumption because the Bureau found that an open-ended rebuttable presumption would unduly restrict access to credit without a corresponding benefit to consumers. *Id.* at 6514.

benefited consumers by providing some downward pressure on prices. Notwithstanding such creditor reticence to price loans beyond the safe harbor threshold, the joint comment stated that there has not been an actual difference in litigation risk (*i.e.,* for rebuttable presumption QMs versus safe harbor QMs) that would reasonably justify increasing the threshold. The joint comment further stated that increasing the safe harbor pricing threshold would not expand consumers' access to credit but instead would facilitate creditors raising prices to take advantage of less competitive markets and result in the same consumers obtaining the same loans but at higher prices.

A research center generally objected to a price-based approach but also stated that increasing the safe harbor threshold would not have a significant impact on access to credit. Based on 2018 loan data, the commenter stated that the current pricing threshold has relatively little impact on originating rebuttable presumption QMs priced 1.5 percentage points or more above APOR. Moreover, the commenter stated that even for rebuttable presumption QMs, litigation risk would be significantly reduced by the proposed rule's income and debt verification safe harbor, as discussed in the section-by-section analysis of § 1026.43(e)(2)(v)(B).

Various commenters, including a research center and multiple consumer advocate and industry commenters, specifically recommended increasing the safe harbor threshold to 2 percentage points, arguing that it would achieve a better balance of ability to repay with access to credit. Several of those commenters referenced the research center's analysis of Fannie Mae and Black Knight McDash data and stated that a 2-percentage-point threshold would increase the delinquency rate for safe harbor QMs. However, that subset of commenters argued that the analysis showed that the increased delinquency rate would nonetheless remain low relative to delinquency rates experienced in the past 20 years. Those commenters stated that addressing access-to-credit concerns with a 2-percentage-point threshold would therefore strike an appropriate balance with ability-to-repay concerns. One consumer advocate commenter stated that delinquency rate improvement, relative to the Great Recession, is largely due to the effects of the Dodd-Frank Act, which has helped ensure stronger product protections, better underwriting, and improved income, employment, and asset verification and documentation. Citing an FHFA working paper that was also cited in the General QM Proposal,[251] a joint comment from consumer advocate and industry groups stated that loans with non-QM features—including interest-only loans, ARM loans that combined teaser rates with subsequent large jumps in payments, negative amortization loans, and loans made with limited or no documentation of the borrower's income or assets—accounted for about half of the rise in risk leading up to the 2008 financial crisis and subsequent passage of the Dodd-Frank Act. Given that the delinquency rate would be low on a relative basis, these commenters stated that addressing access-to-credit concerns with a 2-percentage-point threshold would strike an appropriate balance with ability-to-repay concerns.

Multiple consumer advocate and industry commenters stated that, in contrast to safe harbor QMs, creditors generally are less willing to make rebuttable presumption QMs. These commenters stated that their unwillingness to make rebuttable presumption QMs is evidenced by 2019 HMDA data showing that less than 5 percent of conventional, first-lien purchase loans were priced 1.5 percentage points or more above APOR.[252] Citing Board economists' analysis of 2014 HMDA data,[253] a joint comment from consumer advocate and industry groups stated that creditors reduced the share of higher-priced mortgages that they originated in response to the ATR/QM Rule. A research center stated that, based on 2019 HMDA data, increasing the safe harbor threshold to 2 percentage points would have replaced 75,265 rebuttable presumption QMs with safe harbor QMs instead. The research center stated that, because safe harbor QMs would provide those loans' creditors with greater protection from litigation than rebuttable presumption QMs, it suspects that the reduction in litigation risk would result in better pricing for consumers. The research center, as well as multiple consumer advocate and industry commenters, stated that increasing the safe harbor threshold to 2 percentage points would improve access to credit by reducing racial and ethnic disparities while helping increase lending volumes for every racial and ethnic group.

Several industry commenters elaborated on how rebuttable presumption QMs present more litigation risk to creditors than safe harbor QMs. One commenter stated that—even if a creditor has, in fact, made a reasonable and good faith determination of a consumer's repayment ability at the time of consummation—a creditor could still find itself in court providing evidentiary proof should a consumer challenge a rebuttable presumption QM. As a general matter, another commenter stated that—even if a defendant ultimately prevails in court—legal determinations regarding ''reasonableness'' are expensive to defend as they often require time-consuming litigation, extensive discovery, and possibly a trial. Another commenter stated that—even among creditors that would ultimately prevail in court—some creditors will choose the expense of settling with plaintiffs, rather than incurring the greater expense of paying a legal team to continue defending in court. The commenter stated that the safe harbor's conclusive presumption of compliance is necessary to stop meritless ability-to-repay litigation as early as possible in the legal process and to eliminate the settlement value of such litigation. These industry commenters each stated that increasing the safe harbor threshold to 2 percentage points would help address the negative effect that litigation risk has on access to credit.

Various commenters, including a research center and multiple consumer advocate and industry commenters, stated that increasing the safe harbor threshold in the Bureau's ATR/QM Rule to 2 percentage points would create a more level playing field between conventional and FHA lending. These commenters stated that FHA's own QM rule provides creditors with a safe harbor if the loan's APR is no more than APOR plus the FHA annual mortgage insurance premium plus 115 basis points. These commenters further stated that the current FHA annual mortgage insurance premium is 85 basis points, such that the FHA's QM rule effectively has a 2-percentage-point-over-APOR threshold. Some comments, including one from a consumer advocate commenter and a joint comment from consumer advocate and industry groups, stated that the Bureau's current 1.5-percentage-point safe harbor threshold has the effect of steering consumers, including minority consumers, to FHA loans rather than conventional loans

[251] Davis *et al., supra* note 179.

[252] Bureau of Consumer Fin. Prot., *Data Point: 2019 Mortgage Market Activity and Trends* (June 2020), *https://files.consumerfinance.gov/f/documents/cfpb_2019-mortgage-market-activity-trends_report.pdf* (4.6 percent of conventional, first-lien loans for purchasing one-to-four-family, owner-occupied, site-built homes). As explained in the Assessment Report, because of their nearly identical definitions, HMDA data regarding higher-priced mortgage loans (HPMLs) may serve as a proxy for higher-priced covered transactions under the ATR/QM Rule.

[253] *See* Bhutta & Ringo, *supra* note 223.

and thus limits consumer choice among lenders and product offerings. Those comments further stated that a smaller pool of lenders originate FHA loans and that in 2019 there were approximately 3,200 HMDA reporting lenders for conventional purchase loans versus approximately 1,200 HMDA reporting lenders for FHA purchase loans.

Various commenters, including a research center and multiple consumer advocate and industry commenters, also stated that rate spreads fluctuate over time and recommended that this final rule increase pricing thresholds as a buffer to absorb the pricing impact of future market changes. In particular, regarding FHFA's GSE capital rule,[254] these commenters stated that it would require GSEs to maintain more capital as a precaution against riskier loans in their portfolio (*i.e.,* risk-based capital requirements). These commenters stated that they expect spreads over APOR will likely increase for riskier borrowers as a result of the FHFA's rule. The research center also stated that spreads for refinance loans could widen relative to APOR in response to the additional loan-level price adjustment of 50 basis points on most Fannie Mae and Freddie Mac refinances, effective December 1, 2020. However, an industry commenter stated that such changes also affect APOR itself, which adds further uncertainty regarding the actual magnitude of any future changes to spreads over APOR.

4. The Final Rule

For the reasons discussed below, as proposed, the Bureau is maintaining the current safe harbor threshold in § 1026.43(b)(4), such that a loan is a safe harbor QM under § 1026.43(e)(1) if its APR does not exceed APOR for a comparable transaction by 1.5 percentage points or more as of the date the interest rate is set (or by 3.5 percentage points or more for subordinate-lien transactions).[255] The Bureau concludes that maintaining the current 1.5-percentage-point threshold, in conjunction with the revised General QM requirements in proposed § 1026.43(e)(2), addresses access-to-credit concerns while striking an appropriate balance with ability-to-repay concerns.

The Bureau declines to extend the safe harbor to loans priced 1.5 percentage points or more above APOR given that such loans have higher delinquency rates and have, since the January 2013 Final Rule took effect, received a rebuttable presumption of compliance with the Bureau's ATR/QM rule with no evidence to suggest that the 1.5-percentage-point line has caused a significant disruption of access to responsible, affordable mortgage credit. Further, since the Board's 2008 rule, loans priced above the current 1.5-percentage-point threshold have been subject to an ability-to-repay requirement that is substantially similar to the rebuttable presumption standard for QMs under the Bureau's ATR/QM Rule. Consistent with one of the research center comments discussed above, HMDA data analyzed by the Bureau in the Assessment Report suggest that the safe harbor threshold of 1.5 percentage points has not constrained creditors, as the share of originations above the safe harbor threshold remained steady after the implementation of the ATR/QM Rule.[256] In response to various commenters above who stated that less than 5 percent of conventional, first-lien purchase loans were priced 1.5 percentage points or more above APOR, the Bureau is unaware of reliable data evidencing that the low lending levels at higher rate spreads are caused by the 1.5 percentage point safe harbor threshold as opposed to other factors. Regarding the Board economists' analysis of 2014 HMDA data cited by a joint comment from consumer advocate and industry groups, the Bureau notes that the researchers ''provide evidence in this note that lenders responded to the ATR and QM rules, particularly by favoring loans priced to obtain safe harbor protections,'' but ''the estimated magnitudes indicate the rules did not materially affect the mortgage market in 2014.'' [257] In response to commenters recommending that the Bureau increase the current 1.5-percentage-point safe harbor threshold to create a more level playing field between conventional and FHA lending, the Bureau reiterates that no evidence has been presented to suggest that the existing safe harbor threshold under the Bureau's ATR/QM Rule has caused any significant disruption of access to responsible, affordable mortgage credit. Moreover, the Bureau is balancing access-to-credit concerns with concerns about ability to repay as measured by early delinquency rates.

In declining to provide a conclusive (rather than a rebuttable) QM presumption of compliance for loans priced above the current 1.5-percentage-point threshold, the Bureau concludes that such loans have higher delinquency rates and that access-to-credit concerns do not outweigh those ability to repay concerns.[258] For example, Table 1 shows for 2002–2008 loans a 12 percent early delinquency rate for loans priced 1.50 to 1.74 percentage points above APOR, as compared to a 10 percent early delinquency rate for loans priced 1.25 to 1.49 percentage points above APOR. The comparable early delinquency rates for 2018 loans from Table 2 also show a higher early delinquency rate for loans priced 1.50 to 1.99 percentage points above APOR compared to loans priced 1.00 to 1.49 percentage points above APOR: 2.7 percent versus 1.7 percent.

In response to comments recommending that the Bureau increase the safe harbor threshold to account for possible future rate spread widening in the market, including in response to FHFA's GSE capital rule that was recently finalized and the additional loan-level price adjustment of 50 basis points on most Fannie Mae and Freddie Mac refinances, effective December 1, 2020, the Bureau concludes that it would be premature to increase the safe harbor threshold based on possible future spread widening in the market. For example, as discussed by an industry commenter above, such changes may also affect APOR itself, which would cause uncertainty regarding the actual magnitude of any future changes to spreads over APOR. Moreover, while it is possible that future spread widening could result in some safe harbor QMs instead becoming rebuttable presumption QMs, the Bureau concludes there is insufficient evidence to suggest that shifts in QMs' status from safe harbor to rebuttable presumption due to future spread widening would have a significant impact on access to responsible, affordable mortgage credit.[259] However,

[254] Fed. Hous. Fin. Agency, *Enterprise Regulatory Capital Framework Final Rule* (2020), *https://www.fhfa.gov/SupervisionRegulation/Rules/Pages/Enterprise-Regulatory-Capital-Framework-Final-Rule.aspx* (Final Rule currently available on the FHFA website and awaiting **Federal Register** publication).

[255] Subordinate-lien transactions are discussed below in the section-by-section analysis of § 1026.43(e)(2)(vi).

[256] Assessment Report, *supra* note 63, section 5.5, at 187.

[257] *See* Bhutta & Ringo, *supra* note 223.

[258] As discussed in the section-by-section analysis of § 1026.43(e)(2)(vi)(A) below, this final rule generally provides that, for transactions that are covered by § 1026.43(e)(2)(vi)(A) and priced greater than or equal to 1.5 but less than 2.25 percentage points above APOR, the transaction receives a rebuttable QM (rather than a conclusive QM) presumption of compliance with the ATR requirements.

[259] As discussed in the section-by-section analysis of § 1026.43(e)(2)(vi)(A) below, this final rule generally provides that, for transactions that are covered by § 1026.43(e)(2)(vi)(A) and priced greater than or equal to 1.5 but less than 2.25 percentage

the Bureau will monitor the market and take action as needed to maintain the best balance between consumers' ability to repay and access to responsible, affordable mortgage credit.

As discussed above in part V.B.4, several commenters generally objected to a price-based approach, but the Bureau did not receive comments requesting a lower safe harbor threshold if the Bureau finalizes a price-based approach. In maintaining and not lowering the current 1.5 percentage point safe harbor threshold, the Bureau concludes that there is some uncertainty as to what the consequences would be for the market and consumers with loans that would be safe harbor QMs under the existing rule but rebuttable presumption QMs under a lower safe harbor threshold. Since it took effect, the Bureau's ATR/QM Rule has provided a safe harbor to loans priced below the 1.5-percentage-point threshold—and such loans were never subject to the ability-to-repay requirements in the Board's 2008 HOEPA Final Rule. The 1.5-percentage-point threshold in the Bureau's ATR/QM Rule is the same as that used in the Board's 2008 HOEPA Final Rule. When the Bureau established the safe harbor in the January 2013 Final Rule, the Bureau stated that the ''line the Bureau is drawing is one that has long been recognized as a rule of thumb to separate prime loans from subprime loans'' and, ''under the existing regulations that were adopted by the Board in 2008, only higher-priced mortgage loans are subject to an ability-to-repay requirement. . . .'' [260] Thus, the January 2013 Final Rule stated that ''investors will likely require creditors to agree to . . . representations and warranties when assigning or selling loans under the [Bureau's] new rule'' and, for loans with rate spreads less than 1.5 percentage points, ''this may represent an incremental risk of put-back to creditors, given that such loans are not subject to the current [2008 HOEPA Final Rule] regime, but those loans are being provided a safe harbor if they are qualified mortgages.'' [261] In contrast, for loans with rate spreads of 1.5 percentage points or more, the Bureau stated that ''it is not clear that there is any incremental risk beyond that which exists today under the Board's rule.'' [262] The Bureau's January 2013 Final Rule further stated that there is ''a widespread fear about the litigation risks associated with the Dodd-Frank Act ability-to-repay requirements,'' [263] and that the safe harbor for loans with rate spreads less than 1.5 percentage points helps ensure that ''litigation and secondary market impacts do not jeopardize access to credit.'' [264] As discussed above, there is also concern among some commenters on the General QM Proposal regarding rebuttable presumption QMs presenting more litigation risk to creditors than safe harbor QMs.

Based on the Bureau's analysis of the 2018 NMDB data, the Bureau expects that the early delinquency rate of loans obtaining safe harbor QM status under this final rule will be on par with loans obtaining safe harbor QM status under the current rule, which includes the Temporary GSE QM loan definition. Table 6 shows the early delinquency rate for 2018 NMDB first-lien purchase originations by rate spread and DTI ratio. For loans with rate spreads between 1 and 1.49 percentage points and DTI ratios above 43 percent, the early delinquency rate is 2.3 percent. These are loans that would not meet the current General QM loan definition due to the 43 percent DTI limit, but that would receive safe harbor General QM status under this final rule. If the 2018 data are restricted to only those loans purchased and guaranteed by the GSEs (*i.e.,* loans made under the Temporary GSE QM loan definition), loans with DTI ratios above 43 percent and rate spreads between 1 and 1.49 percentage points had an early delinquency rate of 2.4 percent.

The Bureau acknowledges that removing the 43 percent DTI limit will lead to somewhat higher-risk loans obtaining safe harbor QM status relative to loans within the current General QM loan definition (not including the Temporary GSE QM loan definition). In Table 5, the Bureau compared projected early delinquency rates for 2002–2008 first-lien purchase originations under the General QM loan definition with and without a 43 percent DTI limit under a range of potential rate-spread based safe harbor thresholds. Under the current 43 percent DTI limit for first-lien General QMs, Table 5 indicates that early delinquency rates for loans with rate spreads just below 1.5 percentage points increase with DTI ratio, from 6 percent for loans with a DTI ratio of 20 percent or below to 11 percent for loans with DTI ratios from 41 to 43 percent. For loans with rate spreads just below 1.5 percentage points and DTI ratios above 43 percent, Table 5 indicates early delinquency rates between 12 percent (for loans with 44 to 45 percent DTI ratios) and 15 percent (for loans with DTI ratios of 61 to 70 percent). Therefore, the loans with DTI ratios above 43 percent that would be granted safe harbor status under the price-based approach at a safe harbor threshold of 1.5 percentage points are likely to have a somewhat higher early delinquency rate than those just at or below 43 percent DTI ratios, 12 to 15 percent versus 11 percent. The comparable early delinquency rates for 2018 loans from Table 6 also show a slightly higher early delinquency rate for loans with rate spreads just below 1.5 percentage points with DTI ratios above 43 percent compared to loans with DTI ratios of 36 to 43 percent: 2.3 percent versus 1.5 percent. However, as noted above, if the 2018 data are restricted to loans made under the Temporary GSE QM loan definition, such loans with DTI ratios above 43 percent and rate spreads between 1 and 1.49 percentage points had an early delinquency rate of 2.4 percent. Thus, the Bureau expects that the early delinquency rate of loans obtaining safe harbor QM status under this final rule will be on par with loans obtaining safe harbor QM status under the current rule, which includes the Temporary GSE QM loan definition.

The Bureau concludes that the safe harbor threshold under this final rule strikes the best balance between ability-to-repay risk and the access-to-credit benefits discussed above and the overall safety of the prime QM market relative to the subprime market. As discussed by commenters above, loans that meet the General QM loan definition are relatively low-risk compared to loans with non-QM features. In response to commenters and based on findings in the Assessment Report, the Bureau concludes that loans with non-QM features—including interest-only loans, negative amortization loans, and loans made with limited or no documentation of the borrower's income or assets—had a substantial negative effect on consumers' ability to repay leading up to the 2008 financial crisis and subsequent passage of the Dodd-Frank Act.

In maintaining and not lowering the current 1.5-percentage-point safe harbor threshold as part of this final rule, the Bureau also acknowledges that the January 2013 Final Rule relied in part on the 43 percent DTI limit to support its conclusion that a 1.5 percentage-

points above APOR, the transaction receives a rebuttable QM (rather than a conclusive QM) presumption of compliance with the ATR requirements. The Bureau concludes that a General QM eligibility threshold lower than 2.25 percentage points could unduly limit some consumers to non-QM or FHA loans with materially higher costs, or no responsible, affordable loan at all, given the current lack of a robust non-QM market.

[260] 78 FR 6408, 6513 (Jan. 30, 2013).

[261] *Id.* at 6512–13.

[262] *Id.* at 6513.

[263] *Id.* at 6505.

[264] *Id.* at 6513.

point safe harbor threshold is appropriate. However, as discussed above, the 43 percent DTI limit was only one of several supporting factors listed in the January 2013 Final Rule.[265] Moreover, the January 2013 Final Rule did not include a DTI limit for Temporary GSE QMs but nonetheless provided both those loans and General QMs with the same 1.5-percentage-point safe harbor threshold. The January 2013 Final Rule stated that, ''even in today's credit-constrained market, approximately 22 percent of mortgage loans are made with a debt-to-income ratio that exceeds 43 percent'' and ''many of those loans will fall within the temporary exception that the Bureau is recognizing for qualified mortgages.'' [266] Further, as discussed in the section-by-section-analysis of § 1026.43(e)(2)(v)(A), this final rule imposes requirements for the creditor to consider the consumer's DTI ratio or residual income, income or assets other than the value of the dwelling, and debts to satisfy the General QM loan definition, thus requiring that the creditor consider key aspects of the consumer's financial capacity.[267]

With respect to General QM prime first-lien loans (General QM first-lien loans with an APR that does not exceed APOR by 1.5 or more percentage points), the Bureau concludes that it is appropriate to use its adjustment authority under TILA section 105(a) to retain a conclusive presumption (*i.e.,* a safe harbor). The Bureau concludes this approach strikes the best balance between the competing consumer protection and access-to-credit considerations described above. The Bureau concludes these same considerations support not changing the current safe harbor threshold of 3.5 percentage points for subordinate-lien transactions, which generally perform better and have stronger credit characteristics than first-lien transactions.[268] The Bureau also concludes that providing a safe harbor for prime first-lien and subordinate-lien loans is necessary and proper to facilitate compliance with and to effectuate the purposes of section 129C and TILA, including to assure that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loans.

In addition, the Bureau also is also relying on TILA section 129C(b)(3)(B)(i), which authorizes the Bureau to prescribe regulations that revise, add to, or subtract from the criteria that define a QM, as authority for retaining a conclusive presumption. For the same reasons outlined above, the Bureau concludes that this conclusive presumption is necessary or proper to ensure that responsible, affordable mortgage credit remains available to consumers in a manner consistent with the purposes of TILA section 129C, as well as necessary and appropriate to effectuate the purposes of TILA section 129C and facilitate compliance with section 129C.

The final rule generally maintains the current ATR/QM Rule's rebuttable presumption of compliance for loans that exceed the safe harbor threshold but that otherwise meet the General QM requirements in § 1026.43(e)(2).[269] The Bureau is not revising § 1026.43(e)(1)(ii)(B), which defines the grounds on which the presumption of compliance that applies to higher-priced QMs can be rebutted. The Bureau did not receive comments regarding the grounds on which borrowers can rebut the presumption of compliance. The Bureau concludes that existing § 1026.43(e)(1)(ii)(B) continues to strike the best balance between consumer protection and access to credit considerations and is sufficiently broad to provide consumers a reasonable opportunity to demonstrate that the creditor did not have a good faith and reasonable belief in the consumer's repayment ability, despite meeting the prerequisites of a QM.

VI. Section-by-Section Analysis

1026.43 Minimum Standards for Transactions Secured by a Dwelling

43(b) Definitions

43(b)(4)

Section 1026.43(b)(4) provides the definition of a higher-priced covered transaction. It provides that a covered transaction is a higher-priced covered transaction if the APR exceeds APOR for a comparable transaction as of the date the interest rate is set by the applicable rate spread specified in the ATR/QM Rule. For General QMs under § 1026.43(e)(2), the applicable rate spreads are 1.5 or more percentage points for a first-lien covered transaction and 3.5 or more percentage points for a subordinate-lien covered transaction. Pursuant to § 1026.43(e)(1), a loan that satisfies the requirements of a QM and is a higher-priced covered transaction under § 1026.43(b)(4) is eligible for a rebuttable presumption of compliance with the ATR requirements. A QM that is not a higher-priced covered transaction is eligible for a conclusive presumption of compliance with the ATR requirements.

The Bureau's Proposal

The Bureau proposed to revise § 1026.43(b)(4) to create a special rule for purposes of determining whether certain types of General QMs under § 1026.43(e)(2) are higher-priced covered transactions. Under the proposal, this special rule would have applied to loans for which the interest rate may or will change within the first five years after the date on which the first regular periodic payment will be due. For such loans, the creditor would have been required to determine the APR, for purposes of determining whether a General QM under § 1026.43(e)(2) is a higher-priced covered transaction, by treating the maximum interest rate that may apply during that five-year period as the interest rate for the full term of the loan.

Under the proposed rule, an identical special rule would have applied to loans for which the interest rate may or will change under proposed § 1026.43(e)(2)(vi), which would have revised the definition of a General QM under § 1026.43(e)(2) to implement the price-based approach described in part V of this final rule. The proposed rule stated that the special rules in the proposed revisions to § 1026.43(b)(4) and § 1026.43(e)(2)(vi) would not modify other provisions in Regulation Z for determining the APR for other purposes, such as the disclosures addressed in or subject to the commentary to § 1026.17(c)(1).

Proposed comment 43(b)(4)–4 stated that provisions in subpart C, including commentary to § 1026.17(c)(1), address how to determine the APR disclosures for closed-end credit transactions and that provisions in § 1026.32(a)(3) address how to determine the APR to determine coverage under § 1026.32(a)(1)(i). It further provided that proposed § 1026.43(b)(4) required, only for purposes of a QM under paragraph (e)(2), a different

[265] 78 FR 6408, 6511 (Jan. 30, 2013).

[266] *Id.* at 6528. The January 2013 Final Rule also did not include a DTI limit for balloon-payment QMs under § 1026.43(f). *Id.* at 6539.

[267] *See id.* at 6511 (''Moreover, requiring creditors to prove that they have satisfied the qualified mortgage requirements in order to invoke the presumption of compliance will itself ensure that the loans in question do not contain certain risky features and are underwritten with careful attention to consumers' debt-to-income ratios.'').

[268] Subordinate-lien transactions are discussed below in the section-by-section analysis of § 1026.43(e)(2)(vi).

[269] However, as discussed in the section-by-section analysis of § 1026.43(e)(2)(vi) below, under the final rule a loan is not eligible for QM status (*i.e.,* will not receive any presumption of compliance with the ATR requirements) under § 1026.43(e)(2) if the loan exceeds the separate pricing thresholds in § 1026.43(e)(2)(vi), as finalized.

determination of the APR for purposes of paragraph (b)(4) for a loan for which the interest rate may or will change within the first five years after the date on which the first regular periodic payment will be due. It also cross-referenced proposed comment 43(e)(2)(vi)–4 for how to determine the APR of such a loan for purposes of § 1026.43(b)(4) and (e)(2)(vi).

The Bureau sought comment on all aspects of the special rule it proposed in § 1026.43(b)(4).

The Final Rule

The Bureau is finalizing § 1026.43(b)(4) and comment 43(b)(4)–4 as proposed. The section-by-section analysis of § 1026.43(e)(2)(vi), which the Bureau also is finalizing as proposed, explains the Bureau's reasoning for adopting these provisions as proposed. That section-by-section analysis also summarizes comments received in response to the proposed special rule and provides the Bureau's response to those comments.

Legal authority. As discussed above in part IV, TILA section 105(a) directs the Bureau to prescribe regulations to carry out the purposes of TILA and provides that such regulations may contain additional requirements, classifications, differentiations, or other provisions, and may provide for such adjustments and exceptions for all or any class of transactions that the Bureau judges are necessary or proper to effectuate the purposes of TILA, to prevent circumvention or evasion thereof, or to facilitate compliance therewith. In particular, it is the purpose of TILA section 129C, as amended by the Dodd-Frank Act, to assure that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loans and that are understandable.

As also discussed above in part IV, TILA section 129C(b)(3)(B)(i) authorizes the Bureau to prescribe regulations that revise, add to, or subtract from the criteria that define a QM upon a finding that such regulations are necessary or proper to ensure that responsible, affordable mortgage credit remains available to consumers in a manner consistent with the purposes of section 129C, necessary and appropriate to effectuate the purposes of section 129C and section 129B, to prevent circumvention or evasion thereof, or to facilitate compliance with such section.

The Bureau is finalizing the special rule in § 1026.43(b)(4) regarding the APR determination of certain loans for which the interest rate may or will change pursuant to its authority under TILA section 105(a) to make such adjustments and exceptions as are necessary and proper to effectuate the purposes of TILA, including that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loans. The Bureau concludes that these provisions will ensure that General QM status will not be accorded to certain loans for which the interest rate may or will change that pose a heightened risk of becoming unaffordable relatively soon after consummation. The Bureau is also finalizing these provisions pursuant to its authority under TILA section 129C(b)(3)(B)(i) to revise and add to the statutory language. The Bureau concludes that the special rule's APR determination provisions in § 1026.43(b)(4) will ensure that responsible, affordable mortgage credit remains available to consumers in a manner consistent with the purpose of TILA section 129C, referenced above, as well as effectuate that purpose.

43(c) Repayment Ability

43(c)(4) Verification of Income or Assets

TILA section 129C(a)(4) states that a creditor making a residential mortgage loan shall verify amounts of income or assets that such creditor relies on to determine repayment ability, including expected income or assets, by reviewing the consumer's Internal Revenue Service (IRS) Form W–2, tax returns, payroll receipts, financial institution records, or other third-party documents that provide reasonably reliable evidence of the consumer's income or assets. In the January 2013 Final Rule, the Bureau implemented this requirement in § 1026.43(c)(4), which states that a creditor must verify the amounts of income or assets that the creditor relies on under § 1026.43(c)(2)(i) to determine a consumer's ability to repay a covered transaction using third-party records that provide reasonably reliable evidence of the consumer's income or assets. Section 1026.43(c)(4) further states that a creditor may verify the consumer's income using a tax-return transcript issued by the IRS and lists several examples of other records the creditor may use to verify the consumer's income or assets, including, among others, financial institution records. Additionally, current § 1026.43(e)(2)(v)(A) provides that a General QM is a covered transaction for which the creditor considers and verifies at or before consummation the consumer's current or reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan in accordance with § 1026.43(c)(4), as well as § 1026.43(c)(2)(i) and appendix Q.

The Bureau proposed to add comment 43(c)(4)–4 to clarify that a creditor does not meet the requirements of § 1026.43(c)(4) if it observes an inflow of funds into the consumer's account without confirming that the funds qualify as a consumer's personal income. The proposed comment also stated that, for example, a creditor would not meet the requirements of § 1026.43(c)(4) where it observes an unidentified $5,000 deposit in the consumer's account but fails to take any measures to confirm or lacks any basis to conclude that the deposit represents the consumer's personal income and not, for example, proceeds from the disbursement of a loan. The Bureau did not propose to change the text of § 1026.43(c)(4).

Commenters to the proposal did not address proposed comment 43(c)(4)–4. Accordingly, the Bureau is adopting new comment 43(c)(4)–4 as proposed. The Bureau determines, based on outreach and on its experience supervising creditors, that this clarification would be useful to creditors because the ATR/QM Rule includes ''financial institution records'' as one of the examples of records that a creditor may use to verify a consumer's income or assets. As part of their underwriting process, creditors may seek to use transactions in electronic or paper financial records such as consumer account statements to examine inflows and outflows from consumers' accounts. In many cases, there may be a sufficient basis in transaction data alone, or in combination with other information, to determine that a deposit or other credit to a consumer's account is the consumer's personal income, such that a creditor's use of the data in an underwriting process is distinguishable from the example in the proposed comment, and, therefore, the creditor may use the data in verifying the consumer's income. The Bureau also concludes that this clarification would help creditors understand their verification requirements under the General QM loan definition. Under this final rule, § 1026.43(e)(2)(v)(B) provides that, to satisfy the General QM loan definition, the creditor must verify the consumer's current or reasonably expected income or assets using third-party records that provide reasonably reliable evidence of the consumer's income or assets, in accordance with § 1026.43(c)(4).

The Bureau is adding comment 43(c)(4)–4 pursuant to TILA section 129C(a)(4), which states that a creditor making a residential mortgage loan shall verify amounts of income or assets that such creditor relies on to determine repayment ability, including expected income or assets, by reviewing the consumer's IRS Form W–2, tax returns, payroll receipts, financial institution records, or other third-party documents that provide reasonably reliable evidence of the consumer's income or assets.

43(e) Qualified Mortgages

43(e)(2) Qualified Mortgage Defined—General

43(e)(2)(v)

As discussed above in part V, this final rule removes the specific DTI limit in § 1026.43(e)(2)(vi). Furthermore, as discussed below in this section-by-section analysis, this final rule requires that creditors consider the consumer's DTI ratio or residual income and removes the appendix Q requirements from § 1026.43(e)(2)(v). The Bureau concludes that these amendments necessitate additional revisions to the General QM loan definition to clarify a creditor's obligation to consider and verify certain information for purposes of the General QM loan definition. Consequently, this final rule amends the consider and verify requirements in § 1026.43(e)(2)(v) and its associated commentary.

TILA section 129C contains several requirements that creditors consider and verify various types of information. In the statute's general ATR provisions, TILA section 129C(a)(1) requires that a creditor make a reasonable and good faith determination, based on ''verified and documented information,'' that a consumer has a reasonable ability to repay the loan. TILA section 129C(a)(3) states that a creditor's ATR determination shall include ''consideration'' of the consumer's credit history, current income, expected income the consumer is reasonably assured of receiving, current obligations, DTI ratio or the residual income the consumer will have after paying non-mortgage debt and mortgage-related obligations, employment status, and other financial resources other than the consumer's equity in the dwelling or real property that secures repayment of the loan. TILA section 129C(a)(4) states that a creditor making a residential mortgage loan shall verify amounts of income or assets that such creditor relies on to determine repayment ability, including expected income or assets, by reviewing the consumer's IRS Form W–2, tax returns, payroll receipts, financial institution records, or other third-party documents that provide reasonably reliable evidence of the consumer's income or assets. Finally, in the statutory QM definition, TILA section 129C(b)(2)(A)(iii) provides that, for a loan to be a QM, the income and financial resources relied on to qualify the obligors on the loan must be ''verified and documented.''

In the January 2013 Final Rule, the Bureau implemented the requirements to consider and verify various factors for the general ATR standard in § 1026.43(c)(2), (3), (4), and (7). Section 1026.43(c)(2) states that—except as provided in certain other provisions (including the General QM loan definition)—a creditor must consider several specified factors in making its ATR determination. These factors include, among others, the consumer's current or reasonably expected income or assets, other than the value of the dwelling, including any real property attached to the dwelling, that secures the loan (under § 1026.43(c)(2)(i)); the consumer's current debt obligations, alimony, and child support (§ 1026.43(c)(2)(vi)); and the consumer's monthly DTI ratio or residual income in accordance with § 1026.43(c)(7). Section 1026.43(c)(3) requires a creditor to verify the information the creditor relies on in determining a consumer's repayment ability using reasonably reliable third-party records, with a few specified exceptions. Section 1026.43(c)(3) further states that a creditor must verify a consumer's income and assets that the creditor relies on in accordance with § 1026.43(c)(4). Section 1026.43(c)(4) requires that a creditor verify the amounts of income or assets that the creditor relies on to determine a consumer's ability to repay a covered transaction using third-party records that provide reasonably reliable evidence of the consumer's income or assets. It also provides examples of records the creditor may use to verify the consumer's income or assets.

As noted in part V, the January 2013 Final Rule incorporated some aspects of the general ATR standards into the General QM loan definition, including the requirement to consider and verify income or assets and debt obligations, alimony, and child support. Section 1026.43(e)(2)(v) states that a General QM is a covered transaction for which the creditor considers and verifies at or before consummation: (A) The consumer's current or reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan, in accordance with appendix Q, § 1026.43(c)(2)(i), and (c)(4); and (B) the consumer's current debt obligations, alimony, and child support in accordance with appendix Q and § 1026.43(c)(2)(vi) and (c)(3). The Bureau used its adjustment and exception authority under TILA section 129C(b)(3)(B)(i) to require creditors to consider and verify the consumer's debt obligations, alimony, and child support pursuant to the General QM loan definition.

The Bureau proposed to revise § 1026.43(e)(2)(v) to separate and clarify the requirements to consider and verify certain information for purposes of the General QM loan definition. Proposed § 1026.43(e)(2)(v)(A) contained the ''consider'' requirements and proposed § 1026.43(e)(2)(v)(B) contained the ''verify'' requirements. Specifically, proposed § 1026.43(e)(2)(v) stated that a General QM is a covered transaction for which the creditor: (A) Considers the consumer's income or assets, debt obligations, alimony, child support, and monthly DTI ratio or residual income, using the amounts determined from § 1026.43(e)(2)(v)(B); and (B) verifies the consumer's current or reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan using third-party records that provide reasonably reliable evidence of the consumer's income or assets, in accordance with § 1026.43(c)(4), and the consumer's current debt obligations, alimony, and child support using reasonably reliable third-party records in accordance with § 1026.43(c)(3). Proposed § 1026.43(e)(2)(v)(A) also stated that, for purposes of § 1026.43(e)(2)(v)(A), the consumer's monthly DTI ratio or residual income is determined in accordance with § 1026.43(c)(7), except that the consumer's monthly payment on the covered transaction, including the monthly payment for mortgage-related obligations, is calculated in accordance with § 1026.43(e)(2)(iv). To further clarify the requirements in § 1026.43(e)(2)(v), the Bureau also proposed to add comments 43(e)(2)(v)(A)–1 through –3 and comments 43(e)(2)(v)(B)–1 through –3.

As discussed below, this final rule adopts § 1026.43(e)(2)(v)(A) largely as proposed—with minor technical additions to the rule text—and adopts § 1026.43(e)(2)(v)(B) as proposed. The Bureau is also adopting the proposed commentary for § 1026.43(e)(2)(v)(A) and § 1026.43(e)(2)(v)(B) largely as proposed, with two substantive changes from the proposal. First, the Bureau has added language to comment

43(e)(2)(v)(A)–1 to clarify that, in order to meet the General QM consider requirement, a creditor must maintain written policies and procedures for how it takes into account income, debt, and DTI or residual income and document how it took into account these factors. Second, the Bureau has added a list of specific verification standards to comment 43(e)(2)(v)(B)–3.i, which provides a safe harbor for compliance with the verification requirement in § 1026.43(e)(2)(v)(B). These verification standards include relevant provisions in specified versions of the Fannie Mae Single Family Selling Guide, the Freddie Mac Single-Family Seller/Servicer Guide, the FHA's Single Family Housing Policy Handbook, the VA's Lenders Handbook, and the USDA's Field Office Handbook for the Direct Single Family Housing Program and Handbook for the Single Family Guaranteed Loan Program, current as of the date of the proposal's public release.

The Bureau also proposed to remove comments 43(e)(2)(v)–2 and –3. In general, these comments explain that a creditor must consider and verify any income and debt specified in appendix Q, and that while a creditor may consider and verify any other income and debt, such income and debt would not be included in the DTI ratio determination required by § 1026.43(e)(2)(vi). This final rule removes these comments. The Bureau concludes that these comments are no longer needed due to this final rule's revisions to § 1026.43(e)(2)(v). The first sentence of each of these comments merely restates language in the regulatory text. The second sentence of each of these comments is no longer needed because this final rule removes references to appendix Q from § 1026.43(e)(2)(v). And the third sentence of each of these comments is no longer needed because this final rule removes the DTI limit in § 1026.43(e)(2)(vi).

43(e)(2)(v)(A)

The Bureau's Proposal

Section 1026.43(e)(2)(v) currently provides that a General QM is a covered transaction for which the creditor, at or before consummation, considers and verifies the consumer's current or reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan, debt obligations, alimony, and child support. In the General QM Proposal, the Bureau proposed to separate the consider and verify requirements in § 1026.43(e)(2)(v) into § 1026.43(e)(2)(v)(A) for the ''consider'' requirements and § 1026.43(e)(2)(v)(B) for the ''verify'' requirements. The Bureau proposed to revise § 1026.43(e)(2)(v)(A) to provide that a General QM is a covered transaction for which the creditor, at or before consummation, considers the consumer's income or assets, debt obligations, alimony, child support, and monthly DTI ratio or residual income, using the amounts determined from proposed § 1026.43(e)(2)(v)(B). Proposed § 1026.43(e)(2)(v)(A) also stated that, for purposes of § 1026.43(e)(2)(v)(A), the consumer's monthly DTI ratio or residual income is determined in accordance with § 1026.43(c)(7), except that the consumer's monthly payment on the covered transaction, including the monthly payment for mortgage-related obligations, is calculated in accordance with § 1026.43(e)(2)(iv).

To clarify the consider requirement in proposed § 1026.43(e)(2)(v)(A), the Bureau proposed to add comments 43(e)(2)(v)(A)–1 to –3. Proposed comment 43(e)(2)(v)(A)–1 provided that, in order to comply with the consider requirement, a creditor must take into account income or assets, debt obligations, alimony, child support, and monthly DTI ratio or residual income in its ability-to-repay determination. The proposed comment further stated that, pursuant to requirements in § 1026.25(a) to retain records showing compliance with the rule, a creditor must retain documentation showing how it took into account the required factors. The proposed comment provided examples of the types of documents that a creditor might use to show that it took into account the required factors.

The Bureau proposed comment 43(e)(2)(v)(A)–2 to clarify that creditors have flexibility in how they consider these factors and that the proposed rule would not have prescribed a specific monthly DTI or residual income threshold. The proposed comment also included two examples of how a creditor may comply with the requirement to consider DTI.

The Bureau proposed comment 43(e)(2)(v)(A)–3 to clarify that the requirement in § 1026.43(e)(2)(v)(A) to consider income or assets, debt obligations, alimony, child support, and monthly DTI or residual income would not preclude the creditor from taking into account additional factors that are relevant in making its ability-to-repay determination.

This final rule adopts § 1026.43(e)(2)(v)(A) largely as proposed, with minor technical additions to the rule text. This final rule also adopts comments 43(e)(2)(v)(A)–1 to –3 largely as proposed, with some adjustments in comment 43(e)(2)(v)(A)–1 to clarify that creditors must maintain certain policies and procedures and retain certain documentation to satisfy § 1026.43(e)(2)(v)(A).

Comments Received

The Bureau's general approach to the consider requirement. Both industry and consumer advocate commenters supported the proposal to retain a requirement to consider income or assets, debt obligations, alimony, child support, and monthly DTI or residual income for General QMs. Commenters generally stated that the consider requirement is an important consumer protection for QMs and that such a requirement is necessary to achieve the statutory intent of TILA. Both industry and consumer advocate commenters generally supported the retention of a requirement to consider a consumer's monthly DTI ratio and the option of considering residual income in lieu of DTI. These commenters explained that DTI is an important factor in assessing a consumer's ability to repay and that the residual income option creates space for flexibility and industry innovation. One industry commenter noted that creditors use DTI as part of their underwriting processes and will continue to do so even if the General QM loan definition no longer includes a specific DTI limit. Another industry commenter explained that it uses DTI as part of its underwriting process and makes responsible loans with DTI ratios above 43 percent. Another industry commenter stated that the VA loan program has successfully used residual income for underwriting purposes.

One industry commenter expressed concerns about the requirement to calculate DTI according to § 1026.43(c)(7), arguing that this cross-reference could be interpreted to import a requirement that creditors adopt an ''appropriate'' DTI threshold. The commenter suggested that the Bureau could avoid that interpretation by removing any requirement to calculate a DTI ratio. As explained in the proposed rule and below, the General QM Proposal incorporated the cross-reference only for purposes of calculating monthly DTI, residual income, and monthly payment on the covered loan.

Commentary provisions. Industry commenters generally supported the inclusion of proposed comments 43(e)(2)(v)(A)–1 through –3. These commenters generally stated that the proposed comments provide the clarity needed to facilitate industry compliance and assurance of QM status. Many industry commenters specifically

encouraged the Bureau to adopt the proposed comments because they would provide creditors with flexibility in applying their own underwriting methodologies. One industry commenter stated that the examples in the proposed comments reflected the current underwriting practices of community banks.

Many industry commenters supported the proposed documentation approach to the consider requirement. One industry commenter explained that the proposed documentation approach would be an effective means for a creditor to meet the consider requirement and have assurance of QM status. A comment letter signed by 12 civil rights and consumer groups included a ''term sheet'' that provided a variety of suggested changes to the consider requirement (''joint consumer advocate term sheet'') and asked the Bureau to clearly state that in order to maintain QM status, the creditor must retain documentation of how it satisfied the consider requirement. A consumer advocate commenter that also signed the term sheet explained that, without documentation, examiners could not meaningfully assess whether the creditor had in fact considered the consumer's debts and income. An industry commenter asked the Bureau to adopt a cure provision for situations where a loan file is incomplete due to an alleged oversight.

Several commenters recommended that the Bureau expressly require creditors to develop and maintain procedures to consider debts and income. In its support for the documentation examples in the first proposed comment, one industry commenter suggested that the Bureau require creditors to provide underwriter spreadsheets or other documentation that showed the creditor followed procedures in its consideration of the required factors. Another industry commenter recommended that the Bureau require creditors to maintain an independently developed credit policy setting forth the manner in which they will consider and verify the required factors. The commenter stated that such a requirement would facilitate investor and regulator evaluation of a loan's QM status and would align with OCC guidance and appraiser guidance under the Financial Institutions Reform, Recovery, and Enforcement Act. Another industry commenter asked the Bureau to develop specific operational guidelines for the calculation of DTI and residual income, including minimum threshold values for residual income. Another industry commenter stated that the Bureau should require creditors to comply with a specific set of underwriting criteria that includes compensating factors for consumers with high DTI.

Similar to these industry commenters, consumer advocate commenters asked the Bureau to require creditors to develop and maintain procedures to consider debts and income. One consumer advocate commenter that signed the joint consumer advocate term sheet explained that, without a component requiring such procedures, the consider requirement would exist in name only and individual loan officers could make individual decisions about what meets the consider standard. This commenter explained that without procedures, creditors under pressure to make loans could use their discretion to make a pro forma note of consideration.

Some industry commenters specifically encouraged the Bureau to adopt the language in proposed comment 43(e)(2)(v)(A)–2 explaining that the proposed rule would not prescribe a particular DTI or residual income threshold. One industry commenter stated that it appreciated how the proposed comments provided creditors with flexibility as to how they considered monthly DTI and additional factors in their underwriting processes. One industry commenter asked the Bureau to refrain from enumerating appropriate compensating factors. In contrast, some industry commenters stated that the proposed consider requirement was still too vague and requested additional clarification. One of these commenters warned that risk-averse lenders would not originate loans under the proposed approach.

One industry commenter supported the consider requirement but requested that the Bureau require a creditor to show *that* it took into account the required factors, rather than *how* it took into account the required factors.

Several industry and consumer advocate commenters supported the Bureau's statement in the proposal that if creditors ignore income or assets, debt obligations, alimony, child support, and DTI or residual income, they do not consider these factors sufficiently for purposes of the General QM loan definition.

Both industry and consumer advocate commenters raised concerns that the proposed General QM consider standard, even with the proposed clarifying commentary, would not prevent loans from obtaining QM status if the consumer lacks the ability to repay. One consumer advocate commenter stated that the proposed General QM consider standard needs more specificity to ensure that creditors engage in a meaningful ability-to-repay analysis. The joint consumer advocate term sheet provided a variety of suggested changes to the consider requirement, such as adding extreme examples of non-compliance (100 percent DTI or zero or negative residual income loans); deeming LTV-based loans to be a *per se* violation of the consider requirement; clarifying that not retaining documentation of how the creditor considered the required factors would result in loss of QM status; and expanding the documentation requirement so that an examiner could confirm that a creditor followed its procedures. Another consumer advocate commenter that signed the joint consumer advocate term sheet stated that examples of non-compliant underwriting practices would provide some clarity to consumers and industry; establish an outer bound for responsible mortgage lending; and ensure that lenders adopt systems that would prevent behavior that falls outside the scope of a reasonable consideration of the required factors. This consumer advocate commenter stated that the joint consumer advocate term sheet's recommendation to clearly exclude loans where the creditor relied on LTV ratio in lieu of debt, income, and DTI or residual income would prevent loan flipping practices, which rely on the consumer's existing equity in the home to repeatedly refinance and strip equity in order to pay financed closing costs immediately to the creditor or broker. In contrast, one industry commenter stated that LTV-based lending should not be a concern given the fixed cost of foreclosure and how a creditor determines loan pricing. One industry commenter stated that a loan with 100 percent DTI could meet the proposed General QM consider standard.

The Final Rule

This final rule adopts § 1026.43(e)(2)(v)(A) and comments 43(e)(2)(v)(A)–1 to –3 largely as proposed, with minor technical additions to the rule text and some adjustments in comment 43(e)(2)(v)(A)–1 to clarify that creditors must maintain certain policies and procedures and retain certain documentation. As explained above, the Bureau is separating the consider and verify requirements in § 1026.43(e)(2)(v) into § 1026.43(e)(2)(v)(A) for the ''consider'' requirements and § 1026.43(e)(2)(v)(B) for the ''verify'' requirements. Final § 1026.43(e)(2)(v)(A) provides that a General QM is a covered transaction for which the creditor, at or before consummation, considers the consumer's current or reasonably

expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan, debt obligations, alimony, child support, and monthly DTI ratio or residual income, using the amounts determined from § 1026.43(e)(2)(v)(B). Although the proposed consider provision would have required creditors to consider current or reasonably expected income or assets other than the value of the dwelling through the requirement to use amounts determined from the § 1026.43(e)(2)(v)(B), the final rule makes this connection more clear by including the clauses ''current or reasonably expected'' and ''other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan'' in § 1026.43(e)(2)(v)(A). Final § 1026.43(e)(2)(v)(A) also states that, for purposes of § 1026.43(e)(2)(v)(A), the consumer's monthly DTI ratio or residual income is determined in accordance with § 1026.43(c)(7), except that the consumer's monthly payment on the covered transaction, including the monthly payment for mortgage-related obligations, is calculated in accordance with § 1026.43(e)(2)(iv).

The Bureau's general approach to the consider requirement. The Bureau concludes that requiring creditors to consider DTI as part of the General QM loan definition ensures that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loan. The Bureau determines that DTI continues to be an important factor in assessing a consumer's ability to repay. Comments on the General QM Proposal and on the ANPR indicate that creditors generally use DTI as part of their underwriting process. These comments indicate that requiring as part of the General QM loan definition that creditors consider DTI when determining a consumer's ability to repay—even if the General QM loan definition no longer includes a specific DTI limit—is consistent with current market practices.

As discussed in the June 2013 Final Rule, the Bureau created an exception from the DTI limit for certain small creditors that hold QMs on portfolio.[270] The Bureau determined that, even though the DTI limit was not appropriate for a small creditor that holds loans on their portfolio, DTI (or residual income, as discussed below) was still a fundamental part of the creditor's ability-to-repay determination.[271] The Bureau similarly concludes that DTI is a fundamental part of the creditor's ability-to-repay determination for General QMs.

Section 1026.43(e)(2)(v)(A) provides creditors with the option to consider either a consumer's monthly residual income or DTI. The Bureau concludes that residual income is an appropriate alternative to monthly DTI for creditors to consider under § 1026.43(e)(2)(v). The January 2013 Final Rule adopted a bright-line DTI limit for the General QM loan definition under § 1026.43(e)(2)(vi), but the Bureau concluded that it did not have enough information to establish a bright-line residual income limit as an alternative to the DTI limit.[272] In comparison, consistent with TILA section 129C(a)(3), the January 2013 Final Rule allows creditors to consider either residual income or DTI as part of the general ATR requirements in § 1026.43(c)(2)(vii), and the June 2013 Final Rule allows small creditors originating QMs pursuant to § 1026.43(e)(5) to consider DTI or residual income. Given the elimination of the bright-line DTI limit in § 1026.43(e)(2)(vi), comments on the proposed rule, comments from stakeholders in the January 2013 Final Rule regarding the value of residual income in determining ability to repay,[273] and the Bureau's determination in the June 2013 Final Rule that residual income can be a valuable measure of ability to repay, the Bureau concludes that allowing creditors the option to consider residual income in lieu of DTI would allow for creditor flexibility and innovation and is necessary and proper to preserve access to responsible, affordable mortgage credit.

The Bureau concludes that the amounts considered under § 1026.43(e)(2)(v)(A) should be consistent with the amounts verified according to § 1026.43(e)(2)(v)(B). For example, if the creditor seeks to comply with the consider requirement under § 1026.43(e)(2)(v)(A) using the consumer's assets, the creditor could consider assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan as those assets are calculated under § 1026.43(e)(2)(v)(B).

The final rule also adopts the proposed requirement in § 1026.43(e)(2)(v)(A) to calculate monthly DTI, monthly residual income, and monthly payment for mortgage-related obligations in a manner consistent with the method used in current § 1026.43(e)(2)(vi). As explained in the proposed rule, this calculation method was previously adopted in the January 2013 Final Rule and is being moved to the § 1026.43(e)(2)(v)(A) consider requirement given the Bureau's removal of the DTI limit in § 1026.43(e)(2)(vi) and appendix Q. To preserve the incorporation of alimony and child support that was previously facilitated by appendix Q, the calculation method in § 1026.43(e)(2)(v)(A) now cross-references § 1026.43(c)(7) for purposes of calculating monthly DTI or residual income. The Bureau concludes that incorporating the pre-existing reference to simultaneous loans is no longer necessary because the new cross-reference to § 1026.43(c)(7) requires creditors to consider simultaneous loans. Additionally, given that this final rule allows creditors to consider residual income in lieu of monthly DTI, the Bureau is expanding the calculation method requirement to include residual income. This calculation method also incorporates the pre-existing cross-reference to § 1026.43(e)(2)(iv) to determine the monthly payments for the covered loan.

As explained in the proposed rule, this calculation method was previously adopted in the January 2013 Final Rule. This calculation method does not appear to be unduly burdensome given that, as described further below, only one commenter addressed the proposed calculation provision, and the comment

[270] 78 FR 35430 (June 12, 2013).

[271] *Id.* at 35487 (''The Bureau continues to believe that consideration of debt-to-income ratio or residual income is fundamental to any determination of ability to repay. A consumer is able to repay a loan if he or she has sufficient funds to pay his or her other obligations and expenses and still make the payments required by the terms of the loan. Arithmetically comparing the funds to which a consumer has recourse with the amount of those funds the consumer has already committed to spend or is committing to spend in the future is necessary to determine whether sufficient funds exist.'').

[272] 78 FR 6408, 6528 (Jan. 30, 2013) (''Unfortunately, however, the Bureau lacks sufficient data, among other considerations, to mandate a bright-line rule based on residual income at this time.'').

[273] *Id.* at 6527 (''Another consumer group commenter argued that residual income should be incorporated into the definition of QM. Several commenters suggested that the Bureau use the general residual income standards of the VA as a model for a residual income test, and one of these commenters recommended that the Bureau coordinate with FHFA to evaluate the experiences of the GSEs in using residual income in determining a consumer's ability to repay.''); *id.* at 6528 (''Finally, the Bureau acknowledges arguments that residual income may be a better measure of repayment ability in the long run. A consumer with a relatively low household income may not be able to afford a 43 percent debt-to-income ratio because the remaining income, in absolute dollar terms, is too small to enable the consumer to cover his or her living expenses. Conversely, a consumer with a relatively high household income may be able to afford a higher debt ratio and still live comfortably on what is left over.'').

related not to the calculation method itself but to the commenter's concern that cross-referencing § 1026.43(c)(7) could be interpreted to import a requirement that creditors adopt an ''appropriate'' DTI threshold. The Bureau also believes that providing a calculation method will facilitate compliance and decrease creditor compliance costs by reducing ambiguity as to how DTI must be calculated. Accordingly, the Bureau concludes that the information in the rulemaking record does not support amending the rule to delete or change the calculation method. The Bureau also notes that the requirement merely provides the method for calculating DTI, residual income, and monthly mortgage payments. As detailed in comments 43(e)(2)(v)(A)–2 to –3, General QM creditors still retain the flexibility to determine how the required factors are taken into account in the consumer's ATR determination.

The Bureau declines to remove the requirement to calculate and consider DTI (or residual income) according to § 1026.43(c)(7) in order to address the industry commenter's concern that this could be interpreted to import a requirement that creditors adopt an ''appropriate'' DTI threshold. Instead, as explained in the proposed rule and above, the Bureau emphasizes that this final rule incorporates the cross-reference only for purposes of calculating monthly DTI, residual income, and monthly payment on the covered loan. As comment 43(e)(2)(v)(A)–2 makes clear, creditors have flexibility in how they consider income or assets, debt obligations, alimony, child support, and monthly DTI ratio or residual income and the final rule does not prescribe a specific monthly DTI or residual income threshold. More generally, the Bureau emphasizes that § 1026.43(e)(2)(v)(A) requires only that the creditor ''consider'' the specified factors. It does not permit a broader challenge that a loan is not a General QM because the creditor failed to make a reasonable and good-faith determination of the consumer's ability to repay under § 1026.43(c)(1), as this would undermine the certainty of whether a loan is a General QM.

Commentary provisions. For the reasons discussed below, the Bureau is finalizing comments 43(e)(2)(v)(A)–1 to –3 largely as proposed, with some adjustments in comment 43(e)(2)(v)(A)–1 to clarify that creditors must maintain certain policies and procedures and must retain certain documentation.

This final rule adds comments 43(e)(2)(v)(A)–1 to –3 because the Bureau concludes they are appropriate to ensure that the Rule's requirement to consider the consumer's income or assets, debt obligations, alimony, child support, and DTI or residual income is clear and detailed enough to provide creditors with sufficient certainty about whether a loan satisfies the General QM loan definition. Under the final rule, the General QM loan definition no longer includes a specific DTI limit in § 1026.43(e)(2)(vi) and instead requires in § 1026.43(e)(2)(v)(A) that creditors consider the consumer's income or assets, debt obligations, alimony, child support, and DTI or residual income . By requiring creditors to calculate DTI and compare that calculation to a DTI limit, the DTI limit from the January 2013 Final Rule provided creditors with a bright-line rule demonstrating how to consider the consumer's income or assets and debts for purposes of determining whether the General QM loan requirements are met. Without additional explanation of the requirement to consider DTI or residual income, along with the consumer's income or assets and debts, elimination of the DTI limit could create compliance uncertainty that could leave some creditors reluctant to originate QMs to consumers and could allow other creditors to originate risky loans without considering DTI or residual income and still receive QM status. In addition, without additional explanation, it may be difficult to enforce the requirement to consider. Commentary examples of compliance that reflect standard market practices also may help ensure that the consider requirement is not unduly burdensome. Many commenters supported the Bureau's proposal to maintain the consider requirement in the General QM loan definition, while also emphasizing the importance of clarity of QM safe harbor status and the utility of compliance examples. While commenters generally supported inclusion of the proposed comments, some commenters requested additions such as clarification of the documentation requirement and examples of non-compliance. Accordingly, the Bureau concludes that it is appropriate to provide additional explanation for the § 1026.43(e)(2)(v) consider requirement in comments 43(e)(2)(v)(A)–1 to –3, as discussed below.

Comment 43(e)(2)(v)(A)–1. Consistent with the proposal, comment 43(e)(2)(v)(A)–1 explains that, in order to comply with the requirement to consider, a creditor must take into account current or reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan, debt obligations, alimony, child support, and monthly DTI ratio or residual income in its ability-to-repay determination. As adopted by this final rule, comment 43(e)(2)(v)(A)–1 also provides that a creditor must maintain written policies and procedures for how it takes into account, pursuant to its underwriting standards, income or assets, debt obligations, alimony, child support, and monthly debt-to-income ratio or residual income in its ability-to-repay determination. The Bureau is also adding a clause to comment 43(e)(2)(v)(A)–1 to explain that the creditor must document how it applied its policies and procedures. The Bureau is also clarifying the documentation example to reflect how the creditor may also comply by providing the required documents in combination with any applicable exceptions used from the creditor's policies and procedures. Bureau experience in market outreach and regulation shows that it is standard practice for creditors to maintain written policies and procedures, including underwriting standards, for considering debt, income, and DTI or residual income, and commenters representing creditors explained that their members already have underwriting procedures to take into account DTI in the ability-to-repay determination. The creditor's policies and procedures typically refer to the creditor's underwriting standards and describe how to address exceptions to the creditor's underwriting standards.

The Bureau concludes that this policies and procedures clarification will facilitate confirmation by investors, auditors, consumers, regulators, and other stakeholders that a creditor has, in fact, taken into account the required factors. The Bureau determines that, as some commenters noted, it would be difficult for these stakeholders to identify how a creditor took into account the required factors if the creditor does not have written policies and procedures for how it takes them into account. Further, given the flexibility that this final rule provides to creditors by removing the DTI limit, the Bureau concludes that it is important for creditors to adopt and memorialize their institutional policies and procedures (including underwriting standards) for considering the consumer's income or assets, debt obligations, alimony, child support, and DTI or residual income, to help ensure that the consideration is sufficiently rigorous. The Bureau also

concludes that this clarification will assist creditors in ensuring compliance with the General QM requirements by helping to prevent individual loan officers and underwriters from attempting to originate General QMs without having met the consider requirement. The Bureau additionally concludes that this clarification will impose a limited burden given that standard market practice is to maintain underwriting standards and policies and procedures.

Comment 43(e)(2)(v)(A)–1 also explains that to comply with § 1026.43(e)(2)(v)(A)—and thereby to qualify for General QM status—a creditor must retain documentation showing how it took into account the required factors in its ability-to-repay determination, including how it applied its policies and procedures. This reflects a modification from the proposal, which would have cross-referenced the creditor's obligation under § 1026.25(a) to retain documentation. The requirement continues to defer to creditors on how to consider the required factors, allowing creditors the flexibility to use their own underwriting standards as long as the loan file documents how the required factors were taken into account in the creditor's ability-to-repay determination.

The General QM loan definition currently contains a 43 percent DTI limit, so any third party can compare the consumer's DTI (as reflected in the loan file) to the limit to confirm that the requirement to consider income or assets and debts was met. In contrast, under this final rule, the General QM consider requirement allows the creditor to determine how debt, alimony, child support, income or assets, and DTI or residual income should be taken into account in its ability-to-repay determination. Although there is a general record retention requirement in the ATR/QM Rule, the Bureau agrees with the commenter that this revised consider requirement should include a documentation component because, absent a documentation requirement, only the creditor would know how and whether it took into account the required factors in its ability-to-repay determination. Documentation of how the creditor considered the required factors is necessary for any third party, such as consumers, investors, and regulators, to confirm that the creditor did, in fact, consider the required factors.

Given statements from commenters about the interaction between the documentation requirement and QM status, the Bureau concludes that adding clarifying language to this documentation retention requirement is necessary. The final rule's commentary explains that in order to meet the consider requirement and thereby meet the requirements for a QM under § 1026.43(e)(2)—whether the loan is a safe harbor QM under § 1026.43(e)(1)(i) or a rebuttable presumption QM under § 1026.43(e)(1)(ii)—a creditor must retain documentation showing how it took into account these factors in its ability-to-repay determination, including how it applied its policies and procedures. To clarify that a lack of documentation showing how the creditor took into account the required factors would result in loss of QM status, rather than constituting a mere violation of the record retention requirement in § 1026.25(a), the Bureau is removing the proposed cross-reference to the record retention requirement in § 1026.25(a). The Bureau is adopting the documentation examples in the last sentence, with new language to clarify that a creditor can also comply by relying on any applicable exceptions in the creditor's policies and procedures (in combination with the example underwriting documents) to show how the creditor took into account the required factors. As examples of the type of documents that a creditor might use to show that income or assets, debt obligations, alimony, child support, and DTI or residual income were taken into account, the comment cites an underwriter worksheet or a final automated underwriting system certification, in combination with the creditor's applicable underwriting standards and any applicable exceptions described in its policies and procedures, that shows how these required factors were taken into account in the creditor's ability-to-repay determination.

In summary, comment 43(e)(2)(v)(A)–1 explains that the § 1026.43(e)(2)(v)(A) consider requirement means to take into account income or assets, debt obligations, alimony, child support, and monthly debt-to-income ratio or residual income in the consumer's ability-to-repay determination, including maintaining written policies and procedures to take into account and retaining documentation of how the creditor took into account. As detailed in comments 43(e)(2)(v)(A)–2 and 43(e)(2)(v)(A)–3, a creditor has flexibility in how it considers income or assets, debt obligations, alimony, child support, and monthly debt-to-income ratio or residual income, as long as the creditor documents how it took into account these required factors in its ability-to-repay determination. For example, a creditor might originate a loan with a DTI that deviates from the standard DTI threshold in its underwriting guidelines because the consumer's significant savings meets an exception in those guidelines. Under this example, the internal thresholds and exceptions qualify as procedures for taking into account, and documentation of how the creditor applied this exception to the loan file shows how the required factors were taken into account under § 1026.43(e)(2)(v)(A).

The creditor's maintenance of written policies and procedures facilitates review of the loan file to confirm that the creditor did, in fact, document how it took into account income or assets, debt, alimony, child support, and DTI ratio or residual income. The documentation provision requires a creditor to retain documentation to show how it applied its written policies and procedures, and, to the extent it deviated from them, to further retain documentation of how the creditor nonetheless took into account the required factors. The documentation examples listed in the comment (an underwriter worksheet or a final automated underwriting system certification, in combination with the creditor's applicable underwriting standards and any applicable exceptions described in its policies and procedures, that show how these required factors were taken into account in the creditor's ability-to-repay determination) can be sufficient to show how the creditor applied its written policies and procedures. For example, a typical loan application may fall within the creditor's underwriting standards, so an underwriter worksheet could contain enough information to show how the creditor took into account the required factors under the creditor's underwriting standards. Another example is a loan application that triggers exceptions, where the underwriter worksheet might state that certain exceptions were applied, and referring to the creditor's policies and procedures would clarify how those exceptions took into account the required factors. In contrast to the discussion in the previous paragraph, a creditor would not meet the § 1026.43(e)(2)(v)(A) consider requirement if the creditor deviated from its policies and procedures and its documentation failed to show how the required factors were taken into account. For example, a creditor would not meet the § 1026.43(e)(2)(v)(A) consider requirement if the consumer did not meet its own underwriting standards and the creditor merely made

a note that the loan was approved by management.

As the Bureau explained in the General QM Proposal, the § 1026.43(e)(2)(v)(A) consider requirement means that if a creditor ignores the required factors of income or assets, debt obligations, alimony, child support, and DTI or residual income—or otherwise did not take them into account as part of its ability-to-repay determination—the loan would not be eligible for QM status. Consumer advocate commenters asked the Bureau to add examples of non-compliance, such as loans with 100 percent DTI or zero residual income, and LTV-based loans, arguing that these examples would help prevent loans from receiving QM status when debts and income did not demonstrate a consumer's ability to repay.

The Bureau declines to codify extreme examples of non-compliance in the final rule. Although the Bureau concludes that loans for which a consumer has 100 percent DTI or zero or negative residual income—and no significant assets unrelated to the value of the dwelling that could support the mortgage loan payments—would not meet the General QM consider standard because the only reasonable conclusion would be that the creditor did not consider DTI or residual income, putting such extreme examples in the rule could be incorrectly interpreted to permit any less extreme practices. For example, a creditor might originate a loan to consumer in a family of four with $200 in monthly residual income and no significant assets unrelated to the value of the dwelling. Although the only reasonable conclusion is that the creditor ignored the consumer's residual income and did not meet the General QM consider requirement, creditors might perceive the extreme non-compliance example to mean that only zero or negative residual income loans could violate the rule.

The Bureau concludes that adding an LTV ratio or other home equity discussion to the General QM consider requirement would introduce too much confusion, thereby undermining the need for clarity of QM status, and declines to adopt this recommendation. For example, some creditors may determine that consumers with a higher DTI have an ability to repay according to their underwriting policy, but due to market risk tolerance will only originate that higher DTI loan if the consumer has a relatively low LTV ratio. Although that loan may meet the consider requirement because the creditor applied its underwriting guidelines and showed how that DTI met its established DTI underwriting thresholds, adding a discussion about LTV ratio to the General QM consider requirement could be misconstrued to undermine the loan's General QM status. In contrast, commenters raised concerns about industry practices when a creditor ignores consumer debt, income, and DTI or residual income and instead relies on LTV ratio, such as with loan flipping. As discussed in the General QM Proposal and the January 2013 Final Rule, the Bureau is aware of concerns about creditors relying on factors related to the value of the dwelling, like LTV ratio, and how such reliance may have contributed to the mortgage crisis.[274] The Bureau agrees that reliance on LTV ratio or another measure of current or future home equity, in conjunction with a 100 percent DTI or no residual income and no other significant assets unrelated to the value of the dwelling, support a conclusion that a creditor did not meet the § 1026.43(e)(2)(v)(A) requirement to consider the consumer's current or reasonably expected income or assets other than the value of the dwelling securing the mortgage, debt obligations, alimony, child support, and monthly DTI ratio or residual income.

The Bureau declines to change the General QM consider requirement from a standard to show *how* the creditor took into account to a standard to show *that* the creditor took into account. The suggested language change would remove the requirement for creditors to connect their consideration of the required factors to the ability-to-repay determination, making the consider requirement a check-the-box exercise under which a file could merely state that the factors were considered even if the creditor ignored debts and income. Instead, the Bureau concludes that creditors must show how it took into account the required factors, including, for example, showing how it applied its underwriting procedures to the consumer's loan application.

Comment 43(e)(2)(v)(A)–2. The Bureau is finalizing comment 43(e)(2)(v)(A)–2 as proposed. To reinforce that the General QM loan definition no longer includes a specific DTI limit, comment 43(e)(2)(v)(A)–2 highlights that creditors have flexibility in how they consider these factors. Comment 43(e)(2)(v)(A)–2 clarifies that § 1026.43(e)(2)(v)(A) does not prescribe specifically how a creditor must consider monthly debt-to-income ratio or residual income and also does not prescribe a particular monthly debt-to-income ratio or residual income threshold with which a creditor must comply. To assist creditors in understanding their compliance obligations, the Bureau is finalizing two examples of how to comply with the requirement to consider DTI or residual income. Comment 43(e)(2)(v)(A)–2 provides an example in which a creditor considers monthly DTI or residual income by establishing monthly DTI or residual income thresholds for its own underwriting standards and documenting how those thresholds were applied to determine the consumer's ability to repay. Given that some creditors use several thresholds that depend on any relevant compensating factors, the Bureau is finalizing a second example. The second example provides that a creditor may also consider DTI or residual income by establishing monthly DTI or residual income thresholds and exceptions to those thresholds based on other compensating factors, and documenting application of the thresholds along with any applicable exceptions. The Bureau concludes that both examples are consistent with current market practices and therefore providing these examples would clarify a loan's QM status without imposing a significant burden on the market.

[274] 78 FR 6408, 6561 (Jan. 30, 2013) (''In some cases, lenders and borrowers entered into loan contracts on the misplaced belief that the home's value would provide sufficient protection. These cases included subprime borrowers who were offered loans because the lender believed that the house value either at the time of origination or in the near future could cover any default. Some of these borrowers were also counting on increased housing values and a future opportunity to refinance; others likely understood less about the transaction and were at an informational disadvantage relative to the lender.''); *id.* at 6564 (''During those periods there were likely some lenders, as evidenced by the existence of no-income, no-asset (NINA) loans, that used underwriting systems that did not look at or verify income, debts, or assets, but rather relied primarily on credit score and LTV.''); *id.* at 6559 (''If the lender is assured (or believes he is assured) of recovering the value of the loan by gaining possession of the asset, the lender may not pay sufficient attention to the ability of the borrower to repay the loan or to the impact of default on third parties. For very low LTV mortgages, *i.e.,* those where the value of the property more than covers the value of the loan, the lender may not care at all if the borrower can afford the payments. Even for higher LTV mortgages, if prices are rising sharply, borrowers with even limited equity in the home may be able to gain financing since lenders can expect a profitable sale or refinancing of the property as long as prices continue to rise . . . . In all these cases, the common problem is the failure of the originator or creditor to internalize particular costs, often magnified by information failures and systematic biases that lead to underestimation of the risks involved. The first such costs are simply the pecuniary costs from a defaulted loan—if the loan originator or the creditor does not bear the ultimate credit risk, he or she will not invest sufficiently in verifying the consumer's ability to repay.'').

Comment 43(e)(2)(v)(A)–3. The Bureau is finalizing comment 43(e)(2)(v)(A)–3 as proposed. The Bureau is aware that some creditors look to factors in addition to income or assets, debt obligations, alimony, child support, and DTI or residual income in determining a consumer's ability to repay. For example, the Bureau is aware that some creditors may look to net cash flow into a consumer's deposit account as a method of residual income analysis. A net cash flow calculation typically consists of residual income, further reduced by consumer expenditures other than those already subtracted as part of the residual income calculation. Accordingly, the result of a net cash flow calculation may be useful in assessing the adequacy of a particular consumer's residual income. Comment 43(e)(2)(v)(A)–3 clarifies that the requirement in § 1026.43(e)(2)(v)(A) to consider income or assets, debt obligations, alimony, child support, and monthly DTI or residual income does not preclude the creditor from taking into account additional factors that are relevant in making its ability-to-repay determination.

The comment further provides that creditors may look to existing comment 43(c)(7)–3 for guidance on considering additional factors in determining the consumer's ability to repay. Comment 43(c)(7)–3 explains that creditors may consider additional factors when determining a consumer's ability to repay and provides an example of looking to consumer assets other than the value of the dwelling, such as a savings account.

Legal Authority

The Bureau is finalizing the requirement that the creditor consider the consumer's monthly DTI ratio or residual income, current or reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan, debt obligations, alimony, and child support under § 1026.43(e)(2)(A) pursuant to its adjustment and exception authority under TILA section 129C(b)(3)(B)(i). The Bureau finds that this addition to the General QM criteria is necessary and proper to ensure that responsible, affordable mortgage credit remains available to consumers in a manner that is consistent with the purposes of TILA section 129C and necessary and appropriate to effectuate the purposes of TILA section 129C, which includes assuring that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loan. The Bureau also incorporates this requirement pursuant to its authority under TILA section 105(a) to issue regulations that, among other things, contain such additional requirements or other provisions, or that provide for such adjustments for all or any class of transactions, that in the Bureau's judgment are necessary or proper to effectuate the purposes of TILA, which include the above purpose of section 129C. The Bureau finds that including consideration of DTI or residual income in the General QM loan criteria is necessary and proper to fulfill the purpose of assuring that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loan. The Bureau also finds that § 1026.43(e)(2)(A) is authorized by TILA section 129C(b)(2)(A)(vi), which permits, but does not require, the Bureau to adopt guidelines or regulations relating to DTI ratios or alternative measures of ability to pay regular expenses after payment of total monthly debt.

43(e)(2)(v)(B)

The Bureau's Proposal

The Bureau proposed to revise § 1026.43(e)(2)(v)(B) to provide that a General QM would be a covered transaction for which the creditor, at or before consummation, verifies the consumer's current or reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan using third-party records that provide reasonably reliable evidence of the consumer's income or assets, in accordance with § 1026.43(c)(4) and verifies the consumer's current debt obligations, alimony, and child support using reasonably reliable third-party records in accordance with § 1026.43(c)(3). The proposal would have removed requirements that creditors verify this information in accordance with appendix Q and would have removed appendix Q from Regulation Z entirely.

To clarify the verification requirement in § 1026.43(e)(2)(v)(B), the Bureau proposed to add comments 43(e)(2)(v)(B)–1 through –3. Proposed comment 43(e)(2)(v)(B)–1 stated that § 1026.43(e)(2)(v)(B) does not prescribe specific methods of underwriting that creditors must use. This proposed comment further provided that, as long as a creditor complies with the provisions of § 1026.43(c)(3) with respect to verification of debt obligations, alimony, and child support and § 1026.43(c)(4) with respect to verification of income and assets, creditors would be permitted to use any reasonable verification methods and criteria.

The Bureau proposed comment 43(e)(2)(v)(B)–2 to clarify that ''current and reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan'' is determined in accordance with § 1026.43(c)(2)(i) and its commentary and that ''current debt obligations, alimony, and child support'' has the same meaning as under § 1026.43(c)(2)(vi) and its commentary. The proposed comment further stated that § 1026.43(c)(2)(i) and (vi) and the associated commentary apply to a creditor's determination with respect to what inflows and property it may classify and count as income or assets and what obligations it must classify and count as debt obligations, alimony, and child support, pursuant to its compliance with § 1026.43(e)(2)(v)(B).

Proposed comment 43(e)(2)(v)(B)–3.i provided that a creditor also complies with § 1026.43(e)(2)(v)(B) if the creditor satisfies specified verification standards (verification safe harbor). In the section-by-section analysis of proposed § 1026.43(e)(2)(v)(B), the Bureau stated that these verification standards may include relevant provisions in specified versions of the Fannie Mae Single Family Selling Guide, the Freddie Mac Single-Family Seller/Servicer Guide, the FHA's Single Family Housing Policy Handbook, the VA's Lenders Handbook, and the USDA's Field Office Handbook for the Direct Single Family Housing Program and the Handbook for the Single Family Guaranteed Loan Program (''manuals''), as of the date of the proposal's public release. The Bureau sought comment on whether these or other verification standards should be incorporated into proposed comment 43(e)(2)(v)(B)–3.i. In the section-by-section analysis of proposed § 1026.43(e)(2)(v)(B), the Bureau also encouraged stakeholders to develop additional verification standards and stated that it would review any such standards for potential inclusion in the safe harbor.

Proposed comment 43(e)(2)(v)(B)–3.ii provided that a creditor complies with § 1026.43(e)(2)(v)(B) if it complies with requirements in the verification standards listed in comment 43(e)(2)(v)(B)–3 for creditors to verify income or assets, debt obligations, alimony and child support using specified documents or to include or exclude particular inflows, property, and obligations as income, assets, debt obligations, alimony, and child support.

Proposed comment 43(e)(2)(v)(B)–3.iii stated that, for purposes of compliance with § 1026.43(e)(2)(v)(B), a creditor need not comply with requirements in the verification standards listed in comment 43(e)(2)(v)(B)–3.i other than those that require creditors to verify income, assets, debt obligations, alimony, and child support using specified documents or to classify and count particular inflows, property, and obligations as income, assets, debt obligations, alimony, and child support.

Proposed comment 43(e)(2)(v)(B)–3.iv stated that a creditor also complies with § 1026.43(e)(2)(v)(B) where it complies with revised versions of verification standards listed in comment 43(e)(2)(v)(B)–3.i, provided that the two versions are substantially similar. Finally, proposed comment 43(e)(2)(v)(B)–3.v provided that a creditor complies with § 1026.43(e)(2)(v)(B) if it complies with the verification requirements in one or more of the verification standards specified in comment 43(e)(2)(v)(B)–3.i. The proposed comment stated that, accordingly, a creditor may, but need not, comply with § 1026.43(e)(2)(v)(B) by complying with the verification standards from more than one manual (in other words, by ''mixing and matching'' verification requirements).

For the reasons described below, the Bureau adopts § 1026.43(e)(2)(v)(B) and comments 43(e)(2)(v)(B)–1 through –3 as proposed, except that, in this final rule, § 1026.43(e)(2)(v)(B) lists the applicable verification standards for the verification safe harbor in comment 43(e)(2)(v)(B)–3.i and includes minor edits to provide clarity. The verification standards listed in comment 43(e)(2)(v)(B)–3.i are the same verification standards that the Bureau listed in the proposal and stated that it may include in the verification safe harbor.

Comments Received

Commenters generally supported the Bureau's overall approach of replacing appendix Q with a requirement to use third-party records that provide reasonably reliable evidence of the consumer's income, assets, debt obligations, alimony, and child support. Several commenters recommended modifications to the proposal, as described and organized below based on the topic of concern.[275]

Verification safe harbor. Commenters generally supported including, in the list of specified external verification standards, the portions of the GSE, FHA, VA, and USDA manuals that the Bureau listed in the proposal. Both GSEs supported the safe harbor for the verification standards in their manuals resulting from proposed comment 43(e)(2)(v)(B)–3. Both GSEs stated that the commentary should reference not only the verification standards in their manuals but should also reference amendments, letters, and other creditor-specific waivers of provisions that are not included in their manuals. One GSE stated that the Bureau should require creditors to comply with its entire manual—not just with its verification standards—to receive the verification safe harbor. An industry commenter stated that automatic loan origination system reports, specifically Fannie Mae's Desktop Underwriter and Freddie Mac's Loan Prospector, should be conclusive proof of compliance with the verification requirements of § 1026.43(e)(2)(v)(B) and its related commentary. A research center commenter stated that, for rebuttable presumption General QM loans, income and debt verification is effectively the only issue a consumer might challenge, and therefore the verification safe harbor would result in creditors facing about the same legal exposure on a rebuttable presumption QM as on a safe harbor QM. The commenter asserted that this would provide less protection to consumers and more leverage for increased home prices.

The Bureau declines to extend the verification safe harbor for materials outside of the scope of the verification standards in the specified manuals. The Bureau is concerned that the automatic inclusion of any amendments or modifications to manuals could cause significant changes in the creditor obligations and consumer protections without review by the Bureau. The Bureau will monitor changes to the manuals and incorporate updated versions if necessary. The Bureau is also concerned about incorporating standards that are not publicly available. The Bureau also declines to extend the safe harbor for matters beyond the verification standards within the specified GSE manuals. The Bureau is not aware of a reason why a creditor's compliance with standards unrelated to verification should be required for the creditor to obtain the benefit of the safe harbor for compliance with the Bureau's verification requirement. In addition, referencing the rest of the GSE manuals could lead to confusion among creditors or secondary market participants, because those manuals also contain requirements not related to verification standards—for example, housing expense ratios, DTI limits, or LTV limits that may be inconsistent with the provisions on related issues in the General QM loan definition. The Bureau also declines to extend a verification safe harbor merely for the inclusion of an approval acknowledgment generated by an automated underwriting system maintained by the GSEs or other institution, because modifications to the automated underwriting system approval process may deviate from the specified manuals and the Bureau would not be able to evaluate the nature and extent of such deviations without prior review.

The Bureau additionally disagrees with the research center commenter's assertion that the verification safe harbor would result in creditors facing about the same legal exposure on a rebuttable presumption QM as on a safe harbor QM. The Bureau notes that the verification safe harbor provides creditors with a safe harbor only for compliance with the verification requirement in § 1026.43(e)(2)(v)(B). The verification safe harbor does not preclude consumers from asserting that the creditor did not comply with § 1026.43(e)(2)(v)(A), for example, by failing to take into account the consumer's DTI ratio or residual income in the creditor's ability-to-repay determination. Moreover, consumers could still rebut the presumption by demonstrating that they had insufficient residual income to cover their living expenses as explained in comment 43(e)(1)(ii)–1.

Use of revised manuals that are substantially similar. The Bureau requested comment on whether creditors that comply with verification standards in revised versions of the listed manuals that are substantially similar to the listed versions should also receive a verification safe harbor, as the Bureau proposed. The Bureau also requested comment on whether the Rule should include illustrations of revisions to the manuals that might qualify as substantially similar, and if so, what types of illustrations would provide helpful clarification to creditors and other stakeholders.

Commenters generally supported the inclusion of a verification safe harbor for verification standards in the listed manuals that have been revised but are substantially similar, but some commenters suggested alternative approaches. A GSE supported the substantially similar standard but requested that the Bureau clarify the meaning of substantially similar. In contrast, some industry commenters

[275] The Bureau addresses comments on the Bureau's proposal regarding appendix Q in the section-by-section analysis for appendix Q, below.

stated that creditors should receive a safe harbor for compliance with the revised version of the manuals whether or not they are substantially similar. Some industry commenters stated that the Bureau should adjust the commentary to presume the revised versions of manuals are valid unless they materially deviate from the prior version. Some industry commenters stated that the Bureau should adopt a mechanism by which the Bureau could review and determine if revised manuals are substantially similar to the versions referenced in comment 43(e)(2)(v)(B)–3.i. Some industry commenters stated that the Bureau should include a statement that affirms that verification standards adopted by a creditor that are materially similar to those in the manuals referenced in comment 43(e)(2)(v)(B)–3.i should also receive a verification safe harbor.

The Bureau is adopting comment 43(e)(2)(v)(B)–3.i as proposed. The Bureau determines that commenters' suggested clarifications of the substantially similar standard in fact would not provide greater clarity. For example, the Bureau determines that a standard providing that the revised manual receives a verification safe harbor provided that it does not ''materially deviate'' or is ''materially similar'' would not be appreciably clearer than a standard that the revised manual be ''substantially similar.''

The Bureau additionally notes that, in proposing to extend the verification safe harbor to substantially similar versions of the verification standards in the manuals, the Bureau did not intend for creditors to always be responsible for determining on their own whether a revised version of a listed manual is substantially similar to a version adopted in this final rule. Rather, the Bureau intends to provide further clarity to creditors by releasing guidance, as appropriate, regarding whether future revisions of manuals qualify as ''substantially similar'' for purposes of the verification safe harbor. The following three illustrations show how the Bureau may evaluate future changes to the manuals. The Bureau believes these illustrations may help creditors anticipate if and when the Bureau may address whether future revisions of manuals are eligible for a safe harbor.

First, revisions only to provisions within the manuals that are not referenced in comment 43(e)(2)(v)(B)–3.i would result in a revised version that is substantially similar. For example, a revised version of the FHA's Single Family Housing Policy Handbook that makes changes only to Section III, Servicing and Loss Mitigation, would be substantially similar for purposes of comment 43(e)(2)(v)(B)–3.i because there are no changes to the verification standards contained in Sections II.A.1 and II.A.4–5 of that Handbook.

Second, the portions of the manuals referenced in comment 43(e)(2)(v)(B)–3.i contain not only verification standards, but also additional provisions related to the underwriting of the mortgage. Consistent with comment 43(e)(2)(v)(B)–3.iii, revisions only to these unrelated underwriting provisions would produce a revised version that would be substantially similar. As an illustration, the Freddie Mac Single-Family Seller/Servicer Guide chapter 5401.1 requires a review of the consumer's monthly housing expense-to-income ratio. Chapter 5401.1 is contained within the portions of the Freddie Mac Single-Family Seller/Servicer Guide listed in comment 43(e)(2)(v)(B)–3.i. However, revised versions of Chapter 5401.1 concerning a consumer's monthly housing expense-to-income ratio would be substantially similar to the manual in comment 43(e)(2)(v)(B)–3.i, since these provisions of chapter 5401.1 do not relate to the verification of income, assets, debt obligations, alimony, or child support by use of reasonably reliable third-party records.

Third, revisions to the manuals concerning verification standards may or may not be substantially similar. The Bureau may evaluate such revisions to determine if the revised manual is substantially similar to the version referenced in comment 43(e)(2)(v)(B)–3.i. As an illustration, Fannie Mae Selling Guide chapter B–3–3.2–01 generally requires two years of individual and business tax returns to verify a consumer's income. Business tax returns, however, are not required if the consumer is using personal funds to pay for down payment, closing, and escrow account amounts; the consumer has been in same business for five years; and the consumer's individual tax returns show an increase in self-employment income. A revised version of the Fannie Mae Selling Guide that amends chapter B–3–3.2–01 to change any of these requirements for verifying self-employed income may or may not make the revised Selling Guide substantially similar to the Fannie Mae Selling Guide issued on June 3, 2020. The Bureau may consider providing additional guidance to address any such revisions.

''*Mixing and matching*'' *of verification standards.* The Bureau also sought comment on its proposal to allow creditors to ''mix and match'' verification standards from different manuals, including whether examples of such mixing and matching would be helpful and whether the Bureau should instead limit or prohibit such mixing and matching, and why. Some industry commenters supported the ability of creditors to mix and match the verification standards from the manuals because it would provide flexibility and would not restrict creditors from adopting wholesale verification standards from a single external party. Some consumer advocate commenters opposed permitting creditors to mix and match verification standards from the manuals because allowing mixing and matching would introduce unnecessary subjectivity into the rule, although the commenters did not explain how. These consumer advocate commenters also stated that allowing mixing and matching could enable creditors to exploit differences in approaches between manuals. These commenters did not explain or provide examples of how creditors might do so or of what harm could result.

The Bureau concludes that permitting creditors to mix and match standards for verifying income, assets, debt obligations, alimony, and child support from each of the manuals would provide creditors with greater flexibility without undermining consumer protection. The GSEs and Federal agencies that maintain the manuals have had considerable historical experience in determining which records and supplemental records are reasonably reliable third-party records for purposes of verifying income, assets, debt obligations, alimony, and child support, as well as determining the need for updated information over applicable timeframes. Each of the manuals has also been historically relied upon for those purposes by Congress, the Bureau, secondary market participants, and creditors. Congress included separate QM definitions for loans insured or guaranteed by FHA, VA, and USDA without establishing separate third-party verification standards other than those established by their respective agencies.[276] The third-party verification standards of the GSEs also served as a basis for verification under the Temporary GSE QM loan definition under § 1026.43(e)(4), and the Bureau is not aware of resulting instances of harm caused by inadequately verified income or assets, debt obligations, alimony and child support.

The Bureau has analyzed the relevant provisions of the manuals and has not identified ways that creditors may exploit differences between them or

[276] TILA section 129C(b)(3)(ii); 15 U.S.C. 1639c(b)(3)(ii).

how mixing and matching would add subjectivity to the ATR/QM Rule's verification requirements. As noted, commenters did not cite examples of how this might occur. Permitting creditors to mix and match verification standards may allow creditors to use different manuals, but the Bureau has not identified evidence that combinations of historically accepted third-party record verification standards will, by virtue of their combination, result in insufficient verification of income, assets, debt obligations, alimony, or child support because the creditor uses different manuals for the verification of the information provided. The Bureau also determines, based on its analysis of the relevant provisions of the manuals, that permitting creditors to ''mix and match'' would not add subjectivity to the Rule's verification requirements.

Adding standards created by a self-regulatory organization (SRO). In the General QM Proposal, the Bureau encouraged stakeholders to develop additional verification standards that the Bureau could incorporate into the verification safe harbor and stated that it would review any such standards for potential inclusion in the safe harbor. Commenters did not provide any stakeholder-developed verification standards for review. However, several industry commenters stated that the Bureau should use verification standards adopted by a self-regulatory organization (SRO), in addition to or as a replacement for the standards listed in the proposal. Commenters that suggested this approach generally discussed such adoption as a future objective, as such standards, or even such an SRO, do not appear to exist at this time. One of these commenters recommended that the Bureau include in the safe harbor the GSE and Federal agency manuals listed in the proposal only until an industry-developed standard is established and approved by the Bureau.

The Bureau notes that there is no evidence in the record that such an SRO, much less verification standards created by such an entity or other consortium of industry stakeholders, exists. Accordingly, the Bureau determines that it would be premature to include such standards in the verification safe harbor. However, the Bureau continues to encourage stakeholders, including groups of stakeholders, to develop verification standards.[277] The Bureau is interested in reviewing any such standards that stakeholders develop for potential inclusion in the verification safe harbor. Stakeholder standards could incorporate, in whole or in part, any standards that the Bureau specifies as providing a verification safe harbor, including mixing and matching these standards.

Preventing use of fraudulent documentation. The joint consumer advocate term sheet requested that the Bureau affirm that documentation that is falsified or the subject of fraud by or with the knowledge and consent of the lender, broker, or their agents would not comply with the verification requirement in § 1026.43(e)(2)(v)(B). The Bureau agrees that falsified or fraudulent documentation is, by definition, not a ''reasonably reliable'' third party record. The Bureau further notes that creditors have legal obligations to protect against such instances of mortgage fraud.[278] The Bureau also notes that the manuals listed in the verification safe harbor have embedded limitations and restrictions on what third-party documentation may be used for verification that address similar sources of law. Accordingly, the Bureau determines that the issues presented by commenters are already adequately addressed by this final rule and by existing legal requirements.

The Final Rule

The Bureau is adopting § 1026.43(e)(2)(v)(B) and comments 43(e)(2)(v)(B)–1 through –3 as proposed, except that, in this final rule, § 1026.43(e)(2)(v)(B) lists the applicable verification standards for the verification safe harbor in comment 43(e)(2)(v)(B)–3.i.[279] These verification standards are: (1) Chapters B3–3 through B3–6 of the Fannie Mae Single Family Selling Guide, published June 3, 2020; (2) sections 5102 through 5500 of the Freddie Mac Single-Family Seller/Servicer Guide, published June 10, 2020; (3) sections II.A.1 and II.A.4–5 of the FHA's Single Family Housing Policy Handbook, issued October 24, 2019; (4) chapter 4 of the VA's Lenders Handbook, revised February 22, 2019; (5) chapter 4 of the USDA's Field Office Handbook for the Direct Single Family Housing Program, revised March 15, 2019; and (6) chapters 9 through 11 of the USDA's Handbook for the Single Family Guaranteed Loan Program, revised March 19, 2020. These verification standards are the same standards that the Bureau listed in the proposal and requested comment on. Based on its review of the standards and the comments received, Bureau concludes that each of the verification standards listed in comment 43(e)(2)(v)(B)–3.i is sufficient to satisfy the final rule's verification requirement.

The Bureau concludes that these amendments to § 1026.43(e)(2)(v)(B) will ensure that the ATR/QM Rule's verification requirements are clear and detailed enough to provide creditors with sufficient certainty about whether a loan satisfies the General QM loan definition. The Bureau concludes that, without such certainty, creditors may be less likely to provide General QMs to consumers, reducing the availability of responsible, affordable mortgage credit. The Bureau also finds that these verification requirements are flexible enough to adapt to emerging issues with respect to the treatment of certain types of income, assets, debt obligations, alimony, and child support, advancing the provision of responsible, affordable mortgage credit to consumers. The Bureau aims to ensure that the verification requirement provides substantial flexibility for creditors to adopt innovative verification methods, such as the use of bank account data that identifies the source of deposits to determine personal income, while also specifying examples of compliant verification standards to provide greater certainty that a loan has QM status.

As described above, this final rule provides that creditors must verify income, assets, debt obligations, alimony, and child support in accordance with the general ATR verification provisions in § 1026.43(c)(3) and (4). This final rule also provides a safe harbor for compliance with § 1026.43(e)(2)(v)(B) if a creditor complies with verification standards in the manuals listed in comment 43(e)(2)(v)(B)–3.i. These verification standards are available to the public for free online.[280]

[277] *See, e.g.,* OMB Circular A–119: *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities* (Jan. 27, 2016), *https://www.whitehouse.gov/wp-content/uploads/2020/07/revised_circular_a-119_as_of_1_22.pdf.*

[278] *See, e.g.,* 18 U.S.C. 1001, 1010, 1014, 1028, 1341 through 1344.

[279] The Bureau has also made some non-substantive changes to terminology in final comments 43(e)(2)(v)(B)–1 through –3 to ensure consistent usage of terms throughout the commentary.

[280] The referenced versions of the guides, or relevant sections thereof, are publicly available on the internet. The Fannie Mae Single Family Selling Guide, published June 3, 2020 can be found at *http://www.allregs.com/tpl/public/fnma_freesiteconv_tll.aspx.* The Freddie Mac Single-Family Seller/Servicer Guide, published June 10, 2020 can be found at *https://www.allregs.com/tpl/public/fhlmc_freesite_tll.aspx.* The FHA's Single Family Housing Policy Handbook, issued October 24, 2019 can be found at *https://www.regulations.gov/document?D=CFPB-2020-*

The Bureau determines, based on extensive public feedback and its own experience and review, that these external standards are reasonable and would provide creditors with substantially greater certainty about whether many loans satisfy the General QM loan definition—particularly with respect to verifying income for self-employed consumers, consumers with part-time employment, and consumers with irregular or unusual income streams. The Bureau determines that these types of income would be addressed more fully by these external standards than by appendix Q. The Bureau determines that, as a result, final § 1026.43(e)(2)(v)(B) would increase access to responsible, affordable credit for consumers.

The Bureau emphasizes that a creditor would not be required to comply with any of the verification standards listed in comment 43(e)(2)(v)(B)–3.i in order to comply with § 1026.43(e)(2)(v)(B). Rather, under this final rule, compliance with the listed verification standards constitutes compliance with the verification requirements of § 1026.43(c)(3) and (4) and their commentary, which generally require creditors to verify income, assets, debt obligations, alimony, and child support using reasonably reliable third-party records. The Bureau determines that this would help address the compliance concerns of many creditors and commenters associated with appendix Q's lack of clarity.

The Bureau also determines that this final rule would provide creditors with the flexibility to develop other methods of compliance with the verification requirements of § 1026.43(e)(2)(v)(B), consistent with § 1026.43(c)(3) and (4) and their commentary, an option that the Bureau intends to address the concerns of creditors and commenters that found appendix Q to be too rigid or prescriptive. As explained in comment 43(e)(2)(v)(B)–1, § 1026.43(e)(2)(v)(B) does not prescribe specific methods of underwriting, and as long as a creditor complies with § 1026.43(c)(3) and (4), the creditor is permitted to use any reasonable verification methods and criteria. Furthermore, as comment 43(e)(2)(v)(B)–3.v clarifies, creditors have the flexibility to mix and match the verification requirements in the standards specified in comment 43(e)(2)(v)(B)–3.i, and receive a safe harbor with respect to verification that is made consistent with those standards.

Comment 43(e)(2)(v)(B)–3.iv explains that a creditor complies with § 1026.43(e)(2)(v)(B) if it complies with revised versions of the verification standards specified in comment 43(e)(2)(v)(B)–3.i, provided that the two versions are substantially similar. The GSE and Federal agency standards listed in comment 43(e)(2)(V)(B)–3.i are regularly updated in response to emerging issues with respect to the treatment of certain types of debt or income. This comment explains that the safe harbor described in comment 43(e)(2)(v)(B)–3.i applies not only to verification standards in the specific listed versions, but also to revised versions of these verification standards, as long as the revised version is substantially similar.

As discussed above, the Bureau encourages stakeholders, including groups of stakeholders, to develop verification standards. The Bureau is interested in reviewing any such standards for potential inclusion in the verification safe harbor. Stakeholder standards could incorporate, in whole or in part, any standards that the Bureau specifies as providing a safe harbor, including mixing and matching these standards.

Legal Authority

The Bureau is incorporating the requirement that the creditor verify the consumer's current or reasonably expected income, assets other than the value of the dwelling (including any real property attached to the dwelling), debt obligations, alimony, and child support into the definition of a General QM in § 1026.43(e)(2) and revisions to its commentary pursuant to its authority under TILA section 129C(b)(3)(B)(i). The Bureau finds that these provisions are necessary and proper to ensure that responsible, affordable mortgage credit remains available to consumers in a manner that is consistent with the purposes of TILA section 129C and necessary and appropriate to effectuate the purposes of TILA section 129C, which includes assuring that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loan.

The Bureau also adopts these provisions pursuant to its authority under TILA section 105(a) to issue regulations that, among other things, contain such additional requirements or other provisions, or that provide for such adjustments for all or any class of transactions, that in the Bureau's judgment are necessary or proper to effectuate the purposes of TILA, which include the above purpose of section 129C, among other things. The Bureau finds that these provisions are necessary and proper to achieve this purpose. In particular, the Bureau finds that incorporating the requirement that a creditor verify a consumer's current debt obligations, alimony, and child support into the General QM criteria—as well as clarifying that a creditor complies with the General QM verification requirement where it complies with certain verification standards issued by third parties that the Bureau would specify—ensures that creditors verify whether a consumer has the ability to repay a General QM. Finally, the Bureau concludes that these regulatory amendments are authorized by TILA section 129C(b)(2)(A)(vi), which permits, but does not require, the Bureau to adopt guidelines or regulations relating to debt-to-income ratios or alternative measures of ability to pay regular expenses after payment of total monthly debt.

43(e)(2)(vi)

TILA section 129C(b)(2)(vi) states that the term ''qualified mortgage'' includes any mortgage loan that complies with any guidelines or regulations established by the Bureau relating to ratios of total monthly debt to monthly income or alternative measure of ability to pay regular expenses after payment of total monthly debt, taking into account the income levels of the consumer and such other factors as the Bureau may determine relevant and consistent with the purposes described in TILA section 129C(b)(3)(B)(i). TILA section 129C(b)(3)(B)(i) authorizes the Bureau to revise, add to, or subtract from the criteria that define a QM upon a finding that the changes are necessary or proper to ensure that responsible, affordable mortgage credit remains available to consumers in a manner consistent with the purposes of TILA section 129C, necessary and appropriate to effectuate the purposes of TILA sections 129C and 129B, to prevent circumvention or evasion thereof, or to facilitate compliance with TILA sections 129C and 129B. Current § 1026.43(e)(2)(vi) implements TILA section 129C(b)(2)(vi), consistent with TILA section 129C(b)(3)(B)(i), and provides that, as a condition to be a General QM under § 1026.43(e)(2), the consumer's total monthly DTI ratio may not exceed 43 percent. Section 1026.43(e)(2)(vi) further provides that the consumer's total monthly DTI ratio is generally

0020-0002. The chapter 4 of the VA's Lenders Handbook revised February 22, 2019 can be found at *https://www.regulations.gov/document?D=CFPB-2020-0020-0003.* The USDA's Field Office Handbook for the Direct Single Family Housing Program, revised March 15, 2019 can be found at *https://www.regulations.gov/document?D=CFPB-2020-0020-0005.* The USDA's Handbook for the Single Family Guaranteed Loan Program, revised March 19, 2020 can be found at *https://www.regulations.gov/document?D=CFPB-2020-0020-0004.*

determined in accordance with appendix Q.

For the reasons described in part V above, the Bureau proposed to remove the 43 percent DTI limit in current § 1026.43(e)(2)(vi) and replace it with a price-based approach. The proposal also would have required a creditor to consider the consumer's DTI ratio or residual income, income or assets other than the value of the dwelling, and debts and verify the consumer's income or assets other than the value of the dwelling and the consumer's debts. Specifically, the Bureau proposed to remove the text of current § 1026.43(e)(2)(vi) and to provide instead that, to be a General QM under § 1026.43(e)(2), the APR may not exceed APOR for a comparable transaction as of the date the interest rate is set by the amounts specified in § 1026.43(e)(2)(vi)(A) through (E).[281] Proposed § 1026.43(e)(2)(vi)(A) through (E) provided specific rate-spread thresholds for purposes of § 1026.43(e)(2), including higher thresholds for small loan amounts and subordinate-lien transactions. Proposed § 1026.43(e)(2)(vi)(A) provided that for a first-lien covered transaction with a loan amount greater than or equal to $109,898 (indexed for inflation), the APR may not exceed APOR for a comparable transaction as of the date the interest rate is set by two or more percentage points. Proposed § 1026.43(e)(2)(vi)(B) and (C) provided higher thresholds for smaller first-lien covered transactions. Proposed § 1026.43(e)(2)(vi)(D) and (E) provided higher thresholds for subordinate-lien covered transactions. Under the proposal, loans priced at or above the thresholds in proposed § 1026.43(e)(2)(vi)(A) through (E) would not have been eligible for QM status under § 1026.43(e)(2). The proposal also provided that the loan amounts specified in § 1026.43(e)(2)(vi)(A) through (E) would be adjusted annually for inflation based on changes in the Consumer Price Index for All Urban Consumers (CPI–U).

Proposed § 1026.43(e)(2)(vi) also provided a special rule for determining the APR for purposes of determining a loan's status as a General QM loan under § 1026.43(e)(2) for certain ARMs and other loans for which the interest rate may or will change in the first five years of the loan. Specifically, proposed § 1026.43(e)(2)(vi) provided that, for purposes of § 1026.43(e)(2)(vi), the creditor must determine the APR for a loan for which the interest rate may or will change within the first five years after the date on which the first regular periodic payment will be due by treating the maximum interest rate that may apply during that five-year period as the interest rate for the full term of the loan.

The Bureau proposed these revisions to § 1026.43(e)(2)(vi) for the reasons set forth above in part V.B. As explained above, the Bureau proposed to remove the 43 percent DTI limit in current § 1026.43(e)(2)(vi) and replace it with a price-based approach because the Bureau is concerned that retaining the existing General QM loan definition with the 43 percent DTI limit after the Temporary GSE QM loan definition expires would significantly reduce the size of the QM market and could significantly reduce access to responsible, affordable credit. The Bureau proposed a price-based approach to replace the specific DTI limit approach because it is concerned that imposing a DTI limit as a condition for QM status under the General QM loan definition may be overly burdensome and complex in practice and may unduly restrict access to credit because it provides an incomplete picture of the consumer's financial capacity. In the proposal, the Bureau preliminarily concluded that a price-based General QM loan definition is appropriate because a loan's price, as measured by comparing a loan's APR to APOR for a comparable transaction, is a strong indicator of a consumer's ability to repay and is a more holistic and flexible measure of a consumer's ability to repay than DTI alone.

The Bureau also proposed to remove current comment 43(e)(2)(vi)–1, which relates to the calculation of monthly payments on a covered transaction and for simultaneous loans for purposes of calculating the consumer's DTI ratio under current § 1026.43(e)(2)(vi). The Bureau did so because, under the proposal to move the text of current § 1026.43(e)(2)(vi)(B) and revise it to remove the references to appendix Q, current comment 43(e)(2)(vi)–1 would have been unnecessary. The Bureau proposed to replace current comment 43(e)(2)(vi)–1 with a cross-reference to comments 43(b)(4)–1 through –3 for guidance on determining APOR for a comparable transaction as of the date the interest rate is set. The Bureau also proposed new comment 43(e)(2)(vi)–2, which provided that a creditor must determine the applicable rate-spread threshold based on the face amount of the note, which is the ''loan amount'' as defined in § 1026.43(b)(5), and provided an example of a $75,000 loan amount that would fall into the proposed tier for loans greater than or equal to $65,939 (indexed for inflation) but less than $109,898 (indexed for inflation). In addition, the Bureau proposed comment 43(e)(2)(vi)–3 in which it would have published the annually adjusted loan amounts to reflect changes in the CPI–U. The Bureau also proposed new comment 43(e)(2)(vi)–4 to explain the proposed special rule that, for purposes of § 1026.43(e)(2)(vi), the creditor must determine the APR for a loan for which the interest rate may or will change within the first five years after the date on which the first regular periodic payment will be due by treating the maximum interest rate that may apply during that five-year period as the interest rate for the full term of the loan. The Bureau did not receive comments regarding comments 43(e)(2)(vi)–1 through –3 and is adopting them as proposed, except that the $65,939 and $109,898 loan amount thresholds in comment 43(e)(2)(vi)–2 have been revised to $66,156 and $110,260, respectively, for consistency with the Bureau's recently-issued final rule that adjusted for inflation the related thresholds in comment 43(e)(3)(ii)–1.[282] The Bureau is also adopting comment 43(e)(2)(vi)–4 as proposed and that comment is discussed further below.

For the reasons discussed in part V and below, the Bureau is adopting a price-based approach to defining General QMs in § 1026.43(e)(2)(vi) pursuant to its authority under TILA section 129C(b)(3)(B)(i). The Bureau concludes that a price-based approach to the General QM loan definition is necessary and proper to ensure that responsible, affordable mortgage credit remains available to consumers in a manner that is consistent with the purposes of TILA section 129C and is necessary and appropriate to effectuate the purposes of TILA section 129C, which includes assuring that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loan.

As noted above in part V, the Bureau concludes that a price-based General QM loan definition best balances consumers' ability to repay with ensuring access to responsible, affordable mortgage credit. The Bureau is amending the General QM loan definition because retaining the existing 43 percent DTI limit would reduce the

[281] As explained above in the section-by-section discussion of § 1026.43(e)(2)(v)(A), the Bureau proposed to move to § 1026.43(e)(2)(v)(A) the provisions in existing § 1026.43(e)(2)(vi)(B), which specify that the consumer's monthly DTI ratio is determined using the consumer's monthly payment on the covered transaction and any simultaneous loan that the creditor knows or has reason to know will be made.

[282] 85 FR 50944, 50948 (Aug. 19, 2020).

size of the QM market and likely would lead to a significant reduction in access to responsible, affordable credit when the Temporary GSE QM definition expires. The Bureau continues to believe that General QM status should be determined by a simple, bright-line rule to provide certainty of QM status, and the Bureau concludes that pricing achieves this objective. Furthermore, the Bureau concludes that pricing, rather than a DTI limit, is a more appropriate standard for the General QM loan definition. While not a direct measure of financial capacity, loan pricing is strongly correlated with early delinquency rates, which the Bureau uses as a proxy for repayment ability. The Bureau concludes that conditioning QM status on a specific DTI limit would likely impair access to credit for some consumers for whom it is appropriate to presume their ability to repay their loans at consummation. Although a pricing limit that is set too low could also have this effect, compared to DTI, loan pricing is a more flexible metric because it can incorporate other factors that may also be relevant to determining ability to repay, including credit scores, cash reserves, or residual income. The Bureau concludes that a price-based General QM loan definition is better than the alternatives because a loan's price, as measured by comparing a loan's APR to APOR for a comparable transaction, is a strong indicator of a consumer's ability to repay and is a more holistic and flexible measure of a consumer's ability to repay than DTI alone.

The Bureau concludes that a price-based approach to the General QM loan definition will both ensure that responsible, affordable mortgage credit remains available to consumers and assure that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loan. For these same reasons, the Bureau is adopting a price-based requirement in § 1026.43(e)(2)(vi) pursuant to its authority under TILA section 105(a) to issue regulations that, among other things, contain such additional requirements or other provisions, or that provide for such adjustments for all or any class of transactions, that in the Bureau's judgment are necessary or proper to effectuate the purposes of TILA, which include the above purpose of section 129C, among other things. The Bureau concludes that the price-based addition to the General QM criteria is necessary and proper to achieve this purpose, for the reasons described above in part V. Finally, the Bureau concludes a price-based approach is authorized by TILA section 129C(b)(2)(A)(vi), which permits, but does not require, the Bureau to adopt guidelines or regulations relating to DTI ratios or alternative measures of ability to pay regular expenses after payment of total monthly debt.

43(e)(2)(vi)(A)

The Bureau's Proposal

Proposed § 1026.43(e)(2)(vi)(A) provided that, for a first-lien covered transaction with a loan amount greater than or equal to $109,898 (indexed for inflation), the APR may not exceed APOR for a comparable transaction as of the date the interest rate is set by 2 or more percentage points. Thus, under the proposal, loans priced at or above the proposed 2-percentage-point threshold would not have been eligible for QM status under § 1026.43(e)(2) (except that, as discussed below, the proposal provided higher thresholds for loans with smaller loan amounts and for subordinate-lien transactions).

In the proposal, the Bureau stated that the 2002–2008 time period corresponds to a market environment that, in general, demonstrates looser, higher-risk credit conditions and that ended with very high unemployment and falling home prices. The Bureau's analysis set forth in Table 5 found direct correlations between rate spreads and early delinquency rates across all DTI ranges reviewed. The proposal stated that loans with low rate spreads had relatively low early delinquency rates even at high DTI levels and the highest early delinquency rates corresponded to loans with both high rate spreads and high DTI ratios. For loans with DTI ratios of 41 to 43 percent—the category in Table 5 that includes the current DTI limit of 43 percent—the early delinquency rates reached 16 percent at rate spreads including and above 2.25 percentage points over APOR. At rate spreads inclusive of 1.75 through 1.99 percentage points over APOR—the category that is just below the proposed 2 percentage-point rate-spread threshold—the early delinquency rate reached 22 percent for DTI ratios of 61 to 70 percent. At DTI ratios of 41 to 43 percent and rate spreads inclusive of 1.75 through 1.99 percentage points over APOR, the early delinquency rate is 15 percent.

In the proposal, the Bureau stated that, in contrast to Table 5, the 2018 time period in Table 6 corresponds to a market environment that, in general, demonstrates tighter, lower-risk credit conditions and that featured very low unemployment and rising home prices. The proposal stated that this more recent sample of data provides insight into early delinquency rates under post-crisis lending standards for a dataset of loans that had not undergone an economic downturn. In the 2018 data in Table 6, early delinquency rates also increased as rate spreads increased across each range of DTI ratios analyzed, although the overall performance of loans in the Table 6 dataset was significantly better than those represented in Table 5. For loans with DTI ratios of 36 to 43 percent—the category in Table 6 that includes the current DTI limit of 43 percent—early delinquency rates reached 3.9 percent (at rate spreads of at least 2 percentage points). The highest early delinquency rate associated with the proposed rate-spread threshold (less than 2 percentage points over APOR) is 3.2 percent and corresponds to loans with the DTI ratios of 26 to 35 percent. At the same rate-spread threshold, the early delinquency rate for the loans with the highest DTI ratios is 2.3 percent. The Bureau stated that the apparent anomalies in the progression of the early delinquency rates across DTI ratios at the higher rate spread categories in Table 6 are likely because there are relatively few loans in the 2018 data with the indicated combinations of higher rate spreads and lower DTI ratios and some creditors require that consumers demonstrate more compensating factors on higher DTI loans.

In the proposal, the Bureau stated that, although in Tables 5 and 6 delinquency rates rise with rate spread, there is no clear point at which delinquency rates accelerate and comparisons between a high-risk credit market (Table 5) and a low-risk credit market (Table 6) show substantial expansion of early delinquency rates during an economic downturn across all rate spreads and DTI ratios. Data show that, for example, prime loans that experience a 0.2 percent early delinquency rate in a low-risk market might experience a 2 percent early delinquency rate in a higher-risk market, while subprime loans with a 4.2 percent early delinquency rate in a low-risk market might experience a 19 percent early delinquency rate in a higher-risk market.

The proposal referenced data and analyses provided by CoreLogic and the Urban Institute, as discussed in part V.B.2 above, which the Bureau stated also show a strong positive correlation of delinquency rates with interest rate spreads. The Bureau stated that this evidence collectively suggests that higher rate spreads—including the specific measure of APR over APOR—

are strongly correlated with early delinquency rates. The proposal stated the Bureau's expectation that, for loans just below the respective thresholds, a pricing threshold of 2 percentage points over APOR would generally result in similar or somewhat higher early delinquency rates relative to the current DTI limit of 43 percent. However, the proposal stated that Bureau analysis shows the early delinquency rate for this set of loans is on par with loans that have received QM status under the Temporary GSE QM loan definition. Restricting the sample of 2018 NMDB–HMDA matched first-lien conventional purchase originations to only those purchased and guaranteed by the GSEs, the proposal stated that loans with rate spreads at or above 2 percentage points had an early delinquency rate of 4.2 percent, higher than the maximum early delinquency rates observed for loans with rate spreads below 2 percentage points in either Table 2 (2.7 percent) or Table 6 (3.2 percent). The proposal explained that this comparison uses 2018 data on GSE originations because such loans were originated while the Temporary GSE QM loan definition was in effect and the GSEs were in conservatorship. The proposal further explained that GSE loans from the 2002 to 2008 period were originated under a different regulatory regime and with different underwriting practices (*e.g.,* GSE loans more commonly had DTI ratios over 50 percent during the 2002 to 2008 period), and thus may not be directly comparable to loans made under the Temporary GSE QM loan definition.

In the proposal, the Bureau used 2018 HMDA data to estimate that 95.8 percent of conventional purchase loans currently meet the criteria to be defined as QMs, including under the Temporary GSE QM loan definition. The Bureau also used 2018 HMDA data to project that the proposed 2 percentage-point-over-APOR threshold would result in a 96.1 percent market share for QMs with an adjustment for small loans, as discussed below. The Bureau stated that creditors may also respond to such a threshold by lowering pricing on some loans near the threshold, further increasing the QM market share. The proposal stated that, using the size of the QM market as an indicator of access to credit, the Bureau expects that a pricing threshold of 2 percentage points over APOR, in combination with the proposed adjustments for small loans, would result in an expansion of access to credit as compared to the current rule including the Temporary GSE QM loan definition, particularly as creditors are likely to adjust pricing in response to the rule, allowing additional loans to obtain QM status. The Bureau also acknowledged, however, that some loans that do not meet the current General QM loan definition, but that would be General QMs under the proposed price-based approach, would have been made under other QM definitions (*e.g.,* FHA, small-creditor QM). Further, the Bureau stated that the proposal would result in a substantial expansion of access to credit as compared to the current rule without the Temporary GSE QM loan definition, under which only an estimated 73.6 percent of conventional purchase loans would be QMs.

In the proposal, the Bureau tentatively concluded that, in general, a 2 percentage-point-over-APOR threshold would appropriately balance ensuring consumers' ability to repay with maintaining access to responsible, affordable mortgage credit. The Bureau requested comment on the threshold amount, as well as comment on expected market changes and the possibility of adjusting the threshold in emergency situations. For the reasons discussed below, the Bureau is finalizing § 1026.43(e)(2)(vi)(A) with a threshold of 2.25 percentage points over APOR for transactions with a loan amount greater than or equal to $110,260 (indexed for inflation).

Comments Received

The Bureau received several comments concerning the proposed 2-percentage-point threshold for General QM eligibility under § 1026.43(e)(2)(vi)(A).[283] Various commenters supported finalizing the proposed threshold or raising it by some unspecified amount. A GSE supported the proposed 2-percentage-point threshold to both continue access to affordable credit and ensure consumers' ability to repay. Another GSE supported the 2-percentage-point threshold and stated it was equally supportive of increasing the threshold by an unspecified amount. Similarly, an industry commenter stated that it does not oppose increasing the threshold by some unspecified amount.

Some comments, including one from an academic commenter and a joint comment from consumer advocates, generally opposed a price-based approach but also stated concerns specifically regarding the proposed 2-percentage-point threshold for QM eligibility under § 1026.43(e)(2)(vi)(A). Citing an Urban Institute analysis that was also cited in the proposal,[284] the comments stated that, among loans with rate spreads of 1.51 to 2.00 percentage points originated from 1995 through 2008, even 30-year fixed-rate, fully documented and fully amortizing loans had high delinquency rates—especially those originated during periods of greater rate spread compression. Citing General QM Proposal Tables 1 and 3 regarding 2002–2008 first-lien purchase originations (*i.e.,* reproduced as Tables 1 and 3 above), the comments also stated that the 13 percent early delinquency rate for loans priced 1.75 to 1.99 percentage points above APOR is more than double the 6 percent early delinquency rate for loans with DTI ratios of 41 to 43 percent—and is almost double the 7 percent early delinquency rate for loans with DTI ratios of 46 to 48 percent.

A research center specifically recommended increasing the General QM eligibility threshold to 2.5 percentage points to balance ability to repay with access to credit. The commenter stated that, based on Fannie Mae and Black Knight McDash data, a 2.5-percentage-point threshold would increase the delinquency rate[285] but nonetheless the delinquency rate would remain low relative to delinquency rates experienced in the past 20 years. The research center also stated that, based on 2019 HMDA data, a 2.5-percentage-point threshold would cause 32,044 more loans to be QM-eligible than a 2-percentage-point threshold. The commenter further stated that FHA's QM rule does not limit pricing for rebuttable presumption QMs and thus increasing the Bureau's threshold under § 1026.43(e)(2)(vi)(A) would create a more level playing field and increase consumer choice.

An individual commenter generally supported proposed § 1026.43(e)(2)(vi)(A) but suggested incrementally increasing the General QM eligibility threshold to as high as 2.75 percentage points for transactions with lower points and fees. The commenter stated that the approach would provide more flexibility and help consumers avoid paying upfront points and fees.

Several commenters recommended increasing the General QM eligibility threshold to 3 percentage points. A joint comment from consumer advocate and

[283] As discussed above in part V.C, the Bureau also received comments both for and against increasing the § 1026.43(b)(4) safe harbor threshold spread from 1.5 percentage points to 2 percentage points.

[284] *See* Kaul & Goodman, *supra* note 194.

[285] The analysis provided by the commenter looked at loans that had ever been 60 days or more delinquent, rather than 60 or more days delinquent during the first two years, which is the standard used in the Bureau's analysis.

industry groups included some signatories recommending a 3-percentage-point threshold and no signatories opposing it. Another joint comment from consumer advocate and industry groups supported a 3-percentage-point threshold to balance ability to repay with access to credit. The latter joint comment stated that, based on Fannie Mae data and accounting for current risk-based mortgage insurance premiums, a 3-percentage-point threshold would increase the early delinquency rate but nonetheless the delinquency rate would be low relative to the Great Recession. Citing an FHFA working paper that was also cited by the General QM Proposal,[286] the joint comment further stated that loans with non-QM features—including interest-only loans, ARM loans that combined teaser rates with subsequent large jumps in payments, negative amortization loans, and loans made with limited or no documentation of the borrower's income or assets—accounted for about half of the rise in risk leading up to the 2008 financial crisis and subsequent passage of the Dodd-Frank Act. The joint comment stated that the Bureau should promote more consumers receiving the important benefits of the Dodd-Frank Act's QM product restrictions—including lower-income and minority consumers that would otherwise be disproportionally excluded—by increasing the threshold for QM eligibility under § 1026.43(e)(2)(vi)(A).

The Bureau also received comments—including one from a research center and a joint comment from consumer advocate and industry groups—recommending an increase in the General QM pricing threshold to account for possible future rate spread widening in the market, as also discussed above in part V.C with respect to the safe harbor threshold. The Bureau also received a joint comment from consumer advocates that generally opposed a price-based approach but also stated that the Bureau should not increase the General QM pricing threshold in future emergency situations without notice-and-comment rulemaking.

The Final Rule

For the reasons discussed below, the Bureau is adopting § 1026.43(e)(2)(vi)(A) with a threshold of 2.25 percentage points over APOR for transactions with a loan amount greater than or equal to $110,260 (indexed for inflation). The Bureau concludes that, for most first-lien covered transactions, a 2.25 percentage point pricing threshold strikes the best balance between ensuring consumers' ability to repay and ensuring access to responsible, affordable mortgage credit. The Bureau is adopting § 1026.43(e)(2)(vi)(A) with a $110,260 loan amount threshold for consistency with the Bureau's recently-issued final rule that adjusted for inflation the related $109,898 threshold in comment 43(e)(3)(ii)–1.[287] As discussed below, the final rule provides higher thresholds for loans with smaller loan amounts and for subordinate-lien transactions. The final rule provides an increase from the proposed thresholds for some small manufactured housing loans to ensure continued access to credit.

The Bureau concludes that a General QM eligibility threshold lower than 2.25 percentage points would unduly limit some consumers to non-QM or FHA loans, which generally have materially higher costs, or would unduly result in some consumers not being able to obtain a loan at all despite their ability to afford one, given the current lack of a robust non-QM market.[288] As discussed in part V.B.5 above, Table 7A shows that 96.3 percent of 2018 conventional first-lien purchase originations would have been QMs under this revised ATR/QM Rule, as compared to a 94.7 percent share under the existing ATR/QM Rule, including the Temporary GSE QM loan definition. As discussed in the Bureau's Dodd-Frank Act section 1022(b) analysis below, among loans that fall outside the current General QM loan definition because they have a DTI ratio above 43 percent, the Bureau estimates that 959,000 of these conventional loans in 2018 would fall within this final rule's General QM loan definition. The Bureau concludes that some consumers with those conventional loans with DTI ratios above 43 percent could have instead obtained non-QM or FHA loans, which generally have materially higher costs, but others would not have obtained a loan at all. For example, based on application-level data obtained from nine large lenders, the Assessment Report found that the January 2013 Final Rule eliminated between 63 and 70 percent of non-GSE eligible home purchase loans with DTI ratios above 43 percent.[289] The Bureau concludes that a 2.25 percentage point General QM eligibility threshold helps address those access-to-credit concerns—including concerns related to certain ARMs and manufactured housing loans discussed below—while striking an appropriate balance with ability-to-repay concerns.

A 2.25 percentage point pricing threshold for QM eligibility under § 1026.43(e)(2)(vi)(A) is also supported by the Bureau's conclusion that the Dodd-Frank Act QM product restrictions contribute to ensuring that consumers have the ability to repay their loans and are important for maintaining and expanding access to responsible, affordable mortgage credit. The Bureau concludes that loans with non-QM features—including interest-only loans, negative amortization loans, and loans made with limited or no documentation of the borrower's income or assets—had a substantial negative effect on consumers' ability to repay leading up to the 2008 financial crisis and subsequent passage of the Dodd-Frank Act. The Bureau concludes that promoting access to more QMs with the important benefits of the Act's QM product restrictions will help ensure consumers' ability to repay. Furthermore, for General QMs priced greater than or equal to 1.5 but less than 2.25 percentage points above APOR, consumers would also be afforded the opportunity to rebut the creditor's QM presumption of compliance.

In response to commenters who stated that the early delinquency rate for the proposed 2-percentage-point threshold would be too high to justify a QM presumption of compliance, the Bureau acknowledges that Table 1 for 2002–2008 first-lien purchase originations shows a 14 percent early delinquency rate for loans priced 2.00 to 2.24 percentage points above APOR, as compared to a 13 percent early delinquency rate for loans priced 1.75 to 1.99 percentage points above APOR and a 12 percent early delinquency rate for loans priced 1.50 to 1.74 percentage points above APOR.[290] The comparable

[286] Davis et al., *supra* note 179.

[287] 85 FR 50944, 50948 (Aug. 19, 2020).

[288] The Bureau stated in the January 2013 Final Rule that it believed a significant share of mortgages would be made under the general ATR standard. 78 FR 6408, 6527 (Jan. 30, 2013). However, the Assessment Report found that a robust market for non-QM loans above the 43 percent DTI limit has not materialized as the Bureau had predicted and, therefore, there is limited capacity in the non-QM market to provide access to credit after the expiration of the Temporary GSE QM loan definition. Assessment Report, *supra* note 63, at 198. As described above, the non-QM market has been further reduced by the recent economic disruptions associated with the COVID–19 pandemic, with most mortgage credit now available in the QM lending space. The Bureau acknowledges that the slow development of the non-QM market and the recent economic disruptions associated with the COVID–19 pandemic may significantly hinder its development in the near term.

[289] Assessment Report, *supra* note 63, at 10–11, 117, 131–47.

[290] The Bureau also acknowledges that Table 5 shows that for loans with DTI ratios of 61–70 in the 2002–2008 data, the early delinquency rates were 26 percent for loans priced 2.00 to 2.24 percentage

Continued

early delinquency rates for 2018 loans from Table 2 also show a higher early delinquency rate for loans priced 2.00 percentage points or more above APOR compared to loans priced 1.50 to 1.99 percentage points above APOR: 4.2 percent versus 2.7 percent.[291] However, Bureau analysis shows the early delinquency rate for this set of loans is on par with loans that have received QM status under the Temporary GSE QM loan definition. Specifically, when restricting the sample of 2018 NMDB–HMDA matched first-lien conventional purchase originations to only those purchased and guaranteed by the GSEs, loans with rate spreads at or above 2 percentage points had an early delinquency rate of 4.2 percent. As explained above, this comparison uses 2018 data because such loans were originated while the Temporary GSE QM loan definition was in effect and the GSEs were in conservatorship, whereas GSE loans from the 2002 to 2008 period were originated under a different regulatory regime and with different underwriting practices that may not be directly comparable to loans made under the Temporary GSE QM loan definition.

In response to commenters, and as discussed above in part V.C.4, the Bureau concludes that it would be premature at this point to increase the QM safe harbor threshold based on possible future spread widening both because of uncertainty regarding effects on APOR itself as well as insufficient evidence of a significant access-to-credit difference between safe harbor and rebuttable presumption QMs. But for the General QM eligibility threshold under § 1026.43(e)(2)(vi)(A), notwithstanding the uncertainty regarding effects on APOR itself, the Bureau concludes that a robust non-QM market has not yet emerged and, thus, loans that exceed that threshold may not be available to some consumers, even though they would have been within the consumer's ability to repay. Thus, the Bureau concludes that (in addition to the reasons above) future spread widening also supports the 2.25 percentage point pricing threshold because future spread widening poses a greater potential access-to-credit concern for the General QM eligibility threshold under § 1026.43(e)(2)(vi)(A) than for the safe harbor threshold under § 1026.43(b)(4), if levels of non-QM lending remain low. This conclusion is consistent with the Bureau's findings in the Assessment Report, which suggest that, while the safe harbor threshold of 1.5 percentage points has not constrained lenders from originating rebuttable presumption QMs, only a modest amount of non-QM lending has occurred since the January 2013 Final Rule took effect.[292] Moreover, the Bureau will monitor the market and take action as needed to maintain the best balance between consumers' ability to repay and access to responsible, affordable mortgage credit.

The Bureau concludes that it has insufficient evidence as to whether a threshold higher than 2.25 percentage points would strike the best balance with ability-to-repay concerns, particularly given the limited expected access to credit gains from increasing the threshold higher than 2.25 percentage points.[293] While the 14 percent early delinquency rate in Table 1 for loans priced 2.00 to 2.24 percentage points above APOR is the same early delinquency rate as for loans priced 2.25 percentage points or more above APOR, all loans with rate spreads of 2.25 percentage points or more needed to be grouped to ensure sufficient sample size for reliable analysis of the 2002–2008 data.[294]

43(e)(2)(vi)(B)–(F)

Thresholds for Smaller Loans and Subordinate-Lien Transactions

The Bureau proposed to establish higher pricing thresholds for smaller loans. Under the proposal, smaller loans priced at or above the proposed thresholds would not have been eligible for QM status under § 1026.43(e)(2). Specifically, proposed § 1026.43(e)(2)(vi)(B) provided that, for first-lien covered transactions with loan amounts greater than or equal to $65,939 but less than $109,898, the APR may not exceed APOR for a comparable transaction as of the date the interest rate is set by 3.5 or more percentage points.[295] Proposed § 1026.43(e)(2)(vi)(C) provided that, for first-lien covered transactions with loan amounts less than $65,939, the APR may not exceed the APOR for a comparable transaction as of the date the interest rate is set by 6.5 or more percentage points.

The Bureau also proposed to establish higher thresholds for subordinate-lien transactions. Under the proposal, subordinate-lien transactions priced at or above the proposed thresholds would not have been eligible for QM status under § 1026.43(e)(2). Specifically, proposed § 1026.43(e)(2)(vi)(D) provided that, for subordinate-lien covered transactions with loan amounts greater than or equal to $65,939, the APR may not exceed the APOR for a comparable transaction as of the date the interest rate is set by 3.5 or more percentage points. Proposed § 1026.43(e)(2)(vi)(E) provided that, for subordinate-lien covered transactions with loan amounts less than $65,939, the APR may not exceed the APOR for a comparable transaction as of the date the interest rate is set by 6.5 or more percentage points.

The proposal also provided that the loan amounts specified in § 1026.43(e)(2)(vi)(A) through (E) would be adjusted annually for inflation based on changes in CPI–U. Specifically, the Bureau proposed adjusting the loan amounts in § 1026.43(e)(2)(vi) annually on January 1 by the annual percentage change in the CPI–U that was reported on the preceding June 1. The Bureau proposed publishing adjustments in new comment 43(e)(2)(vi)–3 after the June figures became available each year.

For the reasons discussed below, the Bureau is finalizing § 1026.43(e)(2)(vi)(B) through (E) as proposed, except that proposed § 1026.43(e)(2)(vi)(D) has been redesignated as § 1026.43(e)(2)(vi)(E) and proposed § 1026.43(e)(2)(vi)(E) has been redesignated as § 1026.43(e)(2)(vi)(F) because the Bureau is finalizing a threshold for smaller manufactured housing loans in § 1026.43(e)(2)(vi)(D).[296] The Bureau is also finalizing two additional comments to clarify terms and phrases used in § 1026.43(e)(2)(vi)(D). Specifically, comment 43(e)(2)(vi)–5 clarifies that the term ''manufactured home,'' as used in

points above APOR, relative to 22 percent for loans priced 1.75 to 2.00 percentage points above APOR.

[291] Similarly, Table 6 shows that for the DTI ratios with the highest early delinquency rates (DTI ratios of 26–35), the early delinquency rates were 4.4 percent for loans priced 2.00 or more percentage points over APOR, compared to 3.2 percent for loans priced 1.50 to 1.99 percentage points over APOR.

[292] Assessment Report, *supra* note 63, section 5.5, at 187.

[293] As discussed in part V.B.5 above, Table 7A shows that 96.3 percent of 2018 conventional first-lien purchase originations would have been QMs under this revised ATR/QM Rule including § 1026.43(e)(2)(vi)(A) with a threshold of 2.25 percentage points over APOR. Table 7A shows a 96.6 percent share if the threshold were instead increased to 2.5 percentage points over APOR.

[294] 85 FR 41716, 41732 n.190 (July 10, 2020).

[295] On August 19, 2020, the Bureau issued a final rule adjusting the loan amounts for the limits on points and fees under § 1026.43(e)(3)(i), based on the annual percentage change reflected in the CPI–U in effect on June 1, 2020. 85 FR 50944 (Aug. 19, 2020). To ensure that the loan amounts for § 1026.43(e) remain synchronized, the Bureau is finalizing this rule with a threshold of $66,156, rather than a threshold of $65,939, and $110,260, rather than a threshold of $109,898.

[296] As noted above, and discussed in more detail below, the Bureau is increasing the loan amounts specified in § 1026.43(e)(2)(vi)(A) through (F) because the new adjustments for 2021 have been published. *See* 85 FR 50944 (Aug. 19, 2020).

§ 1026.43(e)(2)(vi)(D), means any residential structure as defined under HUD regulations establishing manufactured home construction and safety standards (24 CFR 3280.2). The comment further clarifies that modular or other factory-built homes that do not meet the HUD code standards are not manufactured homes for purposes of § 1026.43(e)(2)(vi)(D). Comment 43(e)(2)(vi)–6 provides that the threshold in § 1026.43(e)(2)(vi)(D) applies to first-lien covered transactions less than $110,260 (indexed for inflation) that are secured by a manufactured home and land, or by a manufactured home only.

Comments Received

The Bureau received several comments from consumer advocates, the mortgage industry, research centers, and others in response to the proposed pricing thresholds for smaller loans and subordinate-lien transactions. While some commenters supported the Bureau's proposed thresholds, others expressed various concerns, as described below.

Pricing thresholds for smaller loans. Consumer advocates and industry commenters offered differing viewpoints on whether the Bureau should consider the creditor's costs in developing the thresholds for smaller loans. Consumer advocate commenters noted that the statute requires the Bureau to consider the consumer's ability to repay when defining General QM; thus, in developing thresholds, the Bureau should not consider the creditor's costs or profit margins, which the commenter perceived was the Bureau's basis for developing higher thresholds for smaller loans, absent a showing that the available credit is responsible and affordable. Conversely, industry commenters suggested that the Bureau should consider the creditor's costs in developing the thresholds for smaller loans, given the impact these costs have on the price of these loans, specifically manufactured housing loans. For example, these commenters noted that, despite having smaller loan amounts, manufactured housing loans, including chattel loans, tend to have the same or similar origination and servicing costs as traditional mortgages. They also asserted that, unlike traditional mortgages, manufactured housing loans, including chattel loans, lack access to secondary market funding and to private mortgage insurance to offset credit risk and protect against potential losses. Overall, industry commenters stated that the thresholds for smaller loans should provide creditors with the ability to recover their costs for originating and servicing smaller loans, and still originate qualified mortgages.

The Bureau also received comments about the impact of the proposed thresholds on low- to moderate-income and minority consumers and on land installment contracts. With respect to the former, one large credit union expressed concern about the impact the proposed loan amount thresholds for smaller loans would have on these consumers given the rise in home prices. In addition, one State trade association observed that some loans greater than $65,939 exceeded the proposed pricing thresholds due to various risk factors, such as high LTV ratios or negative credit history, and that it was unclear whether these risk factors were more common among low- to moderate-income and minority consumers. With respect to land installment contracts, consumer advocate commenters asserted that under the Bureau's proposed thresholds for smaller loans, land installment contracts would newly be eligible for QM status, which would impede consumer lawsuits against creditors.

Data to support the thresholds for smaller loans. Consumer advocate commenters recommended that the Bureau further refine the data used to support the thresholds for smaller loans. Specifically, they recommended that the Bureau refine the data to include the volume of loans in each rate-spread range, loan performance data using incremental rate-spread ranges instead of cumulative rate-spread ranges, and an analysis that separates chattel loans from real estate-secured mortgages.

A few consumer advocate commenters underscored the need for refining the data by analyzing the early delinquency rates shown in General QM Proposal Table 5,[297] which, according to these commenters, indicate that the proposed thresholds for smaller loans would harm vulnerable consumers. Specifically, these commenters noted that for loans priced 2.25 or more percentage points above APOR and with a DTI ratio greater than 26 percent, early delinquency rates were 10 percent or higher; and for similarly priced loans with DTI ratios between 40 and 50 percent, early delinquency rates were between 16 to 19 percent. These commenters also noted that General QM Proposal Table 5 did not show the early delinquency rate for 2002–2008 first-lien purchase originations in the NMDB at the proposed thresholds for smaller loans (3.5 or 6.5 percentage points above APOR). These commenters recommended that the Bureau make available for comment a revised version of General QM Proposal Table 5 that shows the historical early delinquency rates for first-lien purchase originations categorized by DTI and rate spreads greater than 2.25 percentage points above APOR, before it presumes ability to repay for consumers taking out loans with higher rate spreads.

Aside from noting issues with the Bureau's data, consumer advocate commenters also noted that the limited public data appears to suggest that smaller loans do not perform well, citing a newspaper article on manufactured housing loans, which described features unique to manufactured housing loans and reported that 28 percent of chattel loans fail to perform, as an example.[298]

QM share of manufactured housing loans. A few industry commenters asserted that a substantial share of manufactured housing loans qualifying as General QMs under the current definition would fail to qualify as General QMs under the proposed thresholds. Some of these commenters surveyed their members to obtain information to estimate the decline in shares of manufactured housing loans that would meet the standards to be General QMs. For example, members of a national manufactured housing trade association stated that they expect up to 50 percent of their manufactured housing loans would lose General QM status under the proposed thresholds for smaller loans. Members of a trade group representing credit unions likewise stated that they expect up to 90 percent of their manufactured housing loans would lose General QM status. Other commenters used 2019 HMDA data to estimate the decline in shares of manufactured housing loans that would be eligible for General QM status. For instance, while comparing data from General QM Proposal Table 7 with 2019 HMDA data, a non-depository manufactured housing creditor asserted that, compared to first-lien manufactured housing loans, the Bureau's proposed thresholds would

[297] 85 FR 41716, 41733 (July 10, 2020) (showing early delinquency rates for 2002–2008 first-lien purchase originations in NMDB data categorized according to both their DTI ratios and their approximate rate spreads).

[298] Mike Baker & Daniel Wagner, *The mobile-home trap: How a Warren Buffet empire preys on the poor,* The Seattle Times (Apr. 2, 2015), *https://www.seattletimes.com/business/real-estate/the-mobile-home-trap-how-a-warren-buffett-empire-preys-on-the-poor/#:~:text=Special%20Reports-,The%20mobile%20home%20trap%3A%20How%20a%20Warren%20Buffett,empire%20preys%20on%20the%20poor&text=Billionaire%20philanthropist%20Warren%20Buffett%20controls,loans%20and%20rapidly%20depreciating%20homes.*

allow for far more first-lien conventional purchase loans for site-built housing to be eligible for General QM status.[299]

To prevent a decline in the share of manufactured housing loans eligible for General QM status, commenters recommended the following adjustments or alternatives to the Bureau's proposed thresholds for smaller loans. One industry commenter recommended that the Bureau increase the pricing threshold for smaller loans but did not provide specific thresholds. Two other industry commenters recommended increasing the loan amount thresholds instead, from $65,939 to $110,000 and from $109,898 to $210,000. One of these commenters added that the Bureau should set these thresholds either for all loans or for only manufactured housing loans, while the other added that 91 percent of the first-lien manufactured housing loans originated in 2019 would have been eligible for General QM status if these higher loan amount thresholds were in place. One of these commenters also recommended a complementary DTI approach for manufactured housing loans. Under this approach, a manufactured housing loan would be eligible for General QM status by either satisfying the pricing thresholds or having a DTI ratio no higher than 45 percent, when determined in accordance with GSE or Federal agency underwriting guidelines. Lastly, a manufacturing housing creditor recommended incorporating HOEPA's APR thresholds for high-cost mortgages into a definition of General QM for manufactured housing loans. Specifically, the creditor recommended that a first-lien covered transaction secured by a manufactured home would have a conclusive presumption of compliance if the APR at consummation did not exceed the APOR by more than 1.5 percentage points; a rebuttable presumption of compliance if the APR at consummation did not exceed the APOR by 6.5 percentage points; and a rebuttable presumption of compliance if the transaction was a first-lien, personal property loan under $50,000 and the APR at consummation did not exceed the APOR by 8.5 percentage points. To underscore the importance of preventing an estimated decline in the share of manufactured housing loans that are General QMs, these commenters asserted that, without General QM status, creditors may either extend manufactured housing loans as more expensive non-QMs, or not extend these loans at all.[300]

Consumer advocate commenters, however, asserted that creditors offering manufactured housing loans could adjust the price of these loans to fit within the Bureau's proposed thresholds, noting that creditors were able to price manufactured housing loans below HOEPA's APR thresholds for high-cost mortgages after those thresholds were adopted. Consumer advocate commenters also added that a high threshold would encourage exploitative lending right under the threshold.

QM share of subordinate-lien transactions. A few industry commenters noted that a sizable share of subordinate-lien transactions qualifying as General QMs under the current definition would fail to qualify as General QMs under the proposed thresholds.

To prevent the estimated decline in the share of subordinate-lien transactions that would obtain QM status under the proposed thresholds, one industry commenter recommended that the Bureau retain the current General QM loan definition for higher-priced mortgage loans, increase the pricing threshold for subordinate-lien transactions while using the same proposed loan amount thresholds used for first-lien transactions, or both. Under the commenter's second recommendation, a subordinate-lien transaction would qualify as a General QM if the APR at consummation does not exceed the APOR by 5 percentage points for transactions with a loan amount greater than or equal to $109,898; by 5.5 percentage points for transactions with a loan amount greater than or equal to $65,939 but less than $109,898; and by 8.5 percentage points for transactions with a loan amount less than $65,939. The commenter pointed to General QM Proposal Table 10 to demonstrate that delinquency rates did not materially differ under these recommended thresholds.[301]

The Final Rule

The Bureau is adopting the proposed pricing thresholds for smaller loans and subordinate-lien transactions. However, as described below, the Bureau is finalizing an additional, higher pricing threshold for smaller loans secured by a manufactured home. In developing pricing thresholds under the General QM loan definition for smaller loans, smaller loans secured by a manufactured home, and subordinate-lien transactions, the Bureau balanced considerations related to ensuring consumers' ability to repay with maintaining access to responsible, affordable mortgage credit.[302]

The final rule amends § 1026.43 by revising § 1026.43(e)(2)(vi) to provide higher pricing thresholds to define General QM for smaller loans, smaller loans secured by a manufactured home, and subordinate-lien transactions. The Bureau is also adjusting the loan amounts specified in § 1026.43(e)(2)(vi)(A) through (F). As discussed in the proposal, the Bureau proposed loan amount thresholds of $65,939 and $109,898, because those thresholds aligned with certain thresholds for the limits on points and fees, as updated for inflation, in § 1026.43(e)(3)(i) and the associated commentary.[303] On August 19, 2020, the Bureau issued a final rule adjusting the loan amounts for the limits on points and fees under § 1026.43(e)(3)(i), based on the annual percentage change reflected in the CPI–U in effect on June 1, 2020.[304] To ensure that the loan amounts for § 1026.43(e) remain synchronized, the Bureau is finalizing the loan amount thresholds specified in § 1026.43(e)(2)(vi)(A) through (F) with a threshold of $66,156, rather than a threshold of $65,939, and $110,260, rather than a threshold of $109,898. As clarified in comment 43(e)(2)(vi)–3, these amounts shall be adjusted annually on January 1 by the annual percentage change in the CPI–U that was reported on the preceding June 1.

Final § 1026.43(e)(2)(vi)(B) provides that, for first-lien covered transactions with loan amounts greater than or equal to $66,156 (indexed for inflation) but less than $110,260 (indexed for inflation), the APR may not exceed APOR for a comparable transaction as of the date the interest rate is set by 3.5 or more percentage points. Section 1026.43(e)(2)(vi)(C) provides that, for first-lien covered transactions with loan amounts less than $66,156 (indexed for

[299] 85 FR 41716, 41736 (July 10, 2020) (showing the share of 2018 first-lien conventional purchase loans under various General QM loan definitions).

[300] The non-depository manufactured housing creditor specifically discussed the impact of a manufactured housing loan being subject to TILA's appraisal requirements for higher-priced mortgages because, without QM status, these loans would not be eligible for the exemption from these requirements under 12 CFR 1026.35(c)(2)(i).

[301] 85 FR 41716, 41760 (July 10, 2020) (analyzing credit characteristics and loan performance for subordinate-lien transactions at various rate spreads and loan amounts (adjusted for inflation) using HMDA and Y–14M data).

[302] The Bureau's decisions to adopt basic pricing thresholds of 1.5 and 2.25 percentage points above APOR and to supplement them with higher pricing thresholds for smaller loans, for smaller loans secured by a manufactured home, and for subordinate-lien transactions are each independent of one another.

[303] *Id.* at 41757 n.270.

[304] 85 FR 50944 (Aug. 19, 2020).

inflation), the APR may not exceed APOR for a comparable transaction as of the date the interest rate is set by 6.5 or more percentage points. Section 1026.43(e)(2)(vi)(D) provides that, for first-lien covered transactions secured by a manufactured home with loan amounts less than $110,260 (indexed for inflation), the APR may not exceed APOR for a comparable transaction as of the date the interest rate is set by 6.5 or more percentage points. Section 1026.43(e)(2)(vi)(E) provides that, for subordinate-lien covered transactions with loan amounts greater than or equal to $66,156 (indexed for inflation), the APR may not exceed APOR for a comparable transaction as of the date the interest rate is set by 3.5 or more percentage points. Section 1026.43(e)(2)(vi)(F) provides that, for subordinate-lien covered transactions with loan amounts less than $66,156 (indexed for inflation), the APR may not exceed APOR for a comparable transaction as of the date the interest rate is set by 6.5 or more percentage points.

The Bureau is also adding two comments to provide additional clarification on terms and phrases used in § 1026.43(e)(2)(vi)(D). Comment 43(e)(2)(vi)–5 clarifies that the term ''manufactured home,'' as used in § 1026.43(e)(2)(vi)(D), means any residential structure as defined under HUD regulations establishing manufactured home construction and safety standards (24 CFR 3280.2). Modular or other factory-built homes that do not meet the HUD code standards are not manufactured homes for purposes of § 1026.43(e)(2)(vi)(D). The Bureau is aligning the definition of ''manufactured home'' with the HUD standards to maintain consistency with the definition the Bureau uses elsewhere in Regulation Z.[305] Comment 43(e)(2)(vi)–6 provides that the threshold in § 1026.43(e)(2)(vi)(D) applies to first-lien covered transactions less than $110,260 (indexed for inflation) that are secured by a manufactured home and land, or by a manufactured home only.

Smaller loans. The Bureau is adopting higher thresholds for smaller loans because it is concerned that loans with smaller loan amounts are typically priced higher than loans with larger loan amounts, even though a consumer with a smaller loan may have similar credit characteristics and likelihood of early delinquency, which the Bureau uses as a proxy for measuring whether a consumer had a reasonable ability to repay at the time the loan was consummated. As discussed in the General QM Proposal—and noted by commenters supporting the proposed higher thresholds for smaller loans—many of the creditors' costs for a transaction may be the same or similar between smaller loans and larger loans. For creditors to recover their costs for originating and servicing smaller loans, they may have to charge higher interest rates or higher points and fees as a percentage of the loan amount than they would for comparable larger loans. As a result, smaller loans tend to have higher APRs than larger loans to consumers with similar credit characteristics and who may have a similar ability to repay. The Bureau concludes that its observation of the components of creditors' costs, in this limited regard, is consistent with its statutory obligations. As stated above, TILA section 129C(b)(3)(B)(i) authorizes the Bureau to prescribe regulations that revise, add to, or subtract from the criteria that define a QM upon a finding that those regulations are necessary or proper to ensure that responsible, affordable credit remains available to consumers in a manner consistent with the purposes of TILA section 129C. Here, as further explained below, the Bureau's analysis indicates that consumers who take out smaller loans with APRs within higher thresholds may have similar credit characteristics as consumers who take out larger loans. The Bureau's analysis also indicates that smaller loans with APRs within higher thresholds may have comparable levels of early delinquencies as larger loans within lower thresholds. However, as explained further below, the Bureau's analysis of delinquency levels for smaller loans, compared to larger loans, does not appear to indicate a threshold at which delinquency levels significantly accelerate. Nevertheless, the Bureau concludes that the finalized thresholds for smaller loans best ensure that responsible, affordable credit remains available to consumers taking out smaller loans, while also helping to ensure that the risks are limited. The Bureau thus concludes that smaller loans that are higher-priced loans under § 1026.43(b)(4) but are priced below the applicable thresholds in § 1026.43(e)(2)(vi)(B) or (C) will receive a rebuttable presumption of compliance with the ATR requirements.

Moreover, adopting the same threshold of 2.25 percentage points above APOR for all loans could disproportionately prevent smaller loans with comparable levels of early delinquencies as larger loans, potentially including a disproportionate number of loans to minority consumers, from being originated as General QMs. The Bureau's analysis of 2018 HMDA data found that 3.7 percent of site-built loans to minority consumers are priced 2.25 percentage points or more over APOR, but 2.7 percent of site-built loans to non-Hispanic White consumers are priced 2.25 percentage points or more over APOR. While some loans may be originated under other QM definitions or as non-QM loans, those loans may cost materially more to consumers, and some loans may not be originated at all. As discussed in part V, the non-QM market has been slow to develop, and the negative impact on the non-QM market from the disruptions caused by the COVID–19 pandemic raises further concerns about the capacity of the non-QM market to provide consumers with access to credit through such loans.

The Bureau also notes that, in the Dodd-Frank Act, Congress provided for additional pricing flexibility for creditors making smaller loans, allowing smaller loans to include higher points and fees while still meeting the QM definition. TILA section 129C(b)(2)(A)(vi) defines a QM as a loan for which, among other things, the total points and fees payable in connection with the loan do not exceed 3 percent of the total loan amount. However, TILA section 129C(b)(2)(D) requires the Bureau to prescribe rules adjusting the points-and-fees limits for smaller loans. In the January 2013 Final Rule, the Bureau implemented this requirement in § 1026.43(e)(3), adopting higher points-and-fees thresholds for different tiers of loan amounts less than or equal to $100,000, adjusted for inflation.[306] The Bureau's conclusion that creditors originating smaller loans typically impose higher points and fees or higher interest rates to recover their costs, regardless of the consumer's creditworthiness, and that higher thresholds for smaller loans in § 1026.43(e)(2)(vi) are therefore warranted, is generally consistent with the statutory directive to adopt higher points-and-fees thresholds for smaller loans.

To develop the thresholds for smaller loans in § 1026.43(e)(2)(vi)(B) and (C), the Bureau analyzed evidence related to credit characteristics and loan performance for first-lien purchase transactions at various rate spreads and loan amounts (adjusted for inflation) using HMDA and NMDB data, as shown in Table 9.[307] To ensure a sufficient

[305] *See, e.g.,* 12 CFR 1026.35(c)(1)(iii).

[306] *See* 78 FR 6408, 6528 (Jan. 30, 2013).

[307] *See Bureau of Labor and Statistics, Historical Consumer Price Index for All Urban Consumers*

Continued

sample size was available for a reliable analysis, the Bureau used cumulative rate-spread ranges.

analysis, the Bureau used cumulative rate-spread ranges.

TABLE 9—LOAN CHARACTERISTICS AND PERFORMANCE FOR DIFFERENT SIZES OF FIRST-LIEN TRANSACTIONS AT VARIOUS RATE SPREADS

Loan size group	Rate spread range (percentage points over APOR)	Mean CLTV, 2018 HMDA	Mean DTI, 2018 HMDA	Mean credit score, 2018 HMDA	Percent observed 60+ days delinquent within first 2 years, 2002–2008 NMDB (%)	Percent observed 60+ days delinquent within first 2 years, 2018 NMDB (%)
Under $66,156	1.5–2.0	81.9	32.3	717	6.1	2.8
Under $66,156	1.5–2.5	82.2	32.3	714	6.1	2.3
Under $66,156	1.5–3.0	82.1	32.2	714	6.2	2.3
Under $66,156	1.5–3.5	81.9	32.1	715	6.2	2.5
Under $66,156	1.5–4.0	81.7	32.3	714	6.3	2.5
Under $66,156	1.5–4.5	81.7	32.5	710	6.4	2.6
Under $66,156	1.5–5.0	81.7	32.6	706	6.4	2.5
Under $66,156	1.5–5.5	81.6	32.7	699	6.5	2.4
Under $66,156	1.5–6.0	81.7	32.9	694	6.5	2.5
Under $66,156	1.5–6.5	81.9	33.1	685	6.5	3.4
Under $66,156	1.5 and above	82.0	33.3	676	6.6	4.1
$66,156 to $110,259	1.5–2.0	89.9	35.5	704	11.1	3.4
$66,156 to $110,259	1.5–2.5	90.1	35.4	702	12.2	4.2
$66,156 to $110,259	1.5–3.0	90.0	35.5	702	12.9	4.2
$66,156 to $110,259	1.5–3.5	89.7	35.5	703	13.0	4.3
$66,156 to $110,259	1.5–4.0	89.4	35.6	703	13.1	4.0
$66,156 to $110,259	1.5–4.5	89.3	35.7	701	13.2	4.2
$66,156 to $110,259	1.5–5.0	89.1	35.8	699	13.3	4.1
$66,156 to $110,259	1.5–5.5	89.1	35.9	696	13.4	4.0
$66,156 to $110,259	1.5–6.0	89.2	36.0	692	13.4	4.2
$66,156 to $110,259	1.5–6.5	89.3	36.1	684	13.4	4.5
$66,156 to $110,259	1.5 and above	89.3	36.1	684	13.7	4.5
$110,260 and above, manufactured and site-built housing.	1.5–2.25 (for comparison)	92.4	39.3	698	15.6	2.7

The Bureau's analysis indicates that consumers with smaller loans with APRs within higher thresholds, such as 6.5 or 3.5 percentage points above APOR, have similar credit characteristics as consumers with larger loans with APRs between 1.5 and 2.25 percentage points above APOR.[308]

More specifically, the Bureau analyzed 2018 HMDA data on first-lien conventional purchase loans and found that loans less than $66,156 that are priced between 1.5 and 6.5 percentage points above APOR have a mean DTI ratio of 33.1 percent, a mean combined LTV ratio of 81.9 percent, and a mean credit score of 685. Loans greater than or equal to $66,156 but less than $110,260 that are priced between 1.5 and 3.5 percentage points above APOR have a mean DTI ratio of 35.5 percent, a mean combined LTV of 89.7 percent, and a mean credit score of 703. Loans greater than or equal to $110,260 that are priced between 1.5 and 2.25 percentage points above APOR have a mean DTI ratio of 39.3 percent, a mean combined LTV of 92.4 percent, and a mean credit score of 698. These data comparisons all suggest that the credit characteristics, and potentially the ability to repay, of consumers taking out smaller loans with higher APRs, may be at least comparable to those of consumers taking out larger loans with lower APRs.

With respect to early delinquencies, the evidence summarized in Table 9 generally provides support for higher thresholds for smaller loans. Loans less than $66,156 had lower delinquency rates than loans greater than or equal to $66,156 but less than $110,260 across all rate spread ranges and generally had delinquency rates lower than larger loans (greater than or equal to $110,260) priced between 1.5 and 2.25 percentage points above APOR, except as described below. Loans greater than or equal to $66,156 but less than $110,260 had lower delinquency rates than larger loans between 2002 and 2008, but higher delinquency rates in 2018.

More specifically, the Bureau analyzed NMDB data from 2002 through 2008 on first-lien conventional purchase loans and found that loans less than $66,156 that were priced between 1.5 and 6.5 percentage points above APOR had an early delinquency rate of 6.5 percent. Loans greater than or equal to $66,156 but less than $110,260 that were priced between 1.5 and 3.5 percentage points above APOR had an early delinquency rate of 13 percent. Loans greater than or equal to $110,260

(CPI–U), (Apr. 2020), *https://www.bls.gov/cpi/tables/supplemental-files/historical-cpi-u-202004.pdf.* (Using the CPI–U price index, nominal loan amounts are inflated to June 2020 dollars from the price level in June of the year prior to origination. This effectively categorizes loans according to the inflation-adjusted thresholds for smaller loans that would have been in effect on the origination date. The set of loans categorized within a given threshold remains the same as in the proposal, in which nominal loan amounts were inflated to June 2019 dollars and compared against the corresponding threshold levels of $65,939 and $109,898.)

[308] Portfolio loans made by small creditors, as defined in § 1026.35(b)(2)(iii)(B) and (C), are excluded, as such loans are likely Small Creditor QMs pursuant to § 1026.43(e)(5) regardless of pricing.

that were priced between 1.5 and 2.25 percentage points above APOR had an early delinquency rate of 15.6 percent. These rates suggest that the historical loan performance of smaller loans with higher APRs may be comparable, if not better, than larger loans with lower APRs.

However, the Bureau's analysis found that early delinquency rates for 2018 loans are somewhat higher for smaller loans with higher APRs than larger loans with lower APRs. More specifically, NMDB data from 2018 on first-lien conventional purchase loans indicates that loans less than $66,156 that were priced between 1.5 and 6.5 percentage points above APOR had an early delinquency rate of 3.4 percent and those that were priced 1.5 percentage points over APOR and above had an early delinquency rate of 4.1 percent. Loans greater than or equal to $66,156 but less than $110,260 that were priced between 1.5 and 3.5 percentage points above APOR had an early delinquency rate of 4.3 percent. Loans greater than or equal to $110,260 that were priced between 1.5 and 2.25 percentage points above APOR had an early delinquency rate of 2.7 percent.

Although the data in the rulemaking record do not appear to indicate a particular threshold at which the credit characteristics or loan performance for smaller loans with higher APRs decline significantly, the Bureau concludes that the thresholds in § 1026.43(e)(2)(vi)(B) and (C) for smaller, first-lien covered transactions strike the best balance between ensuring consumers' ability to repay and ensuring access to responsible, affordable mortgage credit.

As described in more detail above, consumer advocate commenters recommended that the Bureau further refine the data before concluding that smaller loans with APRs within higher thresholds have similar credit characteristics and comparable levels of early delinquencies as larger loans. The commenters based their recommendation on specific concerns, including: (1) The absence of loan volume data and the use of cumulative rate-spread ranges, instead of incremental rate-spread ranges, in General QM Proposal Table 9; and (2) the absence of an analysis of chattel loans, separate from that of real-estate secured mortgages. The Bureau understands these concerns to suggest three issues: (1) That without loan volume data, it was not clear if there was a sufficient sample size for a reliable analysis; (2) that cumulative rate-spread ranges resulted in a skewed analysis of the early delinquency rates for smaller loans at or near the threshold; and (3) that differences between chattel loans and real-estate secured mortgages, with respect to pricing and performance, were not adequately considered.

However, the Bureau took all these issues into account when using HMDA and NMDB data to analyze the evidence related to the credit characteristics and loan performance of first-lien purchase transactions at various rate spread and loan amounts. As explained in the General QM Proposal, the Bureau grouped loans at higher rate spreads when a sufficient number of observations did not exist in the data for a reliable analysis. For example, the Bureau grouped loans with rate spreads of 2.25 percentage points or more to ensure a sufficient sample size for a reliable analysis of the 2002–2008 data in Tables 1 and 5 of the General QM Proposal.[309] This grouping ensured that all cells shown in these tables contained at least 500 loans. For similar reasons, the Bureau grouped loans in General QM Proposal Table 9 (and Table 9 above).[310] The Bureau determined that it was necessary to use a cumulative rate-spread range to ensure a sufficient sample size for a reliable analysis of 2018 NMDB data for higher-priced, smaller loans. More specifically, by grouping first-lien loans less than $65,939 ($66,156, when adjusted for inflation), priced between 1.5 and 6.5 percentage points above APOR, the Bureau was able to analyze the performance of 677 loans from 2018 NMDB data compared to only 87 loans if the Bureau looked at first-lien loans less than $65,939 that were priced between 6 and 6.5 percentage points above APOR.

Moreover, an analysis using incremental rate-spread ranges would have also supported higher thresholds for smaller loans. When using only 2002–2008 NMDB data, because of limitations in 2018 NMDB data, loans less than $66,156 and loans greater than or equal to $66,156 but less than $110,260 that were priced at or a half percentage point below the threshold had lower delinquency rates than larger loans (greater than or equal to $110,260) priced between 1.5 and 2.25 percentage points above APOR.

Specifically, loans less than $66,156 that were priced between 6 and 6.5 percentage points above APOR had an early delinquency rate of 7.7 percent. Loans greater than or equal to $66,156 but less than $110,260 that were priced between 3 and 3.5 percentage points above APOR had an early delinquency rate of 13.9 percent. Loans greater than or equal to $110,260 that were priced between 1.5 and 2.25 percentage points above APOR had an early delinquency rate of 15.6 percent. These early delinquency rates suggest that even under an approach using incremental rate-spread ranges, the historical performance of smaller loans with higher APRs remained comparable, if not better, than larger loans with lower APRs.

Some commenters recommended analyzing chattel loans separately from real-estate secured mortgages because of potential differences between the two with respect to pricing and performance. Consumer advocate commenters cited a newspaper article suggesting that chattel loans may not perform well. However, the Bureau is not aware of any data that sufficiently address how pricing at various thresholds correlates with performance or demonstrate how pricing varies with the performance of chattel loans relative to real-estate secured mortgages. Further, the Bureau's own data are not sufficient to separately analyze chattel loans from real-estate secured mortgages at various pricing thresholds. The Bureau's merged historical HMDA and NMDB data do not have reliable indicators for chattel loans. And although 2018 HMDA and NMDB data do have more reliable indicators, there are too few loans in 2018 data to reliably distinguish performance across different rate spread or loan size groupings. Accordingly, the Bureau lacks a reasoned basis for setting a different pricing threshold for chattel loans relative to real-estate secured mortgages, particularly given the access-to-credit concerns and other concerns described below. The Bureau will, however, continue to monitor the market and, if additional data become available and indicate that an adjustment to the thresholds for smaller loans and smaller manufactured housing loans is warranted, the Bureau will consider making an adjustment.

Lastly, as described above, some consumer advocate commenters suggested that land installment contracts would be newly eligible for General QM status under this final rule. The commenters, however, did not provide the Bureau with evidence or data indicating that land installment

[309] 85 FR 41716, 41732 n.190 (July 10, 2020). The Bureau also grouped loans with rate spreads of 2 percentage points or more to ensure a sufficient sample size for a reliable analysis of 2018 data in Tables 2 and 6 of the General QM Proposal. *Id.* at 41732 n.193.

[310] The Bureau grouped loans in General QM Proposal Table 10 for the same reasons. This grouping ensured a sufficient sample size for a reliable analysis of Y–14M data for subordinate-lien transactions.

contracts that were previously ineligible for General QM status would become eligible for General QM status under the amended General QM loan definition in this final rule. As described above, the Bureau anticipates the price-based approach in this final rule will change the share of covered transactions that would be eligible for General QM status. Specifically, loans with DTI ratios over 43 percent priced under the thresholds will be eligible for General QM status, and loans with DTI ratios under 43 percent but priced over the thresholds will not be eligible for General QM status. However, the Bureau does not have data or other evidence indicating that the final rule will change the scope of transactions covered by the Rule so that certain land installment contracts will now be eligible for General QM status.

Smaller manufactured housing loans. As discussed above, commenters asserted that a substantial share of manufactured housing loans that qualify as General QMs under the current definition would fail to qualify under the proposed pricing thresholds. These commenters confirmed the Bureau's concerns, as discussed in the General QM Proposal, regarding the impact a price-based General QM definition, without higher thresholds, would have on the availability of responsible, affordable mortgage credit for manufactured homes. Specifically, the commenters confirmed the Bureau's concern that manufactured housing loans with smaller loan amounts are typically priced higher than loans with larger loan amounts, even though a consumer with a smaller manufactured housing loan may have similar ability to repay; and that while some smaller manufactured housing loans may be originated under other QM definitions or as non-QM loans, those loans may cost materially more to consumers, and some may not be originated at all. The Bureau also analyzed 2018 HMDA data to confirm its concerns on the potential effects on access to credit of a price-based approach to defining a General QM. The Bureau's analysis found that 55 percent of manufactured housing loans are priced 2.25 percentage points or more above APOR. Moreover, as indicated by the various combinations in Table 10 below,[311] the Bureau estimates, based on 2018 HMDA data, that under the current rule—including the Temporary GSE QM loan definition, the General QM loan definition with a 43 percent DTI limit, and the Small Creditor QM loan definition in § 1026.43(e)(5)—83.6 percent of first-lien covered transactions secured by a manufactured home were General QMs. However, under the proposed General QM thresholds for larger loans and smaller loans, the Bureau estimates that 72.3 percent of first-lien covered transactions secured by a manufactured home would have been General QMs.

TABLE 10—SHARE OF 2018 MANUFACTURED HOUSING CONVENTIONAL FIRST-LIEN PURCHASE TRANSACTIONS WITHIN VARIOUS QM DEFINITIONS

[HMDA data]

Approach	QM (share of manufactured housing loans)
Temporary GSE QM + DTI 43	83.6
Proposal	72.3
Final rule with small, manufactured housing loan pricing at 6.5	84.6

In view of commenter confirmation of the Bureau's concerns regarding the potential effects of the proposal on the availability of responsible, affordable mortgage credit for manufactured homes, the Bureau has reconsidered whether the proposed thresholds for smaller loans strike the best balance between ensuring consumers' repayment ability and maintaining access to responsible, affordable mortgage credit for manufactured homes. Specifically, the Bureau concludes that it achieves a better balance of these competing considerations by expanding the proposed rebuttable presumption of compliance with the ATR requirements to loans for manufactured housing less than $110,260 that are higher-priced loans under § 1026.43(b)(4) but are priced below the threshold in § 1026.43(e)(2)(vi)(D). In so concluding, the Bureau acknowledges that Table 9 suggests a higher risk of early delinquency among first-lien covered transactions secured by a manufactured home priced equal to or greater than $66,156. But the Bureau concludes that the degree of risk is acceptable in view of a potentially significant reduction of access to such mortgage credit and the fact that consumers obtaining such loans will retain the opportunity to rebut the presumption of compliance by showing that the creditor in fact lacked a good faith and reasonable belief in the consumer's reasonable ability to repay the loan.

Section 1026.43(e)(2)(vi)(D) as finalized thus provides that, for first-lien covered transactions secured by a manufactured home with a loan amount less than $110,260 (indexed for inflation), the APR may not exceed APOR for a comparable transaction as of the date the interest rate is set by 6.5 or more percentage points. Smaller loans secured by a manufactured home and priced at or above the 6.5-percentage-point threshold are not eligible for QM status under § 1026.43(e)(2).[312] Under the final rule with this threshold, the Bureau estimates that, based on 2018 HMDA data, 84.6 percent of first-lien covered transactions secured by a manufactured home would have been General QMs. This is consistent with the share of first-lien covered transactions secured by a manufactured home that were QMs under the current rule, which includes the Temporary GSE QM loan definition, the General QM loan definition with a 43 percent DTI limit, and the Small Creditor QM loan definition in § 1026.43(e)(5).

The access-to-credit concerns described above are sufficient by themselves to support the Bureau's

[311] All estimates in Table 10 includes loans that meet the Small Creditor QM loan definition in § 1026.43(e)(5).

[312] The Bureau notes that one consequence of this 6.5 percent threshold and the other pricing thresholds in the final rule, like the pricing thresholds in the proposal, is that high-cost mortgages under HOEPA cannot qualify for General QM status. *See* 12 CFR 1026.32(a), 1026.34(a)(4), 1026.43(e)(3), (g)(1). Thus, for the reasons discussed in this final rule for adopting these pricing thresholds, the Bureau is no longer exercising authority under HOEPA to permit certain lower-DTI high-cost mortgages to qualify as General QMs. *Cf.* 78 FR 6855, 6861–62, 6924–25 (Jan. 31, 2013).

decision to adopt a higher pricing threshold for smaller manufactured housing loans. This threshold also is independently supported by the credit characteristics of consumers with these loans. Specifically, the Bureau considered 2018 HMDA data to assess whether consumers who take out smaller manufactured housing loans with higher APRs have similar credit characteristics, and thus similar ability to repay, as consumers who take out larger loans with lower APRs. The Bureau would have also considered whether the consumer was ever 60 or more days past due within the first 2 years after origination, *i.e.,* the early delinquency rate. However, as described above, the Bureau does not have sufficient loan performance data on manufactured housing loans for a reliable analysis of whether consumers who take out these smaller manufactured housing loans had early difficulties in making payments. Accordingly, the Bureau limited its ability-to-repay analysis to the credit characteristics of consumers taking out smaller manufactured housing loans with APRs within higher thresholds, as shown in Table 11.

TABLE 11—LOAN CHARACTERISTICS FOR DIFFERENT SIZES OF MANUFACTURED HOUSING FIRST-LIEN TRANSACTIONS AT VARIOUS RATE SPREADS

Loan size group	Rate spread range (percentage points over APOR)	Mean CLTV, 2018 HMDA	Mean DTI, 2018 HMDA	Mean credit score, 2018 HMDA
Under $66,156	1.5–2.0	74.2	31.8	733
Under $66,156	1.5–2.5	73.7	31.2	735
Under $66,156	1.5–3.0	74.6	31.5	737
Under $66,156	1.5–3.5	75.6	31.6	734
Under $66,156	1.5–4.0	76.3	32.1	728
Under $66,156	1.5–4.5	77.4	32.7	717
Under $66,156	1.5–5.0	77.8	32.8	709
Under $66,156	1.5–5.5	78.1	33.0	697
Under $66,156	1.5–6.0	78.6	33.2	689
Under $66,156	1.5–6.5	79.4	33.6	676
Under $66,156	1.5 and above	80.1	33.6	665
$66,156 to $110,259	1.5–2.0	85.4	23.3	732
$66,156 to $110,259	1.5–2.5	85.2	34.2	735
$66,156 to $110,259	1.5–3.0	85.5	34.6	731
$66,156 to $110,259	1.5–3.5	85.8	35.0	728
$66,156 to $110,259	1.5–4.0	85.9	35.5	723
$66,156 to $110,259	1.5–4.5	86.1	35.9	715
$66,156 to $110,259	1.5–5.0	86.5	36.1	707
$66,156 to $110,259	1.5–5.5	86.8	36.3	699
$66,156 to $110,259	1.5–6.0	87.6	36.5	690
$66,156 to $110,259	1.5–6.5	88.2	36.6	677
$66,156 to $110,259	1.5 and above	88.2	36.7	676
$110,260 and above, manufactured and site-built housing.	1.5–2.25 (for comparison)	92.4	39.3	698

The Bureau's analysis indicates that consumers with smaller manufactured housing loans with APRs up to 6.5 percentage points above APOR have credit characteristics that are comparable to, if not better than, consumers with larger loans priced between 1.5 and 2.25 percentage points above APOR. More specifically, the Bureau found that smaller manufactured housing loans less than $66,156 that are priced between 1.5 and 6.5 percentage points above APOR have a mean DTI ratio of 33.6 percent, a mean combined LTV ratio of 79.4 percent, and a mean credit score of 676. Smaller manufactured housing loans greater than or equal to $66,156 but less than $110,260 that are priced between 1.5 and 6.5 percentage points above APOR have a mean DTI ratio of 36.6 percent, a mean combined LTV ratio of 88.2 percent, and a mean credit score of 677. Loans greater than or equal to $110,260 that are priced between 1.5 and 2.25 percentage points above APOR have a mean DTI ratio of 39.3 percent, a mean combined LTV ratio of 92.4 percent, and a mean credit score of 698. These all suggest that the credit characteristics of consumers taking out smaller manufactured housing loans with higher APRs appear to be at least comparable to, if not better than, those of consumers taking out larger loans with lower APRs. This suggests that consumers taking out smaller manufactured housing loans with higher APRs may have an ability to repay these loans at least comparable to the consumers who take out larger loans with lower APRs.

Although the current data appear to indicate some thresholds at which certain credit characteristics, in particular credit score, decline for smaller manufactured housing loans with higher APRs, the Bureau concludes that the adopted threshold in § 1026.43(e)(2)(vi)(D) for smaller, first-lien covered transactions secured by a manufactured home strikes the best balance between ensuring consumers' ability to repay and ensuring access to responsible, affordable mortgage credit for manufactured homes.

The Bureau is also adding two comments to provide additional clarification on the pricing threshold for smaller loans secured by a manufactured home. Comment 43(e)(2)(vi)–5 clarifies that the term ''manufactured home,'' as used in § 1026.43(e)(2)(vi)(D), means any residential structure as defined under HUD regulations establishing manufactured home construction and safety standards (24 CFR 3280.2). Modular or other factory-built homes that do not meet the HUD code standards are not manufactured homes for purposes of § 1026.43(e)(2)(vi)(D). Comment 43(e)(2)(vi)–6 provides that the threshold in § 1026.43(e)(2)(vi)(D) applies to first-lien covered transactions less than $110,260 (indexed for inflation) that are secured by a manufactured home and land, or by a manufactured home only.

The Bureau is aware that whether a manufactured home is titled as personal property or as real property factors into the cost of the loan and that the price may be relatively higher for a loan in which the manufactured home is titled as personal property (*i.e.,* a chattel loan).[313] However, the Bureau is not adopting a higher threshold for only smaller chattel loans. Doing so would incentivize manufactured home creditors to encourage consumers to title their manufactured homes as personal property to originate a QM-eligible loan. Generally, titling manufactured homes as personal property may have disadvantages for consumers because chattel loans tend to be more expensive,[314] and have fewer consumer protections.[315] Moreover, as explained above, the Bureau does not have sufficient performance data to analyze how chattel loans perform relative to real estate-secured mortgages at various pricing thresholds. Without this data and given the risks for consumers' titling their manufactured homes as personal property, the Bureau has decided to adopt a higher pricing threshold for smaller loans secured by either a manufactured home and land, or by a manufactured home only.

Moreover, the Bureau understands that creditors may either increase or decrease the price of these loans to just below the adopted threshold. To the extent creditors reduce the price of the loan, this would result in more affordable prices; for example, some consumers whose loans would have otherwise been priced above the threshold may now be eligible for loans below the threshold. These loans would also be subject to the QM prohibitions on certain loan features and limits on points and fees, which would provide protections for consumers. However, this development could also lead to an increase in the number of consumers with delinquent loans who would have to rebut the creditor's presumption of compliance to benefit from an ability-to-repay cause of action or defense against foreclosure. Regardless, the Bureau does not have sufficient data to determine whether these developments would occur and the impact these developments would have on the benefits and costs to consumers. However, as described above, the Bureau intends to monitor the market for additional data that might indicate the need for the Bureau to consider a future adjustment.

A few commenters recommended alternatives other than the one adopted here to address the access-to-credit concern for manufactured homes. However, the Bureau concludes that adopting a higher pricing threshold for smaller loans secured by a manufactured home addresses the access-to-credit concerns better than the recommended alternatives. The first recommendation to increase the dollar thresholds defining ''smaller loans,'' would result in a definition that is inconsistent with the meaning of ''smaller loans'' in the small loan exception to the QM points and fees cap, which could potentially lead to certain compliance challenges. The other recommendation to incorporate HOEPA's APR thresholds into the General QM loan definition does not properly acknowledge HOEPA's statutory objective, which was to identify transactions requiring creditors to provide additional disclosures and prohibiting creditors from engaging in certain practices. The Bureau does not believe that it should implement thresholds designed for those discrete uses here, in determining whether the transaction should be eligible for a rebuttable presumption of compliance with the ATR requirements. Lastly, the Bureau declines to adopt a complementary DTI alternative for manufactured housing loans. A complementary DTI alternative would be unduly complex and not necessary given that the Bureau expects the final pricing threshold to improve access to credit for manufactured homes. Moreover, the Bureau believes that a loan's price, as measured by comparing a loan's APR to APOR for a comparable transaction, is a strong indicator of a consumer's ability to repay and is a more holistic and flexible measure of a consumer's ability to repay than DTI alone. For these reasons, the Bureau concludes that adopting a higher pricing threshold for smaller loans secured by a manufactured home strikes a better balance between ensuring consumers' ability to repay and ensuring access to responsible, affordable mortgage credit for manufactured homes.

Subordinate-lien transactions. The Bureau is adopting higher thresholds in § 1026.43(e)(2)(vi)(E) and (F) for subordinate-lien transactions because subordinate-lien transactions may be priced higher than comparable first-lien transactions for reasons other than consumers' ability to repay. In general, the creditor of a subordinate lien will recover its principal, in the event of default and foreclosure, only to the extent funds remain after the first-lien creditor recovers its principal. Thus, to compensate for this risk, creditors typically price subordinate-lien transactions higher than first-lien transactions, even though the consumer in the subordinate-lien transaction may have similar credit characteristics and ability to repay. In addition, subordinate-lien transactions are often for smaller loan amounts, so the pricing factors discussed above for smaller loan amounts may further increase the price of subordinate-lien transactions, regardless of the consumer's ability to repay. To the extent the higher pricing for a subordinate-lien transaction is not related to consumers' ability to repay, applying the same pricing to them as first-lien transactions results in them being excluded from QM status under § 1026.43(e)(2).

In the January 2013 Final Rule, the Bureau adopted higher thresholds for determining if subordinate-lien QMs received a rebuttable presumption or a conclusive presumption of compliance with the ATR requirements.[316] For subordinate-lien transactions, the definition of ''higher-priced covered transaction'' in § 1026.43(b)(4) is used in § 1026.43(e)(1) to set a threshold of 3.5 percentage points above APOR to determine which subordinate-lien QMs receive a safe harbor and which receive a rebuttable presumption of compliance. As discussed above in part V, the Bureau is not proposing to alter the threshold for subordinate-lien transactions in § 1026.43(b)(4). To avoid the odd result that a subordinate-lien transaction would otherwise be eligible to receive a safe harbor under § 1026.43(b)(4) and (e)(1) but would not be eligible for QM status under § 1026.43(e)(2)(vi), the Bureau considered which threshold or thresholds at or above 3.5 percentage points above APOR to propose for subordinate-lien transactions in § 1026.43(e)(2)(vi).

[313] Bureau of Consumer Fin. Prot., *Introducing New and Revised Data Points in HMDA,* at 207 (Aug. 2019), *https://files.consumerfinance.gov/f/documents/cfpb_new-revised-data-points-in-hmda_report.pdf.*

[314] *Id.*

[315] For example, chattel loans are not subject to the TILA–RESPA Integrated Disclosure Rule. *See* 12 CFR 1026.19(e) and (f).

[316] 78 FR 6408, 6506 (Jan. 30, 2013).

To develop the thresholds for subordinate-lien transactions in § 1026.43(e)(2)(vi)(E) and (F), the Bureau considered evidence related to credit characteristics and loan performance for subordinate-lien transactions at various rate spreads and loan amounts (adjusted for inflation) using HMDA and Y–14M data, as shown in Table 12.[317] To ensure a sufficient sample size was available for a reliable analysis, the Bureau used cumulative rate-spread ranges.[318]

TABLE 12—LOAN CHARACTERISTICS AND PERFORMANCE FOR DIFFERENT SIZES OF SUBORDINATE-LIEN TRANSACTIONS AT VARIOUS RATE SPREADS

Loan size group	Rate spread range (percentage points over APOR)	Mean CLTV, 2018 HMDA	Mean DTI, 2018 HMDA	Mean credit score, 2018 HMDA	Percent observed 90+ days delinquent within first 2 years, 2013–2016 Y–14M data (subset) (%)
Under $66,156	2.0–2.5	76.9	36.1	728	2.1
Under $66,156	2.0–3.0	78.4	36.5	724	1.6
Under $66,156	2.0–3.5	79.7	36.8	721	1.4
Under $66,156	2.0–4.0	80.1	36.9	720	1.4
Under $66,156	2.0–4.5	80.2	36.9	719	1.3
Under $66,156	2.0–5.0	80.3	37.0	718	1.3
Under $66,156	2.0–5.5	80.3	37.1	718	1.3
Under $66,156	2.0–6.0	80.3	37.1	717	1.3
Under $66,156	2.0–6.5	80.4	37.2	717	1.3
Under $66,156	2.0 and above	80.7	37.3	715	1.4
$66,156 and above	2.0–2.5	79.5	37.2	738	1.9
$66,156 and above	2.0–3.0	80.5	37.3	735	1.7
$66,156 and above	2.0–3.5	81.0	37.4	732	1.6
$66,156 and above	2.0–4.0	81.3	37.5	732	1.7
$66,156 and above	2.0–4.5	81.3	37.6	731	1.7
$66,156 and above	2.0–5.0	81.5	37.7	731	1.8
$66,156 and above	2.0–5.5	81.6	37.7	730	1.8
$66,156 and above	2.0–6.0	81.6	37.8	729	1.8
$66,156 and above	2.0–6.5	81.7	37.9	729	1.8
$66,156 and above	2.0 and above	81.8	37.9	728	1.9

In general, the Bureau's analysis found strong credit characteristics and loan performance for subordinate-lien transactions at various thresholds greater than 2 percentage points above APOR. The current data do not appear to indicate a particular threshold at which the credit characteristics or loan performance decline significantly.

With respect to larger subordinate-lien transactions, the Bureau's analysis of 2018 HMDA data on subordinate-lien conventional loans found that, for consumers with subordinate-lien transactions greater than or equal to $66,156 that were priced up to 2 to 3.5 percentage points above APOR, the mean DTI ratio was 37.4 percent, the mean combined LTV was 81 percent, and the mean credit score was 732. The Bureau also analyzed Y–14M loan data for 2013 to 2016 and estimated that subordinate-lien transactions greater than or equal to $66,156 that were priced up to 2 to 3.5 percentage points above APOR had an early delinquency rate of approximately 1.6 percent.[319] These factors appear to provide a strong indication of ability to repay, so the Bureau has decided to set the threshold at 3.5 percentage points above APOR for larger subordinate-lien transactions (greater than or equal to $66,156) to be eligible for QM status under § 1026.43(e)(2).

The Bureau recognizes that, because the price-based approach would leave the threshold in § 1026.43(b)(4) for higher-priced QMs at 3.5 percentage points above APOR for subordinate-lien transactions (and that such transactions that are not higher priced would, therefore, receive a safe harbor under § 1026.43(e)(1)(i)), this approach would result in subordinate-lien transactions for amounts over $66,156 either being a safe harbor QM or not being eligible for QM status under § 1026.43(e)(2). No such loans would be eligible to be a rebuttable presumption QM. Nevertheless, the Bureau concludes that the threshold best balances the relatively strong credit characteristics and loan performance of these transactions historically, which is indicative of ability to repay, against the concern that the supporting data are

[317] *See Bureau of Labor and Statistics, Historical Consumer Price Index for All Urban Consumers (CPI–U),* (Apr. 2020), *https://www.bls.gov/cpi/tables/supplemental-files/historical-cpi-u-202004.pdf.* (Using the CPI–U price index, nominal loan amounts are inflated to June 2020 dollars from the price level in June of the year prior to origination. This effectively categorizes loans according to the inflation-adjusted thresholds for smaller loans that would have been in effect on the origination date. The set of loans categorized within a given threshold remains the same as in the proposal, in which nominal loan amounts were inflated to June 2019 dollars and compared against the corresponding threshold levels of $65,939 and $109,898.)

[318] As with its analysis of higher-priced, smaller loans above, the Bureau determined that it was necessary to use cumulative rate-spread ranges to ensure sufficient sample sizes for a reliable analysis of Y–14M data for subordinate lien loans. Without this cumulative grouping, the sample sizes for some rate-spread ranges would be insufficient for reliable analysis.

[319] The loan data were a subset of the supervisory loan-level data collected as part of the Federal Reserve's Comprehensive Capital Analysis and Review, known as Y–14M data. The early delinquency rate measured the percentage of loans that were 90 or more days late in the first two years. The Bureau used loans with payments that were 90 or more days late to measure delinquency, rather than the 60 or more days used with the data discussed above for first-lien transactions, because the Y–14M data do not include a measure for payments 60 or more days late. Data from a small number of lenders were not included due to incompatible formatting.

limited to recent years with strong economic performance and conservative underwriting.

For smaller subordinate-lien transactions, the Bureau's analysis of 2018 HMDA data on subordinate-lien conventional loans found that for consumers with subordinate-lien transactions less than $66,156 that were priced between 2 and 6.5 percentage points above APOR, the mean DTI ratio was 37.2 percent, the mean combined LTV was 80.4 percent, and the mean credit score was 717. The Bureau also analyzed Y–14M loan data for 2013 to 2016 and estimated that subordinate-lien transactions less than $66,156 that were priced between 2 and 6.5 percentage points above APOR, the early delinquency rate was approximately 1.3 percent. Based on these relatively strong credit characteristics and low delinquency rates, the Bureau has decided to set the threshold at 6.5 percentage points above APOR for subordinate-lien transactions less than $66,156 to be eligible for QM status under § 1026.43(e)(2). The Bureau notes that under this approach, these transactions would be eligible only for a rebuttable presumption of compliance under § 1026.43(e)(1)(ii) when higher-priced under § 1026.43(b)(4), and that consumers, therefore, would have the opportunity to rebut the presumption under § 1026.43(e)(1)(ii)(B).

Some subordinate-lien transactions currently meeting the General QM loan definition may fail to do so under the adopted thresholds. However, based on 2018 HMDA data, the Bureau estimates that the adopted thresholds will increase the overall share of subordinate-lien transactions that are eligible for QM status. Accordingly, the Bureau concludes that its approach strikes the best balance between ensuring consumers' ability to repay and access to responsible, affordable credit for subordinate-lien transactions.

Determining the APR for Certain Loans for Which the Interest Rate May or Will Change

The Bureau's Proposal

The Bureau also proposed to revise § 1026.43(e)(2)(vi) to include a special rule for determining the APR for certain types of loans for purposes of whether a loan meets the General QM loan definition under § 1026.43(e)(2). This proposed special rule would have applied to loans for which the interest rate may or will change within the first five years after the date on which the first regular periodic payment will be due. For such loans, for purposes of determining whether the loan is a General QM under § 1026.43(e)(2)(vi), the creditor would have been required under the proposal to determine the APR by treating the maximum interest rate that may apply during that five-year period as the interest rate for the full term of the loan.[320] The proposed special rule would have applied principally to ARMs with initial fixed-rate periods of five years or less (referred to in the proposal as ''short-reset ARMs'') but also would have applied to step-rate mortgages[321] that have an initial period of five years or less. The special rule in the proposed revisions to § 1026.43(e)(2)(vi) would not have modified other provisions in Regulation Z for determining the APR for other purposes, such as the disclosures addressed in or subject to the commentary to § 1026.17(c)(1).

In the proposed rule, the Bureau said that it anticipated that the proposed price-based approach to defining General QMs would in general be effective in identifying which loans consumers have the ability to repay and should therefore be eligible for QM status under § 1026.43(e)(2). However, the Bureau recognized that, absent the special rule, the proposed price-based approach may less effectively capture specific unaffordability risks of certain loans for which the interest rate may or will change relatively soon after consummation. Therefore, the Bureau stated that, for loans for which the interest rate may or will change within the first five years after the date on which the first regular periodic payment will be due, a modified approach to determining the APR for purposes of the rate-spread thresholds under proposed § 1026.43(e)(2) may be warranted.

Proposed comment 43(e)(2)(vi)–4.i stated that provisions in subpart C, including the existing commentary to § 1026.17(c)(1), address the determination of the APR disclosures for closed-end credit transactions and that provisions in § 1026.32(a)(3) address how to determine the APR to determine coverage under § 1026.32(a)(1)(i). It further stated that proposed § 1026.43(e)(2)(vi) requires, for the purposes of that paragraph, a different determination of the APR for a QM under proposed § 1026.43(e)(2) for which the interest rate may or will change within the first five years after the date on which the first regular periodic payment will be due. In addition, proposed comment 43(e)(2)(vi)–4.i stated that an identical special rule for determining the APR for such a loan also applies for purposes of proposed § 1026.43(b)(4).

The Bureau proposed comment 43(e)(2)(vi)–4.ii to explain the application of the special rule in proposed § 1026.43(e)(2)(vi) for determining the APR for a loan for which the interest rate may or will change within the first five years after the date on which the first regular periodic payment will be due. Specifically, it stated that the special rule applies to ARMs that have a fixed-rate period of five years or less and to step-rate mortgages for which the interest rate changes within that five-year period.

Proposed comment 43(e)(2)(vi)–4.iii provided that, to determine the APR for purposes of proposed § 1026.43(e)(2)(vi), a creditor must treat the maximum interest rate that could apply at any time during the five-year period after the date on which the first regular periodic payment will be due as the interest rate for the full term of the loan, regardless of whether the maximum interest rate is reached at the first or subsequent adjustment during the five-year period. Further, the proposed comment cross-referenced existing comments 43(e)(2)(iv)–3 and –4 for additional instruction on how to determine the maximum interest rate during the first five years after the date on which the first regular periodic payment will be due.

The Bureau proposed comment 43(e)(2)(vi)–4.iv to explain how to use the maximum interest rate to determine the APR for purposes of proposed § 1026.43(e)(2)(vi). Specifically, the proposed comment provided that the creditor must determine the APR by treating the maximum interest rate described in proposed § 1026.43(e)(2)(vi) as the interest rate for the full term of the loan. It further provided an example of how to determine the APR by treating the maximum interest rate as the interest rate for the full term of the loan.

The Bureau requested comment on all aspects of the proposed special rule in proposed § 1026.43(e)(2)(vi). In particular, the Bureau requested data regarding short-reset ARMs and those step-rate mortgages that would be subject to the proposed special rule,

[320] The Bureau also stated that, under proposed § 1026.43(b)(4), an identical special rule for determining the APR for certain loans for which the interest rate may or will change also applies under that paragraph for purposes of determining whether a QM under § 1026.43(e)(2) is a higher-priced covered transaction and whether it is therefore subject to a rebuttable presumption as opposed to a conclusive presumption of compliance with the with the ATR requirements.

[321] A step-rate mortgage is a transaction secured by real property or a dwelling for which the interest rate will change after consummation and the rates that will apply and the periods for which they will apply are known at consummation. *See* 12 CFR 1026.18(s)(7)(ii).

including default and delinquency rates and the relationship of those rates to price. The Bureau also requested comment on alternative approaches for such loans, including the ones discussed in the proposed rule, such as imposing specific limits on annual rate adjustments for short-reset ARMs, applying a different rate spread, and excluding such loans from General QM eligibility altogether.

Comments Received

Of the approximately 75 comments the Bureau received in response to its General QM Proposal, approximately 25 comments addressed the ARM special rule proposed in § 1026.43(b)(4) and (e)(2)(vi). Nearly all of these ARM commenters represented industry entities—mostly trade associations and a few individual companies. Two commenters represented a coalition of industry and consumer advocates. One individual consumer advocate submitted a comment.

Most ARM commenters acknowledged that short-reset ARMs pose a heightened risk to consumers, with many commenters acknowledging the risks of payment shock. Some commenters agreed that it is appropriate for the Bureau to adopt more stringent requirements for these loans to obtain QM status. Whether or not they acknowledged the need for more stringent requirements, nearly all commenters urged the Bureau to adopt some alternative instead of the proposed special rule.

Commenter criticism generally fell into two categories: (1) That the special rule would be overly burdensome; and (2) that, because some ARMs allow up to a 2 percentage point increase at the first reset,[322] the special rule would limit or eliminate QM eligibility for some or all short-reset ARMs as they are currently structured—with some commenters predicting that, as a result, some or all short-reset ARMs would cease to be offered in the marketplace. Based on one or both of these criticisms, most ARM commenters recommended that the Bureau either (1) narrow the scope of the special rule to exclude some subset of short-reset ARMs from its coverage or (2) adopt an alternative special rule. One commenter stated that ARMs should no longer be eligible for the QM safe harbor at all, and should instead be designated as rebuttable presumption loans if they are eligible under the General QM loan definition, or non-QM loans if not.

Several commenters criticized the special rule as burdensome. These commenters asserted that the new APR calculation required under the special rule would be ''operationally difficult'' and would require ''significant systems adjustment.'' One commenter specifically stated that the APR calculation would add compliance risk and uncertainty to the mortgage market for creditors offering ARM products by adding to the ''costs of system updates, staff training, and compliance monitoring; costs that would likely be passed on in one form or another to consumers.'' One commenter asserted the adjustments would be ''operationally difficult, if not impossible.'' Three commenters (including two of the aforementioned commenters asserting burden) requested a longer implementation period due to the added complications of the COVID pandemic and the upcoming replacement of the London InterBank Offered Rate (LIBOR) index with the Secured Overnight Financing Rate (SOFR) index.

Several other commenters stated that the special rule would adversely affect the market for GSE short-reset ARMs that have been developed specifically for the new SOFR index and that such ARMs likely would be unable to achieve QM status under the special rule.

In addition to these SOFR-related market concerns, many other commenters more generally asserted that the special rule would limit or eliminate QM eligibility for some or all short-reset ARMs. Of these commenters, seven predicted that the special rule would eliminate or at least reduce short-reset ARM originations. Three industry commenters predicted that the special rule would result in total elimination of short-reset ARM originations. Four other commenters predicted that the special rule would prevent origination of at least some short-reset ARMs, with two asserting that five-year ARMs would be eliminated and one specifying that three-year ARMs would be eliminated.

Several commenters recommended that the Bureau restrict the scope of the special rule—either to exclude five-year ARMs from coverage or to restrict the scope to short-reset ARMs with an initial fixed-rate period of less than five years, three years, or two years. Some of these commenters urged the Bureau to exclude five-year ARMs from coverage and others recommended narrowing the scope of the special rule to three-year ARMs (or shorter). Some commenters recommended excluding from coverage ARMs that reset after exactly five years or, in the alternative, excluding from coverage ARMs with initial terms of three years or less. One commenter recommended narrowing the special rule to apply to ARMs with an initial period of two years or less.

Several commenters recommended that the Bureau adopt an alternative to the proposed special rule. One industry commenter recommended setting the QM rate-spread threshold for ARMs in a manner that references the maximum interest rate possible in the first five years. The commenter suggested, as an example, requiring that the maximum interest rate possible in the first five years be within a given rate spread of APOR. Similarly, another industry commenter recommended that the Bureau adopt a separate qualification test that compares the maximum interest rate possible in the first five years to the APOR plus an appropriate threshold.

Three commenters, including a consumer advocate and a coalition of industry and consumer advocates, recommended adopting a different special rule that uses the Average Initial Interest Rate (AIIR) instead of APOR as the comparison rate. The Bureau understands that commenters are using AIIR to refer to the mean initial interest rate for a particular ARM product, which is one input into the APOR calculation for ARMs. Another commenter recommended removing QM eligibility for most short-reset ARMs but, in the alternative, supported the special rule using AIIR. These commenters generally maintained that a special rule employing AIIR would ease implementation and preserve the availability of short-reset ARMs for certain consumers while still protecting them from payment shock. As described by commenters, the AIIR special rule would be one part of a two-part test. First, creditors would be required to compare the maximum interest rate in the first five years with the AIIR for a comparable ARM product, plus 2.5 percent, regardless of loan size. If the maximum possible rate is less than or equal to the AIIR plus 2.5 percent, the loan potentially would be eligible for QM status. Second, loans satisfying the initial test would then be subject to the same APR-to-APOR rate-spread tests as other loans under the General QM rule for purposes of determining whether the loans are safe harbor QMs, rebuttable presumption QMs, or non-QM loans under the applicable thresholds.

Three industry commenters recommended a different special rule for short-reset ARMs. They recommended that the Bureau establish ''reasonable secondary caps for rate

[322] For example, many GSE ARM products provide for a 2 percentage point cap on the first reset.

changes allowed within the short-reset period'' such that short-reset ARMs meeting those caps would be eligible for QM status. These commenters did not specify their views on what caps on interest rate resets would be reasonable. In the alternative, these commenters, plus a GSE, recommended that the Bureau require creditors to use the fully indexed rate for the remaining loan term after the first five years (rather than the highest possible interest rate in the first five years) to calculate the APR for short-reset ARMs. Although these commenters did not specify which interest rate to use for the first five years, the Bureau understands this approach to be similar to the APR calculation for ARMs in § 1026.17(c)(1), which requires the creditor to disclose a composite APR based on the initial rate for as long as it is charged and, for the remainder of the term, on the fully indexed rate.[323] In a variation of this approach, another GSE recommended that the Bureau adopt that GSE's own requirements for short-reset ARMs in lieu of the special rule. Specifically, the GSE recommended that the Bureau require creditors to calculate the APR using the greater of the fully indexed rate or 2 percent over the initial note rate for the full term of the loan.

The Final Rule

For the reasons set forth herein, the Bureau is finalizing as proposed the revisions to § 1026.43(e)(2)(vi) and comment 43(e)(2)(vi)–4 regarding the special rule for determining the APR for certain types of loans for purposes of whether a loan meets the General QM loan definition under § 1026.43(e)(2). This special rule applies to loans for which the interest rate may or will change within the first five years after the date on which the first regular periodic payment will be due. For such loans, for purposes of determining whether the loan is a General QM under § 1026.43(e)(2)(vi), the creditor is required to determine the APR by treating the maximum interest rate that may apply during that five-year period as the interest rate for the full term of the loan.[324] The special rule applies principally to ARMs with initial fixed-rate periods of five years or less (referred to herein as ''short-reset ARMs'').[325] The Bureau concludes that the risks associated with short-reset ARMs can be effectively addressed without prohibiting them from receiving General QM status altogether. This conclusion is consistent with the fact that the Dodd-Frank Act expressly states that short-reset ARMs are eligible for General QM status and includes a specific provision for addressing the potential for payment shock from such loans.

Careful consideration of its data and rationale, and of comments received, leads the Bureau to conclude that while the price-based approach to defining General QMs is generally effective in identifying which loans consumers have the ability to repay and should therefore be eligible for QM status under § 1026.43(e)(2), the special rule is necessary to effectively capture specific unaffordability risks of certain short-reset ARMs. The Bureau further concludes that the burden of implementing the special rule is not unreasonable, as discussed further below, given that all of the inputs needed to calculate the special rule's APR—including the five year maximum interest rate—are already required under existing provisions in Regulation Z and that creditors can offer short-reset ARMs that satisfy the new General QM pricing requirements under the special rule.

As a general matter, as discussed above, the Bureau is adopting in this final rule a non-QM threshold for loans greater than or equal to $110,260 that is higher than the threshold that it proposed. Specifically, § 1026.43(e)(2) provides that loans greater than or equal to $110,260 may be eligible for QM status if the APR does not exceed APOR 2.25 or more percentage points. The Bureau notes that this change will increase the pool of loans that achieve QM status under the ATR/QM Rule, including short-reset ARMs subject to the special rule. Thus, the 2.25-percentage-point threshold under this final rule will result in more short-reset ARMs achieving QM status than would have under the 2-percentage-point threshold in the proposal. While short-reset ARMs offer consumers who can afford them an important alternative to fixed-rate mortgage loans, the Bureau estimates that the special rule will apply to a relatively small percentage of the mortgage market. Based on 2018 HMDA data, the Bureau estimates that approximately 36,000 conventional purchase loans, or approximately 1.3 percent of conventional purchase loans in the U.S. mortgage market, would have been subject to the special rule had it been in effect that year.

Structure and pricing particular to ARMs. As explained in the proposal, absent special treatment, short-reset ARMs may present particular concerns under an approach that uses APR as an indicator of ability to repay. Short-reset ARMs may be affordable for the initial fixed-rate period but may become unaffordable relatively soon after consummation if the payments increase appreciably after reset, causing payment shock. The APR for short-reset ARMs is not as predictive of ability to repay as for fixed-rate mortgages because of how ARMs are structured and priced and how the APR for ARMs is determined under various provisions in Regulation Z. Several different provisions in Regulation Z address the calculation of the APR for ARMs. For disclosure purposes, if the initial interest rate is determined by the index or formula to make later interest rate adjustments, Regulation Z generally requires the creditor to base the APR disclosure on the initial interest rate at consummation and to not assume that the rate will increase during the remainder of the loan.[326] In some transactions, including many ARMs, the creditor may set an initial interest rate that is lower (or, less commonly, higher) than the rate would be if it were determined by the index or formula used to make later interest rate adjustments. For these ARMs, Regulation Z requires the creditor to disclose a composite APR based on the initial rate for as long as it is charged and, for the remainder of the term, on the fully indexed rate.[327] The fully indexed rate at consummation is the sum of the value of the index at the time of consummation plus the margin, based on the contract. The Dodd-Frank Act requires a different APR calculation for ARMs for the purpose of determining whether ARMs are subject to certain HOEPA requirements.[328] As implemented in § 1026.32(a)(3)(ii), the creditor is required to determine the

[323] Regulation Z requirements for calculating the APR for ARMs are summarized below in the discussion of the structure and pricing particular to ARMs.

[324] As discussed above, the Bureau is also finalizing § 1026.43(b)(4), an identical special rule for determining the APR for certain loans for which the interest rate may or will change, which applies under that paragraph for purposes of determining whether a QM under § 1026.43(e)(2) is a higher-priced covered transaction.

[325] In addition to short-reset ARMs, the special rule applies to step-rate mortgages that have an initial fixed-rate period of five years or less. The Bureau recognizes that the interest rates of step-rate mortgages are known at consummation. However, unlike fixed-rate mortgages and akin to ARMs, the interest rate of step-rate mortgages changes, thereby raising the concern that interest-rate increases relatively soon after consummation may present affordability risks due to higher loan payments. Moreover, applying the APR determination requirement to such loans is consistent with the treatment of step-rate mortgages pursuant to the requirement in the General QM loan definition to underwrite loans using the maximum interest rate during the first five years after the date on which the first regular periodic payment will be due. *See* comment 43(e)(2)(iv)–3.iii.

[326] *See* 12 CFR 1026.17(c)(1) through (8).

[327] *See* 12 CFR 1026.17(c)(1) through (10).

[328] *See* TILA section 103(bb)(1)(B)(ii).

APR for HOEPA coverage for transactions in which the interest rate may vary during the term of the loan in accordance with an index, such as with an ARM, by using the fully indexed rate or the introductory rate, whichever is greater.[329]

The requirements in Regulation Z for determining the APR for disclosure purposes and for HOEPA coverage purposes do not account for any potential increase or decrease in interest rates based on changes to the underlying index. If interest rates rise after consummation, and therefore the value of the index rises to a higher level, the loan can reset to a higher interest rate than the fully indexed rate at the time of consummation. The result would be a higher payment than the one calculated based on the rates used in determining the APR, and a higher effective rate spread (and increased likelihood of delinquency) than the spread that would be taken into account for determining General QM status at consummation under the price-based approach in the absence of a special rule.

ARMs can present more risk for consumers than fixed-rate mortgages, depending on the direction and magnitude of changes in interest rates. In the case of a 30-year fixed-rate loan, creditors or mortgage investors assume both the credit risk and the interest-rate risk (*i.e.,* the risk that interest rates rise above the fixed rate the consumer is obligated to pay), and the price of the loan, which is fully captured by the APR, reflects both risks. In the case of an ARM, the creditor or investor assumes the credit risk of the loan, but the consumer assumes most of the interest-rate risk, as the interest rate will adjust along with the market. The extent to which the consumer assumes the interest-rate risk is established by caps in the note on how high the interest rate charged to the consumer may rise. To compensate for the added interest-rate risk assumed by the consumer (as opposed to the creditor or investor), ARMs are generally priced lower—in absolute terms—than a 30-year fixed-rate mortgage with comparable credit risk.[330] Yet with rising interest rates, the risks that ARMs could become unaffordable, and therefore lead to delinquency or default, are more pronounced. As noted above, the requirements for determining the APR for ARMs in Regulation Z do not reflect this risk because they do not take into account potential increases in the interest rate over the term of the loan based on changes to the underlying index. This APR may therefore understate the risk that the loan may become unaffordable to the consumer if interest rates increase.

Unaffordability risk more acute for short-reset ARMs. As the Bureau noted in the proposal, short-reset ARMs may present greater risks of unaffordability than other ARMs. While all ARMs run the risk of increases in interest rates and payments over time, longer-reset ARMs (*i.e.,* ARMs with initial fixed-rate periods of longer than five years) present a less acute risk of unaffordability than short-reset ARMs. Longer-reset ARMs permit consumers to take advantage of lower interest rates for more than five years and thus, akin to fixed-rate mortgages, provide consumers significant time to pay off or refinance, or to otherwise adjust to anticipated changes in payment during the relatively long period during which the interest rate is fixed and before payments may increase.

Short-reset ARMs can also contribute to speculative lending because they permit creditors to originate loans that could be affordable in the short term, with the expectation that property values will increase and thereby permit consumers to refinance before payments may become unaffordable. Further, creditors can minimize their credit risk on such ARMs by, for example, requiring lower LTV ratios, as was common in the run-up to the 2008 financial crisis.[331] Additionally, creditors may be more willing to market these ARMs in areas of strong housing-price appreciation, irrespective of a consumer's ability to absorb the potentially higher payments after reset, because creditors may expect that consumers will have the equity in their homes to refinance if necessary.

In the Dodd-Frank Act, Congress addressed affordability concerns specific to short-reset ARMs and their eligibility for QM status by providing in TILA section 129C(b)(2)(A)(v) that, to receive QM status, ARMs must be underwritten using the maximum interest rate that may apply during the first five years.[332] The ATR/QM Rule implemented this requirement in Regulation Z at § 1026.43(e)(2)(iv). For many short-reset ARMs, this requirement resulted in a higher DTI that would have to be compared to the Rule's 43 percent DTI limit to determine whether the loans were eligible to receive General QM status. Particularly in a higher-rate environment in which short-reset ARMs could become more attractive, the five-year maximum interest-rate requirement, combined with the Rule's 43 percent DTI limit, would have likely prevented some of the riskiest short-reset ARMs (*i.e.,* those that adjust sharply upward in the first five years and cause payment shock) from obtaining General QM status. As discussed above, the Bureau is finalizing a price-based approach that removes the DTI limit from the General QM loan definition in § 1026.43(e)(2)(vi). As a result, the Bureau finds that, without the special rule, a price-based approach would not adequately address the risk that consumers taking out short-reset ARMs may not have the ability to repay those loans but that such loans would nonetheless be eligible for General QM status under § 1026.43(e)(2).[333]

The price-based approach to addressing affordability concerns. As noted in the proposal, the Bureau's analysis of historical ARM pricing and performance indicates that the General QM product restrictions combined with the price-based approach would have effectively excluded many—but not all—of the riskiest short-reset ARMs from obtaining General QM status. As a result, the Bureau concludes that an additional mechanism is merited to exclude from the General QM loan definition these short-reset ARMs for

[329] *See* 12 CFR 1026.32(a)(3)–3.

[330] The lower absolute pricing of ARMs with comparable credit risk is reflected in the lower ARM APOR, which is typically 50 to 150 basis points lower than the fixed-rate APOR.

[331] Bureau analysis of NMDB data shows crisis-era short-reset ARMs had lower LTV ratios at consummation relative to comparably priced fixed-rate loans.

[332] This approach for ARMs is different from the approach in § 1026.43(c)(5) for underwriting ARMs under the ATR requirements, which, like the APR determination for HOEPA coverage for ARMs under § 1026.32(a)(3), is based on the greater of the fully indexed rate or the initial rate.

[333] As discussed below in the Legal Authority section, the Bureau is exercising its adjustment and revision authorities to amend § 1026.43(e)(2)(vi) to provide that, to determine the APR for short-reset ARMs for purposes of General QM status, the creditor must treat the maximum interest rate that may apply during that five-year period as the interest rate for the full term of the loan. The Bureau observes that the requirement in TILA section 129C(b)(2)(A)(v) to underwrite ARMs for QM purposes using the maximum interest rate that may apply during the first five years is at least ambiguous with respect to whether it independently obligates the creditor to determine the APR for short-reset ARMs in the same manner as the special rule, at least when the Bureau relies on pricing thresholds as the primary indicator of likely repayment ability in the General QM loan definition. Furthermore, the Bureau concludes that it would be reasonable, in light of the definition of a General QM and in light of the policy concerns already described, to construe TILA section 129C(b)(2)(A)(v) as imposing the same obligations as the special rule in § 1026.43(e)(2)(vi). Thus, in addition to relying on its adjustment and revision authorities to amend § 1026.43(e)(2)(vi), the Bureau concludes that it may do so under its general authority to interpret TILA in the course of prescribing regulations under TILA section 105(a) to carry out the purposes of TILA.

which the pricing and structure indicate a risk of delinquency that is inconsistent with the presumption of compliance with the ATR requirements that comes with QM status.

The Bureau's analysis of NMDB data shows that short-reset ARMs originated from 2002 through 2008 had, on average, substantially higher early delinquency rates (14.9 percent) than other ARMs (10.1 percent) or than fixed-rate mortgages (5.4 percent). Many of these short-reset ARMs were also substantially higher-priced relative to APOR and more likely to have product features that TILA and the ATR/QM Rule now prohibit for QMs, such as interest-only payments or negative amortization. In considering only loans without such restricted features and with rate spreads within 2 percentage points of APOR (the proposed non-QM threshold), short-reset ARMs still have the highest average early delinquency rate (5.5 percent), but the difference relative to other ARMs (4.3 percent) and fixed-rate mortgages (4.2 percent) is smaller. While not a factor in the Bureau's decision to finalize the special rule as proposed, the Bureau's analysis of early delinquency rates of loans without restricted features and with rate spreads within 2.25 percentage point of APOR (the non-QM threshold under the Final Rule) yields similar results, though the delinquency rates for short-reset ARMs as compared to all other loans are slightly higher. Under that analysis, the early delinquency rate for short-reset ARMs is 6.2 percent as compared to 4.4 percent for all other ARMs and 4.3 percent for fixed-rate mortgages.[334]

In the proposal, the Bureau requested additional data or evidence comparing loan performance of short-reset ARMs, other ARMs, and fixed-rate mortgages, as well as data comparing the performance of such loans during periods of rising interest rates. In response, a few commenters stated that their internal data for loans originated post-crisis—in an environment of relatively low interest rates—showed generally comparable delinquency rates between certain ARMs and fixed-rate mortgages. Those delinquency rates are generally consistent with those reflected in the data on which the Bureau relied, in part, to propose the special rule. No commenters, however, provided data on comparative loan performance during periods of rising interest rates—which, as discussed herein, is the interest-rate environment for which the special rule's additional safeguards are primarily designed. The Bureau recognizes that rising interest rates may also pose some risk of unaffordability for longer-reset ARMs later in the loan term. However, as also discussed herein, the Bureau is finalizing the special rule to address the specific concern that short-reset ARMs pose a higher risk than other ARMs of becoming unaffordable in the first five years, before consumers have sufficient time to refinance or adjust to the larger payments—a concern Congress also identified in the Dodd-Frank Act. Short-reset ARMs have the potential for a significant interest rate increase early in the loan term and present concerns that the payments may therefore become unaffordable. Commenters did not present evidence controverting that short-reset ARMs may present particular risks. Indeed, most commenters acknowledged that short-reset ARMs do in fact present additional concerns about affordability.

A combination of factors post-financial crisis—including a sharp drop in ARM originations and the restriction of such originations to highly creditworthy borrowers, as well as the prevalence of low interest rates—likely has muted the overall risks of short-reset ARMs. During the peak of the mid-2000s housing boom, ARMs accounted for as much as 52 percent of all new originations. In contrast, the current market share of ARMs is relatively small. Post-crisis, the ARM share had declined to 12 percent by December 2013 and to 1.4 percent by July 2020, only slightly above the historical low of 1 percent in 2009.[335] One major factor contributing to the overall decline in ARM volume is the low-interest-rate environment since the end of the financial crisis. Typically, ARMs are more popular when conventional interest rates are high, since the rate (and monthly payment) during the initial fixed period is typically lower than the rate of a comparable conventional fixed-rate mortgage.

Consistent with TILA section 129C(b)(2)(A), the January 2013 Final Rule prohibited ARMs with higher-risk features such as interest-only payments or negative amortization from receiving General QM status. According to the Assessment Report, short-reset ARMs comprised 17 percent of ARMs in 2012, prior to the January 2013 Final Rule, and fell to 12.3 percent in 2015, after the effective date of the Rule.[336] The Assessment Report also found that short-reset ARMs originated after the effective date of the Rule were restricted to highly creditworthy borrowers.[337] The Assessment Report further found that conventional, non-GSE short-reset ARMs originated after the effective date of the Rule had early delinquency rates of only 0.2 percent.[338] Due to the post-crisis low interest rate environment and restriction of ARM originations to highly creditworthy borrowers, these recent originations may not accurately reflect the potential unaffordability of short-reset ARMs under different market conditions than those that currently prevail.

Special rule for APR determination for short-reset ARMs.[339] Given the potential that rising interest rates could cause short-reset ARMs to become unaffordable for consumers following consummation and the fact that the price-based approach does not account for some of those risks because of how APRs are determined for ARMs, the Bureau is finalizing the proposed special rule to determine the APR for short-reset ARMs for purposes of defining General QM under § 1026.43(e)(2). As noted above, in defining QM in TILA, Congress adopted a special requirement to address affordability concerns for short-reset ARMs. Specifically, TILA provides that, for an ARM to be a QM, the underwriting must be based on the maximum interest rate permitted under the terms of the loan during the first five years. With the 43 percent DTI limit in the current ATR/QM Rule, implementing the five-year underwriting requirement is straightforward: The Rule requires a creditor to calculate DTI using the mortgage payment that results from the maximum possible interest rate that could apply during the first five years.[340] This ensured that the creditor calculates the DTI using the highest interest rate that the consumer may experience in the first five years, and the loan is not eligible for QM status under § 1026.43(e)(2) if the DTI calculated using that interest rate exceeds 43 percent. The Bureau concludes that using the fully indexed rate to determine the APR for purposes of the rate-spread thresholds in § 1026.43(e)(2)(vi) as finalized would

[334] Many ARMs in the data during this period do not report the time between consummation and the first interest-rate reset, and so are excluded from this analysis.

[335] Laurie Goodman *et al.,* Urban Inst., *Housing Finance at a Glance,* at 9 (Sept. 2020), *https://www.urban.org/sites/default/files/publication/102979/september-chartbook-2020.pdf.*

[336] Assessment Report, *supra* note 63, at 94 (fig. 25).

[337] *Id.* at 93–95.

[338] *Id.* at 95 (fig. 26).

[339] As noted above, the special rule also applies to step-rate mortgages for which the interest rate changes in the first five years.

[340] 12 CFR 1026.43(e)(2)(iv).

not provide a sufficiently meaningful safeguard against the elevated likelihood of delinquency for short-reset ARMs. For that reason, the Bureau is finalizing the proposed special rule for determining the APR for such loans.

The Bureau concludes the statutory five-year underwriting requirement provides a basis for the special rule for determining the APR for short-reset ARMs for purposes of General QM rate-spread thresholds under § 1026.43(e)(2). Specifically, under the special rule, the creditor must determine the APR by treating the maximum interest rate that may apply during the first five years, as described in § 1026.43(e)(2)(vi), as the interest rate for the full term of the loan. That APR determination is then compared to the APOR [341] to determine General QM status. This approach addresses in a targeted manner the primary concern about short-reset ARMs—payment shock—by accounting for the risk of delinquency and default associated with payment increases under these loans. And it would do so in a manner that is consistent with the five-year framework embedded in TILA for such ARMs and implemented in the current ATR/QM Rule.

In sum, the Bureau finds that the special rule is consistent with both TILA's statutory mandate for short-reset ARMs and the proposed price-based approach. As discussed above in part V, the rate spread of APR over APOR is strongly correlated with early delinquency rates. As a result, such rate spreads may generally serve as an effective indicator for a consumer's ability to repay. However, the structure and pricing of ARMs can result in early interest rate increases that are not fully accounted for in Regulation Z provisions for determining the APR for ARMs. Such increases could diminish the effectiveness of the rate spread as an indicator and lead to heightened risk of early delinquency for short-reset ARMs relative to other loans with comparable APR over APOR rate spreads. The special rule, by requiring creditors to more fully incorporate this interest-rate risk in determining the APR for short-reset ARMs, will more fully ensure that the resulting pricing accounts for that risk for such loans.

The special rule requires that the maximum interest rate in the first five years be treated as the interest rate for the full term of the loan to determine the APR. The Bureau concludes that a composite APR determination based on the maximum interest rate in the first five years and the fully indexed rate for the remaining loan term could understate the APR for short-reset ARMs by failing to sufficiently account for the risk that consumers with such loans could face payment shock early in the loan term. Accordingly, to account for that risk, and to ensure that the QM presumption of compliance is accorded to short-reset ARMs for which the consumer has the ability to repay, the Bureau is requiring that the APR for short-reset ARMs be based on the maximum interest rate during the first five years.

Commenter criticism of the special rule: Burden and market effects. As noted above, commenter criticism of the proposed special rule generally fell into two categories: (1) The special rule would be overly burdensome; and (2) because some ARMs allow up to a 2 percentage point increase at the first reset, the special rule would limit or eliminate QM eligibility for some or all short-reset ARMs—with some commenters predicting that, as a result, some or all short-reset ARMs would cease to be offered in the marketplace.

With regard to the first criticism, some commenters asserted that the special rule would increase burden by adding operational complexity and compliance uncertainty. These commenters provided no further explanation or data to justify their claims. The Bureau recognizes that the special rule's APR calculation is a new regulatory requirement. However, the Bureau concludes that its special rule addresses the risk posed by short-reset ARMs without adding unreasonable burden. Cognizant of reducing burden resulting from calculating a new APR, the Bureau proposed the special rule, in part, because it parallels the underwriting requirement in existing § 1026.43(e)(2)(iv), which already requires creditors to calculate the five-year maximum interest rate for short-reset ARMs. As such, the special rule's APR calculation is based on an input already required for short-reset ARMs under the underwriting calculation. Moreover, creditors already have all of the other inputs required for the special rule's APR calculation from existing APR regulatory requirements. The Bureau expects that these factors will mitigate the burden of implementing systems changes to comply with the special rule. The Bureau also notes that the different APR calculation required under § 1026.32(a)(3)(ii) for purposes of determining whether ARMs are subject to certain HOEPA requirements has not resulted in compliance uncertainty.

Three commenters raised concerns that adapting to the special rule would be burdensome because it would overlap with the transition from the LIBOR index to the SOFR index (and because of the pandemic) and therefore requested a longer implementation period. The implementation period of the Final Rule is addressed in part VII below.

A few other commenters stated that the special rule would adversely affect the market for GSE short-reset ARMs that have been developed specifically for the new SOFR index, and that such ARMs likely would be unable to obtain QM status under the special rule. The Bureau notes that the special rule does not depend on which index a creditor uses to determine the interest rate of a short-reset ARM. Thus, the transfer from LIBOR ARMs to SOFR ARMs has no effect on the application of the special rule, as it is the structure of the rate resets permitted under the contract within the first five years that will determine the maximum interest rate for the purposes of calculating the APR under the special rule. Creditors offering ARM products, including short-reset ARMs, will have to complete the work to transition from LIBOR to SOFR regardless of the parameters of the Bureau's special rule. Moreover, the Bureau understands that the 2 percentage point cap on the initial reset of most GSE short-reset ARMs is the same for both GSE LIBOR ARMs and GSE SOFR ARMs. While the current ATR/QM Rule's GSE Patch granted QM status to all GSE-eligible ARMs, under this final rule, GSE ARMs will require similar adjustments due to their rate reset caps in order to qualify for QM status—regardless of which index is used. Further, the Bureau notes that only approximately 5 percent of 2018 conventional purchase ARMs that would have been subject to the special rule were GSE loans. In sum, the Bureau recognizes the operational challenges posed by the transition from LIBOR to SOFR, but the Bureau finds that the special rule would not exacerbate these challenges and that these challenges are unrelated to the types of ARMs that qualify for a QM presumption of compliance under the special rule.

With respect to the remaining criticisms of the special rule's projected market effects, commenters claimed that, because some short-reset ARMs allow up to a 2 percentage point increase at the first reset, the special rule would limit or eliminate QM eligibility for some or all short-reset ARMs. A few of these commenters

[341] This refers to the standard APOR for ARMs. The requirement modifies the determination for the APR of ARMs but does not affect the determination of the APOR. The Bureau notes that the APOR used for step-rate mortgages is the ARM APOR because, as with ARMs, the interest rate in step-rate mortgages adjusts and is not fixed. Thus, the APOR for fixed-rate mortgages would be inapt.

further predicted that, as a result, some or all short-reset ARMs would cease to be offered in the marketplace. These commenters did not provide additional data or evidence to support their projections. As discussed above, the Bureau is increasing the rate-spread threshold for eligibility under the General QM loan definition from the proposed 2-percentage-point threshold to 2.25 percentage points for loans less than or equal to $110,260. As a result of this increased threshold, more short-reset ARMs will achieve QM status than would have under the proposal. This is especially true for many five-year ARMs, including existing GSE five-year ARMs, which under the proposed special rule might have required modifications to the current interest rate cap to obtain QM status. Under the 2.25-percentage-point threshold, many of these loans may qualify as QMs as currently structured. Because most GSE five-year ARMs (both LIBOR and SOFR) provide for a 2 percentage point cap on the first reset, many of these short-reset ARMs will fall within the new QM threshold. Due to this increased threshold, any five-year ARM with an initial APR within 0.25 percentage points of the APOR at origination can have an initial adjustment of up to 2 percent and still qualify as a QM under the special rule.

The Bureau recognizes that, because the QM safe harbor threshold remains unchanged, many of the short-reset ARMs that achieve QM status under the Final Rule's expanded spread will receive a rebuttable presumption of compliance rather than a conclusive presumption. Due to the risk that these short-reset ARMs (*i.e.,* those with relatively high interest rate caps) may become unaffordable after early resets, the Bureau concludes that rebuttable presumption status, as opposed to safe harbor status, is appropriate for such loans. Furthermore, according to the Bureau's evidence, as discussed in the proposal and above, the fact that many of these loans may qualify only for a rebuttable presumption and not a safe harbor is not likely to have a significant impact on access to responsible, affordable mortgage credit. As discussed in more detail above, creditors readily make rebuttable presumption QMs, thus indicating that the non-QM threshold is the more relevant threshold in determining access to responsible, affordable mortgage credit under the General QM amendments.

The Bureau is aware that the increase in the rate-spread threshold will have a greater impact on QM eligibility of five-year ARMs as compared to three-year ARMs. For example, GSE three-year ARMs permit interest rate increases as high as 6 percentage points in the first five years and as such likely will not qualify for General QM status. The Bureau notes that the purpose of the special rule is to ensure that General QM status will not be accorded to certain loans for which the interest rate may sharply increase in the first five years, resulting in pricing that exceeds the non-QM threshold in this final rule and in potentially unaffordable payments. Consistent with this purpose, the special rule would preclude such loans from obtaining General QM status, including many three-year ARMs with interest rates that may increase by as much as 6 percentage points in the first five years. Loans for which the interest rate may increase so sharply early in the term of the loan do not warrant the General QM presumption of compliance with the ATR requirements.

To the extent the increased rate-spread threshold does not address commenter concerns with regard to access to credit, the Bureau notes that creditors can and do market QM-eligible ARMs that either satisfy the requirements of the special rule by not permitting resets above 2.25 percentage points within the first five years or that fall outside the purview of the special rule by resetting later than five years (60 months) after the first payment is due. Market participants currently originate some five-year ARMs with sufficiently low initial reset caps or with an initial reset that occurs shortly after 60 months. For example, the definition of a GSE five-year ARM allows an initial fixed-rate period of up to 66 months.[342] Thus, GSEs and creditors can offer ARMs that satisfy the General QM pricing requirements under the special rule or that fall outside the scope of the special rule. Also, while interest rate reset data for privately-held non-agency loans is not reliably available, the Bureau notes that both FHA and VA ARMs, although subject to their own agency QM rules, contain interest rate reset caps that would fall within the parameters of the special rule as finalized.[343]

A few commenters asked for clarification of certain aspects of the special rule. One commenter requested that the Bureau clarify whether the special rule applies to five-year ARMs. Specifically, the commenter asked for clarification as to whether the first interest rate reset of a five-year ARM is included in the special rule's APR calculation, given the special rule's applicability to loans for which the interest rate may or will change within the first five years after the date on which the first regular periodic payment will be due. To the extent that the first interest rate reset of a five-year ARM occurs on the five-year anniversary of the due date of the first periodic payment, such ARMs are subject to the special rule. As noted in the proposal, the special rule is identical in this regard to the existing underwriting requirement for short-reset ARMs in § 1026.43(e)(2)(iv). Also, comment 43(e)(2)(vi)–4.ii, which the Bureau is finalizing as proposed, clarifies that the special rule applies to five-year ARMs.

One commenter posed several questions concerning how the special rule applies to certain loan products or in various factual scenarios. To the extent that the commenter's questions are not addressed in the final rule, the Bureau notes that it has a variety of tools for answering such questions once a final rule is issued, including external guidance materials and an informal guidance function.

Commenter recommendations. Commenters that criticized the special rule generally recommended one of two ways to address their criticisms: Narrow the scope of the special rule or substitute an alternative special rule.

Some commenters recommended narrowing the scope of the special rule to expand the number of short-reset ARMs that obtain QM status—either to exclude five-year ARMs from coverage or to restrict the scope to short-reset ARMs with an initial fixed-rate period of less than five years, three years, or two years. The Bureau declines to adopt these recommendations and is finalizing the special rule as proposed to cover short-reset ARMs with initial fixed-rate periods of five years or less, for the following reasons and those discussed above.

The majority of these commenters specifically recommended excluding five-year ARMs from coverage. The Bureau notes that coverage of the special rule is already relatively narrow. Including five-year ARMs, the Bureau estimates that the special rule would apply to 36,000 conventional purchase loans annually, according to 2018 HMDA data. Excluding five-year ARMs from the scope of the special rule would reduce that number to 3,500 loans. Further, as discussed above, because the Bureau is increasing the rate-spread threshold from 2 percentage points to

[342] Fannie Mae, *Standard ARM Plan Matrix for 2020* (Apr. 2020), *https://singlefamily.fanniemae.com/media/6951/display.*

[343] VA caps all interest rate increases at 1 percent a year for all VA ARMS. FHA caps interest rate increases at 1 percent for one-year and three-year ARMs. FHA caps annual interest rate increases at 1 percent for a lifetime cap of 5 percent or 2 percent increases for a lifetime cap of 6 percent.

2.25 percentage points for loans greater than or equal to $110,260, more five-year ARMs will obtain QM status under the special rule as finalized.

The Bureau reiterates that the purpose of the special rule is to prevent certain short-reset ARMs from obtaining QM status if there may be a sharp rise in interest rates soon after origination. This rise may occur with three-year ARMs, which may have contracts that permit the interest rate to increase by as much as 6 percentage points in the first five years. Because consumers may lack sufficient time to adjust to larger payments early in the loan term or to build enough equity to refinance, such ARMs pose a higher risk of early delinquency. For these additional reasons, the Bureau declines to narrow coverage to short-reset ARMs with initial fixed-rate periods of three years or less.

Some commenters recommended the Bureau implement alternative special rules to address the risks presented by short-reset ARMs. The Bureau declines to adopt the alternative special rules recommended by these commenters. To the extent that commenters are advocating for alternative special rules to increase the number of short-reset ARMs that could obtain QM status, the Bureau notes that the increase of the rate-spread threshold in the Final Rule will expand the pool of QM-eligible short-reset ARMs compared to the proposal.

As noted above, a few commenters recommended adopting a special rule that uses the maximum interest rate in the first five years of the loan (as opposed to using the APR required by the special rule) to compare with the AIIR (instead of APOR), plus the additional cushion of 2.5 percentage points (''AIIR special rule''). As the Bureau understands this recommendation, short-reset ARMs satisfying the initial test would then be subject to the same APR-to-APOR rate-spread tests as other loans under the General QM loan definition for purposes of determining whether the loans receive a safe harbor or a rebuttable presumption or are non-QM under the applicable thresholds.

The Bureau recognizes that adopting this AIIR special rule would expand the number of short-reset ARMs that would achieve QM status, as interest rate increases of up to 2.5 percentage points early in the life of the loan would meet that special rule's pricing threshold. The Bureau also recognizes that using the five-year maximum interest rate in this special rule could be a burden-reduction measure, since creditors will already have calculated that input, as it is currently required for underwriting loans pursuant to § 1026.43(e)(2)(iv).

The AIIR special rule would expand the pool of QM-eligible short-reset ARMs to those whose interest rates increase by as much as 2.5 percentage points. However, commenters provided no evidence that this threshold would appropriately identify which loans are likely affordable and should receive a presumption of compliance. Moreover, the Bureau concludes that any potential burden-reduction benefits are outweighed by the complexity of introducing into the General QM loan definition a new measure—the AIIR—and a new formula that requires, as the first step in a two-step process, comparing the maximum five-year interest rate to the AIIR and then adding 2.5 percentage points. (Then, if the short-reset ARM meets the threshold of the first test, it is still subject to the price-based APR–APOR rate-spread test.) In addition, because ''AIIR'' is not a commonly used term, the Bureau is concerned that creditors may not understand AIIR to mean what the Bureau believes the commenters intended, *i.e.,* the mean initial interest rate for a particular ARM product. As such, a requirement to use the AIIR could necessitate significant regulatory explanation, likely adding implementation and compliance burden. Additionally, the AIIR special rule would deviate from the final rule's straight-forward APR-to-APOR comparison, requiring an additional comparison of interest rates. For these reasons, the Bureau declines to adopt the AIIR special rule.

Two commenters recommended a special rule using the maximum interest rate in the first five years for short-reset ARMs instead of the APR calculation required by the special rule (''five-year maximum interest rate special rule''). These commenters advocated this alternative special rule as way to expand QM eligibility for short-reset ARMs and to ease burden, as this calculation of the five-year maximum interest rate is already required for underwriting short-reset ARMs in the current ATR/QM Rule [344] and therefore would not require an additional calculation. One commenter recommended setting the General QM rate-spread threshold for short-reset ARMs in a manner that compares the maximum interest rate possible in the first five years with a given rate spread of APOR. The other commenter similarly recommended adopting a separate qualification test that compares the highest interest rate within five years to the APOR plus an appropriate threshold.

The Bureau recognizes that the five-year maximum interest rate special rule suggested by the commenter would expand the pool of QM-eligible short-reset ARMs. However, this would be accomplished in part by excluding from the APR calculation non-interest finance charges, which are included for other types of loans subject to the Rule. Such finance charges are key components of a loan's pricing and therefore contribute to making pricing an effective indicator of a consumer's ability to repay. As such, the Bureau declines to exclude non-interest finance charges from the APR calculation for short-reset ARMs.

The Bureau further notes that the interest-rate-to-APOR comparison would allow riskier loans—that is, loans that may reset to a significantly higher interest rate in the first five years—to obtain QM status. As discussed above, the intended effect of the Bureau's special rule is to guard against certain short-reset ARMs with early, potentially unaffordable, sharp increases in interest rates from obtaining QM status. For these reasons, the Bureau declines to adopt the five-year maximum interest rate special rule.

As noted above, a few commenters recommended replacing the special rule with reasonable secondary interest rate caps during the first five years for short-reset ARMs (''rate cap special rule''). While this alternative special rule would directly address the threat of payment shock, these commenters did not specify what rate caps would be reasonable or how such caps would operate in relation to the contractual rate caps under the ARM note. In the proposed rule, for these same reasons, the Bureau considered and declined to propose interest rate caps that commenters had suggested in response to the ANPR and noted that the special rule would address the problem in a more streamlined manner. Additionally, the rate cap special rule would deviate from the pricing approach that would apply to other ARMs and fixed-rate mortgages subject to this final rule. Moreover, commenters provided no evidence indicating that rate caps in general or that specific rate caps would identify more accurately than the Bureau's special rule those short-reset ARMs likely to be affordable and thus meriting a presumption of compliance.

The commenters that recommended secondary rate caps alternatively recommended that the Bureau require creditors to use the fully indexed rate for the remaining loan term after the first five years to calculate the APR for short-reset ARMs (without specifying

[344] 12 CFR 1026.43(e)(2)(iv).

which interest rate to use for the first five years). The Bureau understands this approach to be similar to the general APR requirements for ARMs in § 1026.17(c)(1), which require the creditor to disclose a composite APR based on the initial rate for as long as it is charged and, for the remainder of the term, on the fully indexed rate. Absent the Bureau's special rule, this would be the applicable APR formula for short-reset ARMs under the price-based approach. Another GSE recommended the Bureau adopt that GSE's own requirements for short-reset ARMs, which the GSE described as using the greater of the fully indexed rate or 2 percent over the initial note rate for the full term of the loan.

The Bureau declines to adopt either of these approaches. Using the fully indexed rate to calculate the APR for short-reset ARMs—for some or all of the loan term—would not adequately address the risk that such ARMs can become unaffordable. As noted above, if interest rates rise after consummation, and therefore the value of the index rises to a higher level, the loan can reset to a higher interest rate than the fully indexed rate at the time of consummation. The result would be a higher payment than the one that would be calculated based on the rates used in determining the APR. Requiring the use of 2 percent over the initial note rate (if greater than the fully indexed rate) also would not adequately address this risk. As noted above, many short-reset ARMs are permitted to adjust substantially more than 2 percent early in the life of the loan, particularly those structured to have multiple adjustments within the first five years. The interest rate of such ARMs can adjust upward 6 percentage points in the first five years of the loan. By requiring that the APR for short-reset ARMs be determined by treating the maximum interest rate during the first five years as the interest rate for the full term of the loan, the Bureau's special rule is designed to account for that risk, and to ensure that General QM status is accorded to short-reset ARMs that merit a presumption of compliance.

Legal authority. As discussed above in part IV, TILA section 105(a), directs the Bureau to prescribe regulations to carry out the purposes of TILA, and provides that such regulations may contain additional requirements, classifications, differentiations, or other provisions, and may provide for such adjustments and exceptions for all or any class of transactions that the Bureau judges are necessary or proper to effectuate the purposes of TILA, to prevent circumvention or evasion thereof, or to facilitate compliance therewith. In particular, a purpose of TILA section 129C, as amended by the Dodd-Frank Act, is to assure that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loans.

As also discussed above in part IV, TILA section 129C(b)(3)(B)(i) authorizes the Bureau to prescribe regulations that revise, add to, or subtract from the criteria that define a QM upon a finding that such regulations are necessary or proper to ensure that responsible, affordable mortgage credit remains available to consumers in a manner consistent with the purposes of section 129C, necessary and appropriate to effectuate the purposes of section 129C and section 129B, to prevent circumvention or evasion thereof, or to facilitate compliance with such section.

The Bureau is finalizing the special rule in § 1026.43(e)(2)(vi) regarding the APR determination of certain loans for which the interest rate may or will change pursuant to its authority under TILA section 105(a) to make such adjustments and exceptions as are necessary and proper to effectuate the purposes of TILA, including that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loans. The Bureau concludes that these provisions will ensure that General QM status would not be accorded to short-reset ARMs and certain other loans that pose a heightened risk of becoming unaffordable relatively soon after consummation. The Bureau is also finalizing these provisions pursuant to its authority under TILA section 129C(b)(3)(B)(i) to revise and add to the criteria that define a QM. The Bureau believes that the special rule's APR determination provisions in § 1026.43(e)(2)(vi) will ensure that responsible, affordable mortgage credit remains available to consumers in a manner consistent with the purpose of TILA section 129C, referenced above, as well as effectuate that purpose.

43(e)(4)

TILA section 129C(b)(3)(B)(ii) directs HUD, VA, USDA, and RHS to prescribe rules defining the types of loans they insure, guarantee, or administer, as the case may be, that are QMs. Pending the other agencies' implementation of this provision, the Bureau included in the ATR/QM Rule a temporary category of QMs in the special rules in § 1026.43(e)(4)(ii)(B) through (E) consisting of mortgages eligible to be insured or guaranteed (as applicable) by HUD, VA, USDA, and RHS. The Bureau also created the Temporary GSE QM loan definition in § 1026.43(e)(4)(ii)(A).

Section 1026.43(e)(4)(i) currently states that, notwithstanding § 1026.43(e)(2), a QM is a covered transaction that satisfies the requirements of § 1026.43(e)(2)(i) through (iii)—the General QM loan-feature prohibitions and points-and-fees limits—as well as one or more of the criteria in § 1026.43(e)(4)(ii). Section 1026.43(e)(4)(ii) currently states that a QM under § 1026.43(e)(4) must be a loan that is eligible under enumerated ''special rules'' to be (A) purchased or guaranteed by the GSEs while under the conservatorship of the FHFA (the Temporary GSE QM loan definition), (B) insured by HUD under the National Housing Act, (C) guaranteed by VA, (D) guaranteed by USDA pursuant to 42 U.S.C. 1472(h), or (E) insured by RHS. Section 1026.43(e)(4)(iii)(A) currently states that § 1026.43(e)(4)(ii)(B) through (E) shall expire on the effective date of a rule issued by each respective agency pursuant to its authority under TILA section 129C(b)(3)(ii) to define a QM. Section 1026.43(e)(4)(iii)(B) currently states that, unless otherwise expired under § 1026.43(e)(4)(iii)(A), the special rules in § 1026.43(e)(4) are available only for covered transactions consummated on or before January 10, 2021.

In the General QM Proposal, the Bureau proposed to replace current § 1026.43(e)(4) with a provision stating that, notwithstanding § 1026.43(e)(2), a QM is a covered transaction that is defined as a QM by HUD under 24 CFR 201.7 or 24 CFR 203.19, VA under 38 CFR 36.4300 or 38 CFR 36.4500, or USDA under 7 CFR 3555.109. The Bureau proposed these amendments because, in the Extension Proposal, the Bureau proposed to revise § 1026.43(e)(4)(iii)(B) to state that, unless otherwise expired under § 1026.43(e)(4)(iii)(A), the special rules in § 1026.43(e)(4) would be available only for covered transactions consummated on or before the effective date of a final rule issued by the Bureau amending the General QM loan definition.[345] In the General QM Proposal, the Bureau also noted that, after the promulgation of the January 2013 Final Rule, each of the agencies described in § 1026.43(e)(4)(ii)(B) through (E) adopted separate definitions of qualified mortgages.[346] The Bureau noted that, as a result, the special rules in § 1026.43(e)(4)(ii)(B) through (E) are

[345] 85 FR 41448 (July 10, 2020).

[346] 78 FR 75215 (Dec. 11, 2013) (HUD); 79 FR 26620 (May 9, 2014) and 83 FR 50506 (Oct. 9, 2018) (VA); and 81 FR 26461 (May 3, 2016) (USDA).

already superseded by the actions of HUD, VA, and USDA. The Bureau's proposed amendments to § 1026.43(e)(4) provided cross-references to each of these other agencies' definitions so that creditors and practitioners have a single point of reference for all QM definitions.

The Bureau proposed to amend comment 43(e)(4)–1 to reflect the cross-references to the QM definitions of other agencies and to clarify that a covered transaction that meets another agency's definition is a QM for purposes of § 1026.43(e). The Bureau proposed to amend Comment 43(e)(4)–2 to clarify that covered transactions that met the requirements of § 1026.43(e)(2)(i) through (iii), were eligible for purchase or guarantee by Fannie Mae or Freddie Mac, and were consummated prior to the effective date of any final rule promulgated as a result of the proposal would still be considered a QM for purposes of § 1026.43(e) after the adoption of such potential final rule. Comments 43(e)(4)–3, –4, and –5 would have been removed. The Bureau requested comment on the proposed amendments to § 1026.43(e)(4) and related commentary. Comments on the proposal did not discuss the proposed amendments to § 1026.43(e)(4) and its related commentary.

In this final rule, the Bureau amends § 1026.43(e)(4) as proposed, with modifications to the commentary to clarify the application of this final rule's effective date to the availability of the Temporary GSE QM loan definition.

As noted above, on October 20, 2020, the Bureau issued the Extension Final Rule to replace the January 10, 2021 sunset date of the Temporary GSE QM loan definition with a provision stating that the Temporary GSE QM loan definition will be available only for covered transactions for which the creditor receives the consumer's application before the mandatory compliance date of this final rule.[347] As noted in part VII below, this final rule will have an effective date of March 1, 2021, and a mandatory compliance date of July 1, 2021. As a result, the Temporary GSE QM loan definition will still be used by creditors after the effective date of March 1, 2021 and will not expire until July 1, 2021. In this final rule, the Bureau is making changes to proposed comment 43(e)(4)–2 to reflect this final rule's effective date and mandatory compliance date.

As noted above, the Bureau proposed to remove 43(e)(4)–3. In this final rule, the Bureau is instead revising comment 43(e)(4)–3 to cross-reference new comment 43–2. As discussed further in part VII below, new comment 43–2 clarifies that, for transactions for which a creditor received an application on or after March 1, 2021, but prior to July 1, 2021, a creditor has the option of complying either with 12 CFR part 1026 as it is in effect or with 12 CFR part 1026 as it was in effect on February 26, 2021. The Bureau believes this comment will assist creditors and secondary market participants with compliance with the final rule because it will clarify that, even though the Temporary GSE QM loan definition will not appear in § 1026.43(e)(4) after this final rule's effective date of March 1, 2021, creditors may continue to use it for transactions for which they received the consumer's application prior to July 1, 2021.

The Bureau is amending § 1026.43(e)(4) and related commentary pursuant to TILA section 129C(b)(3)(B)(ii), since the respective agencies directed to create their own definitions of qualified mortgages have done so and the Temporary GSE patch provisions will cease to be applicable on July 1, 2021.

Conforming Changes

As discussed above, the Bureau proposed, among other things, to revise the requirements in § 1026.43(e)(2)(v) that creditors consider and verify certain information; to remove the DTI limit in § 1026.43(e)(2)(vi); to remove references to appendix Q from § 1026.43; and to remove appendix Q from Regulation Z entirely. Accordingly, the Bureau proposed non-substantive conforming changes in certain provisions to reflect these proposed changes.

Specifically, the Bureau proposed to update comment 43(c)(7)–1 by removing the reference to the DTI limit in § 1026.43(e). The Bureau also proposed conforming changes to provisions related to small creditor QMs in § 1026.43(e)(5)(i) and to balloon-payment QMs in § 1026.43(f)(1). Both § 1026.43(e)(5) and (f)(1) currently provide that as part of the respective QM definitions, loans must comply with the requirements in existing § 1026.43(e)(2)(v) to consider and verify certain information. As discussed above, the Bureau proposed to reorganize and revise § 1026.43(e)(2)(v) in order to provide that creditors must consider DTI or residual income and to clarify the requirements for creditors to consider and verify income or assets, debts, and other information. The proposed conforming changes to § 1026.43(e)(5) and (f)(1) would generally have inserted the substantive requirements of existing § 1026.43(e)(2)(v) into § 1026.43(e)(5)(i) and (f)(1), respectively, and would have provided that loans under § 1026.43(e)(5) and (f) do not have to comply with revised § 1026.43(e)(2)(v) or (vi). However, the proposed conforming changes would not have inserted the requirement that creditors consider and verify income or assets, debts, and other information in accordance with appendix Q because the Bureau proposed to remove appendix Q from Regulation Z. The Bureau also proposed conforming changes to the related commentary.

The Bureau did not receive any comments on the proposed conforming changes. While the Bureau, in this final rule, is making some modifications to the proposal, none of these modifications affects the proposed conforming changes. Therefore, this final rule adopts the conforming changes to comment 43(c)(7)–1 and to the provisions related to small creditor QMs in § 1026.43(e)(5)(i) and balloon-payment QMs in § 1026.43(f)(1) as proposed.

Appendix Q to Part 1026—Standards for Determining Monthly Debt and Income

Appendix Q to part 1026 contains standards for calculating and verifying debt and income for purposes of determining whether a mortgage satisfies the 43 percent DTI limit for General QMs. As explained in the section-by-section analysis of § 1026.43(e)(2)(v)(B) above, the Bureau proposed to remove appendix Q from Regulation Z entirely in light of concerns from creditors and investors that its rigidity, ambiguity, and static nature result in standards that are both confusing and outdated. The Bureau sought comment on whether, instead of removing appendix Q entirely, it should retain appendix Q as an option for complying with the ATR/QM Rule's verification requirements.

Commenters generally supported removing appendix Q. Commenters stated that appendix Q's requirements to consider and verify income and debt are outdated, ambiguous, and inflexible. Commenters also stated that appendix Q is difficult for creditors to use for self-employed and gig economy consumers and in some cases has resulted in reduced access to credit. A consumer advocate, for example, stated that appendix Q consisted of ''ossified and complex detail'' and supported the Bureau's proposal to amend § 1026.43(e)(2)(v). These commenters generally supported replacing appendix Q with the provisions of § 1026.43(e)(2)(v) discussed above. In

[347] 85 FR 67938 (Oct. 26, 2020).

contrast, two industry commenters supported retaining appendix Q and suggested detailed edits to its provisions. However, both comment letters discussed such edits to appendix Q in the context of retaining a DTI limit within the General QM loan definition, which is not being adopted for the reasons discussed in part V above.

This final rule removes the appendix Q requirements from § 1026.43(e)(2)(v) and removes appendix Q from Regulation Z entirely, as the Bureau proposed. The Bureau determines that, due to the well-founded and consistent concerns articulated by stakeholders and described in detail in the General QM Proposal,[348] appendix Q does not provide sufficient compliance certainty to creditors and does not provide flexibility to adapt to emerging issues with respect to the treatment of certain types of debt or income categories. The Bureau does not anticipate that removing appendix Q and using the new requirements of 1026.43(e)(2)(v) to consider and verify income, assets, debts, alimony, and child support will lead to higher risk loans obtaining QM status beyond loans that will receive such status from the removal of DTI limits as discussed in part C.4 above.

The Bureau recognizes that some findings in the Assessment Report suggest that the issues raised by creditors with respect to appendix Q do not appear to have had a substantial impact for certain loans. For example, although creditors have stated that it may be difficult to comply with certain appendix Q requirements for self-employed borrowers, the Assessment Report noted that application data indicated that the approval rates for non-high DTI, non-GSE eligible self-employed borrowers have decreased by only 2 percentage points since the January 2013 Final Rule became effective.[349] The Bureau concludes, however, that this limited decrease in approvals for such applications does not undermine creditors' concerns that appendix Q's definitions of debt and income are rigid and difficult to apply and do not provide the level of compliance certainty that the Bureau anticipated in the January 2013 Final Rule. Additionally, the Assessment Report showed that about 40 percent of respondents to a lender survey indicated that they ''often'' or ''sometimes'' originate non-QM loans if the borrower cannot provide documentation required by appendix Q. The Bureau concluded in the Assessment Report that these results left open the possibility that appendix Q requirements may have had an impact on access to credit.[350]

The Bureau declines to retain and revise appendix Q. As noted above, the Bureau concludes that appendix Q is inflexible, ambiguous and static, which results in standards that are both confusing and outdated. The Bureau concludes that it would be time- and resource-intensive to revise appendix Q in a manner to try to resolve these concerns. The Bureau therefore concludes that removing appendix Q entirely would be more efficient and practicable than retaining and revising it. The Bureau also does not anticipate a decrease in consumer protection as a result of removing appendix Q and adopting the provisions of 1026.43(e)(2)(v).

VII. Effective Date

A. The Bureau's Proposal

The Bureau proposed an effective date for a revised General QM loan definition of six months after publication in the **Federal Register** of a final rule. The Bureau further proposed that the revised regulations would apply to covered transactions for which creditors receive an application on or after that effective date. In the proposal, the Bureau tentatively determined that a six-month period between **Federal Register** publication of a final rule and the final rule's effective date would give creditors enough time to bring their systems into compliance with the revised regulations. The Bureau also stated it did not intend to issue a final rule amending the General QM loan definition early enough for it to take effect before April 1, 2021.

For the reasons described below, this final rule adopts an effective date of March 1, 2021, and a mandatory compliance date of July 1, 2021, resulting in an optional early compliance period between March 1, 2021 and July 1, 2021.[351] This final rule adds new comment 43–2, which explains that, for transactions for which a creditor received the consumer's application on or after March 1, 2021 and prior to July 1, 2021, creditors have the option of using either the current General QM loan definition (*i.e.,* the version in effect on February 26, 2021) or the revised General QM loan definition. Comment 43–2 also explains that, for transactions for which a creditor received the consumer's application on or after July 1, 2021, creditors seeking to originate General QMs are required to use the revised General QM loan definition. Comment 43–2 also specifies the meaning of ''application'' for these purposes.

B. Comments Received

The Bureau received several comments concerning the effective date and implementation period.[352] Several industry commenters supported the proposal to link the effective date to the date the creditor received the consumer's application. One of these commenters stated that using the application date is preferable to using the consummation date because, while a loan is being processed and underwritten, the consummation date remains unknown, making it difficult for the creditor to anticipate which General QM loan definition to apply. Another commenter recommended clarifying that ''application'' has the same definition as under the Bureau's TILA–RESPA Integrated Disclosure Rule (TRID) because that definition is commonly used by the secondary market.

As discussed below, this final rule adds new comment 43–2 to clarify the operation of the final rule's effective date and mandatory compliance date, including clarifying that the effective date and mandatory compliance date are linked to the date the creditor received the consumer's application. Comment 43–2 also clarifies that, for transactions subject to TRID, creditors determine the date the creditor received the consumer's application, for purposes of this final rule's effective date and mandatory compliance date, in accordance with the TRID definition of application in § 1026.2(a)(3)(ii). This new comment also clarifies that, for transactions that are not subject to TRID, creditors can determine the date the creditor received the consumer's application, for purposes of this final rule's effective date and mandatory compliance date, in accordance with either § 1026.2(a)(3)(i) or (ii). The Bureau concludes that the clarifications

[348] 85 FR 41448, 41752 (July 10, 2020).

[349] *See* Assessment Report, *supra* note 63, at 11.

[350] *See id.* at 155.

[351] The Bureau's use of the term ''mandatory compliance date'' does not imply that creditors are required to use the General QM loan definition to comply with the ATR/QM Rule's ability-to-repay requirements. Unless a loan is eligible for QM status—such as under § 1026.43(e)(2), § 1026.43(e)(5), or § 1026.43(f)—a creditor must make a reasonable and good faith determination of the consumer's ability to repay and does not receive a presumption of compliance.

[352] This final rule uses the term ''implementation period'' to refer to the period between the date the Bureau issues this final rule and the date that creditors seeking to originate General QMs must comply with the General QM loan definition as amended by this final rule. Under the General QM Proposal, this implementation period would have ended on the effective date, while under this final rule the implementation period will end on the mandatory compliance date.

provided in comment 43–2 will reduce uncertainty throughout the origination process.

Several industry commenters addressed the length of the implementation period. One industry commenter supported the Bureau's proposed effective date of six months after the final rule's publication in the **Federal Register**. Another industry commenter requested an implementation period extending to June 2021 and a 90-day grace period during which loans would still be reviewed for compliance with the revised definition but the Bureau would take no action to penalize simple mistakes and interpretation differences. The commenter stated that it took many months for small-to-mid-size creditors and investor channels to adjust to TRID.

Several industry commenters stated that an implementation period longer than six months is needed for creditors to work with vendors to develop and install software updates, conduct testing, update training policies, complete staff training, and educate consumers on product offerings. These commenters' recommendations for the length of the implementation period ranged from 12 months to 24 months. One of these industry commenters did not recommend a specific timeframe but stated that implementation would, on average, take from six months to 12 months depending on the size and complexity of both the vendor and creditor—or even up to 18 months depending on the overall complexity of the final rule, the timing of its effective date, and its impact on key operations such as underwriting. Another of these industry commenters requested at least one year for implementation while also stating that: Many creditors needed more than a year to implement the January 2013 Final Rule; a longer implementation period might avoid wasted time and expense if the regulation is changed again as a result of the 2020 elections; and small-to-mid-size creditors need more implementation time than larger creditors. Several industry commenters—including the commenter that generally supported the proposed effective date—stated that, in particular, the APR calculation for certain ARMs under proposed § 1026.43(e)(2)(vi) would require a significant (but unspecified) amount of implementation time.

As noted above, this final rule adopts a mandatory compliance date of July 1, 2021. This date is approximately six months after the date the Bureau expects this final rule to be published in the **Federal Register**. Therefore, this final rule adopts an implementation period similar to the six-month implementation period the Bureau proposed. The Bureau declines to adopt a longer implementation period because the Bureau concludes that a six-month period gives creditors and the secondary market enough time to prepare to comply with the amendments in this final rule. For example, with respect to the price-based thresholds in revised § 1026.43(e)(2)(vi), the Bureau understands that creditors currently calculate the APR and APOR for mortgage loans. With respect to the consider and verify requirements in revised § 1026.43(e)(2)(v), the Bureau understands that the revised consider requirements generally reflect existing market practices and that creditors currently use and are familiar with the verification standards in the verification safe harbor. The Bureau also concludes that this final rule is less complex to implement relative to other rules the Bureau has issued, such as the January 2013 Final Rule or TRID. The Bureau further concludes that it would be imprudent to provide a longer than necessary implementation period based on mere speculation that the Bureau might propose additional changes in the future. The Bureau declines to adopt a 90-day grace period or allow more implementation time for small-to-mid-size creditors because the Bureau concludes, for the reasons described above, that a six-month period gives all creditors and secondary market participants enough time to prepare to comply with the amendments in this final rule. The Bureau also concludes that establishing an optional early compliance period will facilitate implementation for all creditors, including small-to-mid-size creditors, for the reasons described below in the discussion of the final rule.

Several industry commenters also stated that this final rule's implementation period should generally account for other simultaneous challenges for creditors, including responding to the COVID–19 pandemic and its economic effects; transitioning indices away from LIBOR; [353] and implementing the GSEs' redesigned Uniform Residential Loan Application (URLA).[354] One of those commenters specified that this final rule's implementation period should extend at least six months after the URLA's March 2021 mandatory compliance date. The Bureau concludes that a six-month implementation period gives creditors and secondary market participants enough time to prepare for the amendments in this final rule, even in light of these other commitments. As stated above, the Bureau concludes that this final rule is less complex to implement relative to other rules, such as the January 2013 Final Rule or TRID, and will not require significant changes to creditors' existing practices. Moreover, the Bureau concludes that current market conditions do not require a longer implementation period.

Several industry commenters responded to the General QM Proposal by requesting that the Bureau establish a period during which the Temporary GSE QM loan definition would remain in effect *after* the date creditors are required to transition from the current General QM loan definition to the revised General QM loan definition (Overlap Period). With respect to the length of the Overlap Period, commenters suggested periods between six months and one year. The Bureau also received several requests for an Overlap Period in response to the Extension Proposal, with commenters suggesting that the period last between four months and one year. The Bureau declines to adopt an Overlap Period in this final rule for the same reasons it declined to adopt an Overlap Period in the Extension Final Rule. In that final rule, the Bureau concluded that establishing an Overlap Period would keep the Temporary GSE QM loan definition in place longer than necessary to facilitate a smooth and orderly transition to a revised General QM loan definition and would prolong the negative effects of the Temporary GSE QM loan definition on the mortgage market.[355]

In contrast with an Overlap Period, one group of industry commenters requested an optional early compliance period during which the revised General QM loan definition would become available, on an optional basis, *before* the date creditors are required to transition from the current General QM loan definition to the revised General QM loan definition. The group did not specify how much earlier, in its view, the Bureau should make the revised General QM loan definition available. As discussed below, the Bureau concludes that establishing an optional early compliance period will facilitate a smooth and orderly transition to a

[353] The Bureau has separately proposed to amend Regulation Z to facilitate creditors' transition away from using LIBOR as an index for variable-rate consumer credit products. 85 FR 36938 (June 18, 2020).

[354] *See* Fannie Mae & Freddie Mac, *Extended URLA Implementation Timeline* (Apr. 14, 2020), *https://singlefamily.fanniemae.com/media/22661/display.*

[355] 85 FR 67938, 67951 (Oct. 26, 2020).

revised General QM loan definition without prolonging the negative effects of the Temporary GSE QM loan definition.

C. The Final Rule

For the reasons discussed below (and above in response to commenters), this final rule adopts an effective date of March 1, 2021, and a mandatory compliance date of July 1, 2021, resulting in an optional early compliance period between March 1, 2021 and July 1, 2021.[356] This final rule adds new comment 43–2, which explains that, for transactions for which a creditor received the consumer's application on or after March 1, 2021, and prior to July 1, 2021, creditors seeking to originate General QMs have the option of complying with either the current General QM loan definition (*i.e.,* the version in effect on February 26, 2021) or the revised General QM loan definition. This comment also explains that, for transactions for which a creditor received the consumer's application on or after July 1, 2021, creditors seeking to originate General QMs must use the revised General QM loan definition. Comment 43–2 also specifies the meaning of ''application'' for these purposes.

The Bureau also notes that the Temporary GSE QM loan definition will be available for transactions for which the creditor receives the consumer's application before July 1, 2021, unless the applicable GSEs ceases to operate under conservatorship before July 1, 2021.[357] As noted above, the Extension Final Rule amended Regulation Z to replace the January 10, 2021 sunset date of the Temporary GSE QM loan definition with a provision stating that the Temporary GSE QM loan definition will be available only for covered transactions for which the creditor receives the consumer's application before the mandatory compliance date of final amendments to the General QM loan definition in Regulation Z. Under this final rule, which amends the General QM loan definition, that mandatory compliance date is July 1, 2021. The Extension Final Rule did not amend the conservatorship clause in § 1026.43(e)(4)(ii)(A). As a result, the Temporary GSE QM loan definition will be available for transactions for which the creditor receives the consumer's application before July 1, 2021, unless the applicable GSE ceases to operate under conservatorship before July 1, 2021.

Consistent with the practice of other agencies in similar contexts, the revised General QM loan definition will be incorporated into the Code of Federal Regulations on the March 1, 2021 effective date. Comment 43–2 clarifies that for transactions for which the creditor receives the application on or after March 1, 2021, but prior to July 1, 2021, the creditor has the option of complying either with Regulation Z (as interpreted by the commentary) as it is in effect (including the amendments set forth in this final rule) or as it was in effect on February 26, 2021, together with any amendments that become effective other than the amendments set forth in this final rule.[358] The Bureau concludes that this final rule will reduce uncertainty throughout the origination process by linking the effective date and mandatory compliance date to the date the creditor received the consumer's application.

The applicability of this final rule's effective date and mandatory compliance date, as well as compliance with this final rule's revisions to Regulation Z, is determined on a loan-by-loan basis. For example, if a creditor receives an application for a given loan on March 1, 2021 March 1, 2021, and that loan satisfies the current General QM loan definition (including satisfying the 43 percent DTI limit), then the loan is eligible for General QM status—even if the loan does not satisfy the revised General QM loan definition (*e.g.,* exceeds the applicable § 1026.43(e)(2)(vi) pricing threshold). Similarly, if a creditor receives an application for a different loan on March 1, 2021, and that loan satisfies the revised General QM loan definition (including satisfying the applicable § 1026.43(e)(2)(vi) pricing threshold), then the loan is eligible for General QM status—even if the loan does not satisfy the current General QM loan definition (*e.g.,* exceeds the 43 percent DTI limit).

As discussed above, the Bureau concludes that a mandatory compliance date of July 1, 2021, will provide stakeholders with a sufficient amount of time—approximately six months—to prepare to implement the revised General QM loan definition. While the Bureau proposed an effective date that would vary based on the date of publication in the **Federal Register**, the Bureau concludes that using a date certain for the mandatory compliance date (July 1, 2021) will facilitate implementation of this final rule by allowing stakeholders to begin preparing to implement by a particular date (*i.e.,* no later than July 1, 2021) as soon as the Bureau issues this final rule, rather than when the **Federal Register** publishes the final rule some days later.

The Bureau has decided to adopt an optional early compliance period starting on March 1, 2021 (*i.e.,* to allow creditors to begin using the revised General QM loan definition for applications received on or after the March 1, 2021 effective date). In the General QM Proposal, the Bureau stated that it did not intend to issue a final rule early enough for it to take effect before April 1, 2021. With this statement, the Bureau sought to reassure creditors and other market participants that creditors seeking to originate General QMs would not be required to discontinue using the existing General QM loan definition or to implement the revised General QM loan definition before April 1, 2021.[359] In the proposal, the Bureau expected that this would occur on the final rule's effective date, because the proposal did not provide for an optional early compliance period with a separate mandatory compliance date. In contrast, under this final rule, creditors may continue using the existing General QM loan definition or wait to implement the revised General QM loan definition, should they wish to do so, until the rule's mandatory compliance date, which is July 1, 2021. This mandatory compliance date of July 1, 2021 is consistent with the Bureau's expectation, at the proposal stage, that

[356] The Bureau's use of the term ''mandatory compliance date'' does not imply that creditors are required to use the General QM loan definition to comply with the ATR/QM Rule's ability-to-repay requirements. Unless a loan is eligible for QM status—such as under § 1026.43(e)(2), § 1026.43(e)(5) or § 1026.43(f)—a creditor must make a reasonable and good faith determination of the consumer's ability to repay and does not receive a presumption of compliance.

[357] In that case, pursuant to the conservatorship clause, the Temporary GSE QM loan definition would expire with respect to that GSE on the date that GSE ceases to operate under conservatorship.

[358] The Seasoned QM Final Rule, which the Bureau is releasing simultaneously with this final rule, has an effective date of 60 days after publication of the final rule in the **Federal Register**. Unlike this final rule, there is no optional early compliance period for the Seasoned QM Final Rule.

[359] In the Extension Proposal, which the Bureau released concurrently with the General QM Proposal, the Bureau proposed to extend the Temporary GSE QM loan definition until the effective date of a final rule amending the General QM loan definition. *See supra* part III.C. Thus, when the Bureau issued the General QM Proposal, it expected that the Temporary GSE QM loan definition would expire on the effective date of this final rule, along with the current General QM loan definition (unless one or both of the GSEs were to cease to operate under conservatorship prior to the effective date). However, the Extension Final Rule extended the Temporary GSE QM loan definition until the mandatory compliance date, not the effective date, of a final rule amending the General QM loan definition. As a result, the Temporary GSE QM loan definition will be available until the mandatory compliance date of this final rule (July 1, 2021), unless one or both of the GSEs cease to operate under conservatorship prior to July 1, 2021. *See supra* part III.D.

creditors seeking to originate General QMs would not be required to implement the revised General QM loan definition before April 1, 2021 (as creditors have the option of waiting until July 1, 2021).

The Bureau further concludes that the flexibility afforded under the optional early compliance period may help creditors implement the provisions of the final rule more quickly and easily. To the extent that large creditors are more likely to avail themselves of optional early compliance, the Bureau notes that small-to-mid-size correspondent lenders will also benefit, as they often wait for larger wholesale creditors to implement a rule before finalizing their own implementation strategy to ensure their systems are compatible with the wholesale creditors.

New comment 43–2 clarifies that, for transactions subject to TRID, creditors determine the date the creditor received the consumer's application, for purposes of this comment, in accordance with the TRID definition of application in § 1026.2(a)(3)(ii). This new comment also clarifies that, for transactions that are not subject to TRID, creditors can determine the date the creditor received the consumer's application, for purposes of this comment, in accordance with either § 1026.2(a)(3)(i) or (ii).

As discussed in the Extension Final Rule,[360] Regulation Z contains two definitions of ''application.'' Section 1026.2(a)(3)(i) defines ''application'' as the submission of a consumer's financial information for the purposes of obtaining an extension of credit. This definition applies to all transactions covered by Regulation Z. Section 1026.2(a)(3)(ii) also contains a more specific definition of ''application.'' Under this definition, for transactions subject to § 1026.19(e), (f), or (g)—*i.e.,* transactions subject to TRID—an application consists of the submission of the consumer's name, the consumer's income, the consumer's social security number to obtain a credit report, the property address, an estimate of the value of the property, and the mortgage loan amount sought. The more specific definition of application in § 1026.2(a)(3)(ii) applies not just for purposes of TRID, but extends to all transactions subject to TRID. Therefore, for transactions that are subject to the ATR/QM Rule and that are also subject to TRID, the Bureau concludes that the more specific definition applies for purposes of the ATR/QM Rule as well. However, for transactions that are subject to the ATR/QM Rule but that are not subject to TRID, the Bureau finds that there may be ambiguity as to when the creditor received the consumer's application for purposes of the effective date of the revised General QM loan definition, optional compliance provision, and mandatory compliance date.[361] This potential ambiguity arises because the general definition of application in § 1026.2(a)(3)(i) is less precise than the TRID definition.

To address this potential ambiguity, new comment 43–2 clarifies that, for transactions that are not subject to TRID, creditors can determine the date the creditor received the consumer's application, for purposes of this comment, in accordance with either § 1026.2(a)(3)(i) or (ii). The Bureau concludes that this clarification is appropriate because it will facilitate compliance with this final rule by reducing uncertainty throughout the origination process.

VIII. Dodd-Frank Act Section 1022(b) Analysis

A. Overview

As discussed above, this final rule amends the General QM loan definition to, among other things, remove the specific DTI limit and add pricing thresholds. In developing this final rule, the Bureau has considered the potential benefits, costs, and impacts as required by section 1022(b)(2)(A) of the Dodd-Frank Act. Specifically, section 1022(b)(2)(A) of the Dodd-Frank Act requires the Bureau to consider the potential benefits and costs of a regulation to consumers and covered persons, including the potential reduction of access by consumers to consumer financial products or services, the impact on depository institutions and credit unions with $10 billion or less in total assets as described in section 1026 of the Dodd-Frank Act, and the impact on consumers in rural areas. The Bureau consulted with appropriate prudential regulators and other Federal agencies regarding the consistency of this final rule with prudential, market, or systemic objectives administered by such agencies as required by section 1022(b)(2)(B) of the Dodd-Frank Act.

1. Data and Evidence

The discussion in these impact analyses relies on data from a range of sources. These include data collected or developed by the Bureau, including HMDA[362] and NMDB[363] data, as well as data obtained from industry, other regulatory agencies, and other publicly available sources. The Bureau also conducted the Assessment and issued the Assessment Report as required under section 1022(d) of the Dodd-Frank Act. The Assessment Report provides quantitative and qualitative information on questions relevant to this final rule, including the extent to which DTI ratios are probative of a consumer's ability to repay, the effect of rebuttable presumption status relative to safe harbor status on access to credit, and the effect of QM status relative to non-QM status on access to credit. Consultations with other regulatory agencies, industry, and research organizations inform the Bureau's impact analyses.

The data the Bureau relied upon provided detailed information on the number, characteristics, pricing, and performance of mortgage loans originated in recent years. As discussed above, commenters provided some supplemental data and estimates with more information relevant to pricing and APR calculations (particularly PMI costs) for originations before 2018. PMI costs are an important component of APRs, particularly for loans with smaller down payments, and thus should be included or estimated in calculations of rate spreads relative to APOR. The data provided by commenters show a strong positive

[360] 85 FR 67938, 67952 (Oct. 26, 2020).

[361] The ATR/QM Rule generally applies to closed-end consumer credit transactions that are secured by a dwelling, as defined in 12 CFR 1026.2(a)(19), including any real property attached to a dwelling. 12 CFR 1026.43(a). Therefore, the Rule applies to a dwelling, as defined in § 1026.19(a), whether or not it is attached to real property. In contrast, TRID generally applies to closed-end consumer credit transactions secured by real property or a cooperative unit. 12 CFR 1026.19(e)(1)(i). Therefore, some transactions that are a secured by a dwelling that is not considered real property under State or other applicable law will be subject to the ATR/QM Rule but not TRID.

[362] HMDA requires many financial institutions to maintain, report, and publicly disclose loan-level information about mortgages. These data help show whether creditors are serving the housing needs of their communities; they give public officials information that helps them make decisions and policies; and they shed light on lending patterns that could be discriminatory. HMDA was originally enacted by Congress in 1975 and is implemented by Regulation C. *See* Bureau of Consumer Fin. Prot., *Mortgage data (HMDA), https://www.consumerfinance.gov/data-research/hmda/.*

[363] The NMDB, jointly developed by the FHFA and the Bureau, provides de-identified loan characteristics and performance information for a 5 percent sample of all mortgage originations from 1998 to the present, supplemented by de-identified loan and borrower characteristics from Federal administrative sources and credit reporting data. *See* Bureau of Consumer Fin. Prot., *Sources and Uses of Data at the Bureau of Consumer Financial Protection,* at 55–56 (Sept. 2018), *https://www.consumerfinance.gov/documents/6850/bcfp_sources-uses-of-data.pdf.* (Differences in total market size estimates between NMDB data and HMDA data are attributable to differences in coverage and data construction methodology.)

relationship between rate spread over APOR and delinquency rates, similar to the relationship shown in the Bureau's analyses of 2002–2008 data and 2018 data.

The data do not provide information on creditor costs. As a result, analyses of any impacts of this final rule on creditor costs, particularly realized costs of implementing underwriting criteria or potential costs from legal liability, are based on more qualitative information. Similarly, estimates of any changes in burden on consumers resulting from increased or decreased verification requirements are based on qualitative information.

Finally, a group of consumer advocate commenters submitted a joint letter arguing that because the mortgage finance market is in flux, any assumptions made regarding the impact of pricing as an adequate substitute for more direct measures of ability to repay are rendered uncertain by the current economic conditions, and thus the Bureau should refrain from revising the General QM definition. In the proposal, the Bureau acknowledged the importance of economic disruptions and mortgage market changes due to the COVID–19 pandemic. However, the Bureau did not receive data or evidence from commenters that would lead it to anticipate that market changes or other circumstances will significantly alter its estimates of the benefits and costs of this final rule. These commenters also stated that the Bureau must fulfill its statutory obligation ''to study ability-to-repay'' before amending the General QM definition. However, the Bureau has already done so by completing the Assessment Report and through its monitoring of the performance of mortgage loans and the availability of mortgage credit.

Description of the Baseline

The Bureau considers the benefits, costs, and impacts of this final rule against the baseline in which the Bureau takes no action and the Temporary GSE QM loan definition expires when the GSEs cease to operate under conservatorship. Under this final rule, creditors that wish to originate General QMs will be required to comply with the amended General QM loan definition either at the time or after the Temporary GSE QM loan definition expires, depending on whether the GSEs remain in conservatorship on the mandatory compliance date of this final rule. As a result, this final rule's direct market impacts are considered relative to a baseline in which the Temporary GSE QM has expired and no changes have been made to the General QM loan definition. While there is not a fixed date on which the Temporary GSE QM loan definition will expire in the absence of this final rule, the Bureau anticipates that the GSEs will cease to operate under conservatorship in the foreseeable future and the baseline will occur at that time. Unless described otherwise, estimated loan counts under the baseline, final rule, and alternatives are annual estimates.

Under the baseline, conventional loans could receive QM status under the Bureau's rules only by underwriting according to the General QM requirements, Small Creditor QM requirements, Balloon Payment QM requirements, or the expanded portfolio QM amendments created by the 2018 Economic Growth, Regulatory Relief, and Consumer Protection Act. The General QM loan definition, which would be the only type of QM available to larger creditors for conventional loans, requires that consumers' DTI ratio not exceed 43 percent and requires creditors to determine debt and income in accordance with the standards in appendix Q.

The Bureau anticipates that, under the baseline in which the Temporary GSE QM loan definition expires, there are two main types of conventional loans that would be affected: Over-43-Percent-DTI [364] GSE loans and GSE-eligible loans without appendix Q-required documentation. These loans are currently originated as QMs due to the Temporary GSE QM loan definition but would not be originated as General QMs, and may not be originated at all, if the Temporary GSE QM loan definition were to expire without this final rule's amendments to the General QM loan definition. This section 1022 analysis refers to these loans as potentially displaced loans.

The proposal's analysis of the potential market impact of the Temporary GSE QM loan definition's expiration cited data and analysis from the Bureau's ANPR, as described below. None of the comments on the proposal challenged the data or analysis from the ANPR or the proposal related to the potential market impacts of the Temporary GSE QM loan definition's expiration. The Bureau concludes that the data and analysis in the proposal and ANPR provide a well-supported estimate of the potential impact of the Temporary GSE QM loan definition's expiration for this final rule.

Over-43-Percent-DTI GSE Loans. The ANPR provided an estimate of the number of loans potentially affected by the expiration of the Temporary GSE QM loan definition.[365] In providing the estimate, the ANPR focused on loans that fall within the Temporary GSE QM loan definition but not the General QM loan definition because they have DTI ratios above 43 percent. This final rule refers to these loans as Over-43-Percent-DTI GSE loans. Based on NMDB data, the Bureau estimated that there were approximately 6.01 million closed-end first-lien residential mortgage originations in the United States in 2018.[366] Based on supplemental data provided by the FHFA, the Bureau estimated that the GSEs purchased or guaranteed 52 percent—roughly 3.12 million—of those loans.[367] Of those 3.12 million loans, the Bureau estimated that 31 percent—approximately 957,000 loans—had DTI ratios greater than 43 percent.[368] Thus, the Bureau estimated that, as a result of the General QM loan definition's 43 percent DTI limit, approximately 957,000 loans—16 percent of all closed-end first-lien residential mortgage originations in 2018—were Over-43-Percent-DTI GSE loans.[369] This estimate does not include Temporary GSE QMs that were eligible for purchase by the GSEs but were not sold to the GSEs.

Loans Without Appendix Q-Required Documentation That Are Otherwise GSE-Eligible. In addition to Over-43-Percent-DTI GSE loans, the Bureau noted that an additional, smaller number of Temporary GSE QMs with DTI ratios of 43 percent or less, when calculated using GSE underwriting guides, may not fall within the General QM loan definition because their method of verifying income or debt is incompatible with appendix Q.[370] These loans would also likely be affected once the Temporary GSE QM loan definition expires. The Bureau understands, from extensive public feedback and its own experience, that appendix Q does not

[364] The Assessment Report, the ANPR, the Extension Proposal, the General QM Proposal, and the Extension Final Rule used the term ''High-DTI loans'' to refer to loans with DTI ratios over 43 percent. For greater precision and because this final rule is eliminating the 43 percent DTI limit, this final rule instead uses the term ''Over-43-Percent-DTI loans'' to refer to such loans.

[365] 84 FR 37155, 37158–59 (July 31, 2019).

[366] *Id.* at 37158–59.

[367] *Id.* at 37159.

[368] *Id.* The Bureau estimates that 616,000 of these loans were for home purchases, and 341,000 were refinance loans. In addition, the Bureau estimates that the share of these loans with DTI ratios over 45 percent has varied over time due to changes in market conditions and GSE underwriting standards, rising from 47 percent in 2016 to 56 percent in 2017, and further to 69 percent in 2018.

[369] *Id.* at 37159.

[370] *Id.* at 37159 n.58. Where these types of loans have DTI ratios above 43 percent, they would be captured in the estimate above relating to Over-43-Percent-DTI GSE loans.

specifically address whether and how to verify certain forms of income. The Bureau understands these concerns are particularly acute for self-employed consumers, consumers with part-time employment, and consumers with irregular or unusual income streams.[371] As a result, these consumers' access to credit may be affected if the Temporary GSE QM loan definition were to expire without amendments to the General QM loan definition.

The Bureau's analysis of the market under the baseline focuses on Over-43-Percent-DTI GSE loans because the Bureau estimates that most potentially displaced loans are Over-43-Percent-DTI GSE loans. The Bureau also lacks the loan-level documentation and underwriting data necessary to estimate with precision the number of potentially displaced loans that do not fall within the other General QM requirements and are not Over-43-Percent-DTI GSE loans. However, the Assessment did not find evidence of substantial numbers of loans in the non-GSE-eligible jumbo market being displaced when appendix Q verification requirements became effective in 2014.[372] Further, the Assessment Report found evidence of only a limited reduction in the approval rate of self-employed applicants for non-GSE eligible mortgages.[373] Based on this evidence, along with qualitative comparisons of GSE and appendix Q verification requirements and available data on the prevalence of borrowers with non-traditional or difficult-to-document income (*e.g.,* self-employed borrowers, retired borrowers, those with irregular income streams), the Bureau estimates this second category of potentially displaced loans is considerably less numerous than the category of Over-43-Percent-DTI GSE loans.

Additional Effects on Loans Not Displaced. While the most significant market effects under the baseline are displaced loans, loans that continue to be originated as QMs after the expiration of the Temporary GSE QM loan definition would also be affected. After the expiration date, all loans with DTI ratios at or below 43 percent which are or would have been purchased and guaranteed as GSE loans under the Temporary GSE QM loan definition—approximately 2.16 million loans in 2018—and that continue to be originated as General QMs after the provision expires would be required to verify income and debts according to appendix Q, rather than only according to GSE guidelines. Given the concerns raised about appendix Q's ambiguity and lack of flexibility, this would likely entail both increased documentation burden for some consumers as well as increased costs or time-to-origination for creditors on some loans.[374]

B. Benefits and Costs to Covered Persons and Consumers

1. Benefits to Consumers

The primary benefit to consumers of this final rule is increased access to credit, largely through the expanded availability of Over-43-Percent-DTI conventional QMs. Given the large number of consumers who obtain Over-43-Percent-DTI GSE loans rather than available alternatives, including loans from the private non-QM market and FHA loans, such Over-43-Percent-DTI conventional QMs may be preferred due to their pricing, underwriting requirements, or other features. Based on HMDA data, the Bureau estimates that 959,000 Over-43-Percent-DTI conventional loans in 2018 would fall outside the QM definitions under the baseline, but fall within this final rule's amended General QM loan definition.[375] In addition, some consumers who would have been limited in the amount they could borrow due to the DTI limit under the baseline will likely be able to obtain larger mortgages at higher DTI levels.

Under the baseline, a sizeable share of potentially displaced Over-43-Percent-DTI GSE loans may instead be originated as FHA loans. Thus, under this final rule, any price advantage of GSE or other conventional QMs over FHA loans will be a realized benefit to consumers. Based on the Bureau's analysis of 2018 HMDA data, FHA loans comparable to the loans received by Over-43-Percent-DTI GSE borrowers, based on loan purpose, credit score, and combined LTV ratio, on average have $3,000 to $5,000 higher upfront total loan costs at origination. APRs provide an alternative, annualized measure of costs over the life of a loan. FHA borrowers typically pay different APRs, which can be higher or lower than APRs for GSE loans depending on a borrower's credit score and LTV ratio. Borrowers with credit scores at or above 720 pay an APR 30 to 60 basis points higher than borrowers of comparable GSE loans, leading to higher monthly payments over the life of the loan. However, FHA borrowers with credit scores below 680 and combined LTV ratios exceeding 85 percent pay an APR 20 to 40 basis points lower than borrowers of comparable GSE loans, leading to lower monthly payments over the life of the loan.[376] For a loan size of $250,000, these APR differences amount to $2,800 to $5,600 in additional total monthly payments over the first five years of mortgage payments for borrowers with credit scores above 720, and $1,900 to $3,800 in reduced total monthly payments over five years for borrowers with credit scores below 680 and LTV ratios exceeding 85 percent.[377] Thus, all FHA borrowers are likely to pay higher costs at origination, while some pay higher monthly mortgage payments, and others pay lower monthly mortgage payments. Assuming for comparison that all 959,000 additional loans falling within the amended General QM loan definition would be made as FHA loans in the absence of this final rule, the average of the upfront pricing estimates results in total savings for consumers of roughly $4 billion per year on upfront costs.[378] The total savings or costs over the life of the loan based on APR differences

[371] For example, in qualitative responses to the Bureau's Lender Survey conducted as part of the Assessment, underwriting for self-employed borrowers was one of the most frequently reported sources of difficulty in originating mortgages using appendix Q. These concerns were also raised in comments submitted in response to the Assessment RFI, noting that appendix Q is ambiguous with respect to how to treat income for consumers who are self-employed, have irregular income, or want to use asset depletion as income. *See* Assessment Report, *supra* note 63, at 200.

[372] *Id.* at 107 ("For context, total jumbo purchase originations increased from an estimated 108,700 to 130,200 between 2013 and 2014, based on nationally representative NMDB data.").

[373] *Id.* at 118 ("The Application Data indicates that, notwithstanding concerns that have been expressed about the challenge of documenting and verifying income for self-employed borrowers under the General QM standard and the documentation requirements contained in appendix Q to the Rule, approval rates for non-High DTI, non-GSE eligible self-employed borrowers have decreased only slightly, by 2 percentage points . . . .").

[374] *See* part V.B for additional discussion of concerns raised about appendix Q.

[375] This estimate includes only HMDA loans which have a reported DTI and rate spread over APOR, and thus may underestimate the true number of loans gaining QM status under the proposal.

[376] The Bureau expects consumers could continue to obtain FHA loans where such loans were cheaper or preferred for other reasons.

[377] Based on NMDB data, the Bureau estimates that the average loan amount among High-DTI GSE borrowers in 2018 was $250,000. While the time to repayment for mortgages varies with economic conditions, the Bureau estimates that half of mortgages are typically closed or paid off five to seven years into repayment. Payment comparisons based on typical 2018 HMDA APRs for GSE loans, 5 percent for borrowers with credit scores over 720, and 6 percent for borrowers with credit scores below 680 and LTVs exceeding 85 percent.

[378] This approximation assumes $4,000 in savings from total loan costs for all 959,000 consumers. Actual expected savings would vary substantially based on loan and credit characteristics, consumer choices, and market conditions.

would vary substantially across borrowers depending on credit scores, LTV ratios, and length of time holding the mortgage. While this comparison assumed all potentially displaced loans would be made as FHA loans, higher costs (either upfront or in monthly payments) are likely to prevent some borrowers from obtaining loans at all.

In the absence of this final rule, some of these potentially displaced consumers, particularly those with higher credit scores and the resources to make larger down payments, likely would be able to obtain credit in the non-GSE private market at a cost comparable to or slightly higher than the costs for GSE loans, but below the cost of an FHA loan. As a result, the above cost comparisons between GSE and FHA loans provide an estimated upper bound on pricing benefits to consumers of this final rule. However, under the baseline, some potentially displaced consumers may not obtain loans, and thus will experience benefits of credit access under this final rule. As discussed above, the Assessment Report found that the January 2013 Final Rule eliminated between 63 and 70 percent of home purchase loans with DTI ratios above 43 percent that were not Temporary GSE QMs.[379]

This final rule will also benefit those consumers with incomes difficult to verify using appendix Q to obtain General QM status, as this final rule's General QM amendments will no longer require the use of appendix Q for verification of income. Under this final rule—as under the current rule—creditors will be required to verify income and assets in accordance with § 1026.43(c)(4) and debt obligations, alimony, and child support in accordance with § 1026.43(c)(3). This final rule also states that a creditor complies with the General QM requirement to verify income, assets, debt obligations, alimony, and child support if it complies with verification requirements in standards the Bureau specifies. The greater flexibility of verification standards allowed under this final rule is likely to reduce effort and costs for these consumers, and in the most difficult cases in which consumers' documentation cannot satisfy appendix Q, this final rule will allow consumers to obtain General QMs rather than potential FHA or non-QM alternatives. These consumers—likely including self-employed borrowers and those with non-traditional forms of income—will likely benefit from cost savings under this final rule, similar to those for High-DTI consumers discussed above.

Finally, as noted below under ''Costs to consumers,'' the Bureau estimates that 25,000 low-DTI conventional loans which are QM under the baseline will fall outside the amended QM definition under this final rule, due to exceeding the pricing thresholds in § 1026.43(e)(2)(vi). If consumers of such loans are able to obtain non-QM loans with the amended General QM loan definition in place, they will gain the benefit of the ability-to-repay causes of action and defenses against foreclosure. However, some of these consumers may instead obtain FHA loans with QM status.

2. Benefits to Covered Persons

This final rule's primary benefit to covered persons, specifically mortgage creditors, is the expanded profits from originating Over-43-Percent DTI conventional QMs. Under the baseline, creditors would be unable to originate such loans under the Temporary GSE QM loan definition and would instead have to originate loans with comparable DTI ratios as FHA, Small Creditor QM, or non-QM loans, or originate at lower DTI ratios as conventional General QMs. Creditors' current preference for originating large numbers of Over-43-Percent-DTI Temporary GSE QMs likely reflects advantages in a combination of costs or guarantee fees (particularly relative to FHA loans), liquidity (particularly relative to Small Creditor QM), or litigation and credit risk (particularly relative to non-QM loans). Moreover, QMs—including Temporary GSE QMs—are exempt from the Dodd-Frank Act risk retention requirement whereby creditors that securitize mortgage loans are required to retain at least 5 percent of the credit risk of the security, which adds significant cost. As a result, this final rule conveys benefits to mortgage creditors originating Over-43-Percent-DTI conventional QMs on each of these dimensions.

In addition, for those lower-DTI GSE loans that could satisfy General QM requirements, creditors may realize cost savings from underwriting loans using the more flexible verification standards allowed under this final rule compared with using appendix Q. Under this final rule, creditors will be required to consider DTI or residual income in addition to income or assets other than the value of the dwelling and debts but will not need to comply with the appendix Q standards required for General QMs under the baseline. For conventional consumers unable to provide documentation compatible with appendix Q, this final rule allows such loans to continue receiving QM status, providing comparable benefits to creditors as described for Over-43-Percent-DTI GSE loans above.

Finally, creditors with business models that rely most heavily on originating Over-43-Percent-DTI GSE loans will likely see a competitive benefit from the continued ability to originate such loans as General QMs. Under the baseline, creditors that primarily originate FHA or private non-QM loans likely would have gained market share at the expense of creditors originating many Over-43-Percent-DTI GSE loans. The final rule will prevent this shift from occurring, which is effectively a transfer in market share to the creditors originating many Over-43-Percent-DTI GSE loans.

3. Costs to Consumers

As discussed above, relative to the baseline, the Bureau estimates that 959,000 additional Over-43-Percent-DTI loans could be originated as General QMs under this final rule. Some of these loans would have been non-QM loans (if originated) under the baseline. As a result, this final rule is likely to increase the number of consumers who become delinquent on QMs, meaning an increase in consumers with delinquent loans who do not have the benefit of the ability-to-repay causes of action and defenses against foreclosure.

Tables 5 and 6 in part V provide historical early delinquency rates for loans under different combinations of DTI ratio and rate spread. Under this final rule, conventional loans originated with rate spreads below 2.25 percentage points and DTI above 43 percent will newly fall within the amended General QM loan definition relative to the baseline. Based on the number and characteristics of 2018 HMDA originations, the Bureau estimates that between 8,000 and 58,000 additional General QMs annually could become delinquent within two years of origination, based on the observed early delinquencies from Table 6 (2018) and Table 5 (2002–2008), respectively.[380] Further, consumers who would have been limited in the amount they could borrow due to the DTI limit under the baseline may obtain larger mortgages at higher DTI levels, further increasing the expected number of delinquencies. However, given that many of these loans may have been originated as FHA (or other non-General QM) loans under the baseline, the increase in delinquent

[379] *See* Assessment Report *supra* note 63, at 10–11, 117, 131–47.

[380] In the proposal, the Bureau stated that 8,000 to 59,000 additional loans annually would become delinquent within two years of origination under the proposal. The Bureau's has revised its range of estimates under the proposal to 8,000 to 56,000.

loans held by consumers without the ability-to-repay causes of action and defenses against foreclosure is likely smaller than the upper bound estimates cited above.

For the estimated 25,000 consumers obtaining low-DTI General QM or Temporary GSE QMs priced 2.25 percentage points or more above APOR under the baseline, the amended General QM loan definition may restrict access to conventional QM credit. There are several possible outcomes for these consumers. Many may instead obtain FHA loans, likely paying higher total loan costs, as discussed above. Others may be able to obtain General QMs priced below 2.25 percentage points over APOR due to creditor responses to this final rule or obtain loans under the Small Creditor QM definition. However, some consumers may not be able to obtain a mortgage at all.

In addition, this final rule reduces the scope of the non-QM market relative to the baseline, which could slow the development of new non-QM loan products which may have become available under the baseline. To the extent that some consumers would prefer some of these products to conventional QMs due to pricing, verification flexibility, or other advantages, the delay of their development will be a cost to consumers of this final rule.

4. Costs to Covered Persons

For creditors retaining the credit risk of their General QM mortgages (*e.g.,* portfolio loans and private securitizations), an increase in Over-43-Percent-DTI General QM originations may lead to increased risk of credit losses. However, some of this increased risk may be offset by lender pricing responses. Further, on average the effects on portfolio lenders may be small. Creditors that hold loans on portfolio have an incentive to verify ability to repay regardless of liability under the ATR provisions, because they hold the credit risk. While portfolio lenders (or those that manage the portfolios) may recognize and respond to this incentive to different degrees, this final rule is likely on average to cause a small increase in the willingness of these creditors to originate loans with a greater risk of default and credit losses, such as certain loans with high DTI ratios. The credit losses to investors in private securitizations are harder to predict. In general, these losses will depend on the scrutiny that investors are willing and able to give to the non-QM loans under the baseline that become QMs (with high DTI ratios) under this final rule. It is possible, however, that the reduction in liability under the ATR provisions will lead to securitizations with more loans that have a greater risk of default and credit losses.

In addition, creditors will generally no longer be able to originate low-DTI conventional loans priced 2.25 percentage points or higher above APOR as General QMs under this final rule.[381] Creditors may be able to originate some of these loans at prices below 2.25 percentage points above APOR or as non-QM loans or other types of QMs, but in these cases may pay higher costs or receive lower revenues relative to under the baseline. If creditors are unable to originate such loans at all, they will see a larger reduction in revenue.

This final rule also generates what are effectively transfers between creditors relative to the baseline, reflecting reduced loan origination volume for creditors that primarily originate FHA or private non-QM loans and increased origination volume for creditors that primarily originate conventional QMs. Business models vary substantially within market segments, with portfolio lenders and lenders originating non-QM loans most likely to forgo market share gains possible under the baseline, while GSE-focused bank and non-bank creditors are likely to maintain market share that might be lost in the absence of this final rule.

5. Other Benefits and Costs

This final rule may limit the development of the secondary market for non-QM mortgage loan securities. Under the baseline, loans that do not fit within General QM requirements represent a potential new market for non-QM loan securitizations. Thus, this final rule will reduce the scope of the potential non-QM loan market, likely lowering total profits and revenues for participants in the private secondary market. This will effectively be a transfer from these non-QM loan secondary market participants to participants in the agency or other QM secondary markets.

6. Consideration of Alternatives

The Bureau considered potential alternatives to this final rule, including maintaining the General QM loan definition's DTI limit but at a higher level, for example, 45 or 50 percent. The Bureau estimates the effects of such alternatives relative to this final rule, assuming no change in consumer or creditor behavior. For an alternative General QM loan definition with a DTI limit of 45 percent, the Bureau estimates that 673,000 fewer loans would have been General QM due to DTI ratios over 45 percent, while 28,000 additional loans with rate spreads above the final rule's QM pricing thresholds would have newly fit within the General QM loan definition due to DTI ratios at or below 45 percent. For an alternative DTI limit of 50 percent, the Bureau estimates 51,000 fewer loans would have fit within the General QM loan definition due to DTI ratios over 50 percent, while 35,000 additional loans with rate spreads above the final rule's QM pricing thresholds would have newly fit within the General QM loan definition due to DTI ratios at or below 50 percent.

In addition to these effects on the composition of loans within the General QM loan definition, the Bureau uses the historical delinquency rates from Tables 5 and 6 in part V to estimate the number of loans that would have been expected to become delinquent within the General QM loan definition relative to this final rule. The Bureau estimates that under an alternative DTI limit of 45 percent, 4,000 to 37,000 fewer General QMs would have become delinquent relative to this final rule, based on delinquency rates for 2018 and 2002–2008 originations respectively. Under an alternative DTI limit of 50 percent, the Bureau estimates approximately 1,000 additional General QMs would have become delinquent relative to this final rule, due to loans priced 2.25 percentage points or more above APOR gaining QM status.

For an alternative DTI limit of 45 percent, these estimates collectively indicate that substantially fewer loans would have fit within the General QM loan definition relative to this final rule, which would also have reduced the number of General QMs becoming delinquent. By contrast, the estimates indicate that an alternative DTI limit of 50 percent would have led to a comparable number of General QMs relative to this final rule, both overall and among those that would have become delinquent. However, consumer and creditor responses to such alternatives, such as reducing loan amounts to lower DTI ratios, could have increased the number of loans that would have fit within the alternative General QM loan definitions relative to this final rule.

The Bureau considered other potential alternatives to the proposed rule, including imposing a DTI limit only for loans above a certain pricing

[381] The comparable thresholds are 6.5 percentage points over APOR for loans priced under $66,156, 3.5 percentage points over APOR for loans priced under $110,260 but at or above $66,156, and 6.5 percentage points over APOR for loans for manufactured housing priced under $110,260.

threshold, for example a DTI limit of 50 percent for loans with rate spreads at or above 1 percentage point. Such an alternative would have functioned as a hybrid of this final rule and an alternative which maintains a DTI limit at a higher level, 50 percent in the case of this example. As a result, the number of loans fitting within the General QM loan definition would have generally been between the Bureau's estimates for this final rule and its estimates for the corresponding alternative which would have maintained the higher DTI limit. Thus, this hybrid approach would have brought fewer loans within the General QM loan definition compared to this final rule but more loans within the General QM loan definition compared to the alternative DTI limit of 50 percent, both overall and among loans that would have become delinquent.

C. Potential Impact on Depository Institutions and Credit Unions With $10 Billion or Less in Total Assets, as Described in Section 1026

This final rule's expected impact on depository institutions and credit unions that are also creditors making covered loans (depository creditors) with $10 billion or less in total assets is similar to the expected impact on larger depository creditors and on non-depository creditors. As discussed in part VIII.B.4 (Costs to Covered Persons), depository creditors originating portfolio loans may forgo potential market share gains that would occur under the baseline. In addition, depository creditors with $10 billion or less in total assets that originate portfolio loans can originate Over-43-Percent-DTI Small Creditor QMs under the rule. These depository creditors may currently rely less on the Temporary GSE QM loan definition for originating Over-43-Percent-DTI loans. If the expiration of the Temporary GSE QM loan definition in the absence of this final rule would confer a competitive advantage to these small creditors in their origination of Over-43-Percent-DTI loans, this final rule will offset this outcome.

Conversely, those small depository creditors that primarily rely on the GSEs as a secondary market outlet because they do not have the capacity to hold numerous loans on portfolio or the infrastructure or scale to securitize loans may continue to benefit from the ability to make Over-43-Percent-DTI GSE loans as QMs. Under the baseline, these creditors would be limited to originating GSE loans as QMs only with DTI ratios at or below 43 percent under the current General QM loan definition. These creditors may also originate FHA, VA, or USDA loans or non-QM loans for private securitizations, likely at a higher cost relative to originating Temporary GSE QMs. This final rule will allow these creditors to originate more GSE loans under the General QM loan definition and have a lower cost of origination relative to the baseline.[382]

D. Potential Impact on Rural Areas

This final rule's expected impact on rural areas is similar to the expected impact on non-rural areas. Based on 2018 HMDA data, the Bureau estimates that Over-43-Percent-DTI conventional purchase mortgages originated for homes in rural areas are approximately as likely to be reported as initially sold to the GSEs (52.5 percent) as loans in non-rural areas (52 percent).[383] In addition, the Bureau estimates that in 2018, 94.6 percent of conventional purchase loans originated for homes in rural areas would have been QMs under this final rule, similar to the Bureau's estimate for all conventional purchase loans in rural and non-rural areas (96.3 percent).[384]

IX. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, requires each agency to consider the potential impact of its regulations on small entities, including small businesses, small governmental units, and small not-for-profit organizations. The RFA defines a ''small business'' as a business that meets the size standard developed by the Small Business Administration pursuant to the Small Business Act.[385]

The RFA generally requires an agency to conduct an initial regulatory flexibility analysis (IRFA) and a final regulatory flexibility analysis (FRFA) of any rule subject to notice-and-comment rulemaking requirements, unless the agency certifies that the rule would not have a significant economic impact on a substantial number of small entities (SISNOSE).[386] The Bureau also is subject to certain additional procedures under the RFA involving the convening of a panel to consult with small business representatives before proposing a rule for which an IRFA is required.[387]

In the proposal, the Bureau certified that an IRFA was not required because the proposal, if adopted, would not have a SISNOSE. The Bureau did not receive comments on its analysis of the impact of the proposal on small entities. As the below analysis makes clear, relative to the baseline, this final rule has only one sizeable adverse effect. Certain loans with DTI ratios under 43 percent that would otherwise be originated as rebuttable presumption QMs under the baseline will be non-QM loans under this final rule. This final rule will also have a number of more minor effects on small entities which are not quantified in this analysis, including adjustments to the APR calculation used for certain ARMs when determining QM status and amendments to the Rule's requirements to consider and verify income, assets, debt obligations, alimony, and child support. The Bureau expects only small increases or decreases in burden from these more minor effects.

The analysis divides potential originations into different categories and considers whether this final rule has any adverse impact on originations relative to the baseline. Note that under the baseline, the category of Temporary GSE QMs no longer exists. The Bureau has identified five categories of small entities that may be subject to this final rule: Commercial banks, savings institutions and credit unions (NAICS 522110, 522120, and 522130) with assets at or below $600 million; mortgage brokers (NAICS 522310) with average annual receipts at or below $8 million; and mortgage companies (NAICS 522292 and 522298) with average annual receipts at or below $41.5 million. As discussed further below, the Bureau relies primarily on 2018 HMDA data for the analysis.[388]

[382] Alternative approaches, such as retaining a DTI limit of 45 or 50 percent, would have had similar effects of allowing small depository creditors to originate more GSE loans under an expanded General QM loan definition relative to the baseline, while offsetting potential competitive advantages for small depository creditors that originate Small Creditor QMs.

[383] These statistics are estimated based on originations from the first nine months of the year, to allow time for loans to be sold before HMDA reporting deadlines. In addition, a higher share of Over-43-Percent-DTI conventional purchase non-rural loans (33.3 percent) report being sold to other non-GSE purchasers compared to rural loans (22.3 percent).

[384] For alternative approaches, the Bureau estimates 83.3 percent of conventional purchase loans for homes in rural areas would have been QMs under a DTI limit of 45 percent, and 95.1 percent of conventional purchase loans for homes in rural areas would have been QMs under a DTI limit of 50 percent.

[385] 5 U.S.C. 601(3) (the Bureau may establish an alternative definition after consultation with the Small Business Administration and an opportunity for public comment).

[386] 5 U.S.C. 603 through 605.

[387] 5 U.S.C. 609.

[388] Non-depositories are classified as small entities if they had fewer than 5,188 total originations in 2018. The classification for non-depositories is based on the SBA small entity definition for mortgage companies (less than $41.5 million in annual revenues) and an estimate of $8,000 for revenue-per-origination from the Assessment Report, *supra* note 63, at 78. The

Type I: First Liens That Are Not Small Loans, DTI Is Over 43 Percent

Under the baseline, small entities cannot originate Type I loans as safe harbor or rebuttable presumption QMs unless they are also small creditors and comply with the additional requirements of the small creditor QM category. Neither the removal of DTI requirements nor the addition of the pricing conditions has an adverse impact on the ability of small entities to originate these loans.

Type II: First Liens That Are Not Small Loans, DTI Is 43 Percent or Under

Under the baseline, small entities can originate these loans as either safe harbor QMs or rebuttable presumption QMs, depending on pricing. The removal of DTI requirements has no adverse impact on the ability of small entities to originate these loans. The addition of the pricing conditions has no adverse impact on the ability of small creditors to originate these loans as safe harbor QMs: A loan with APR within 1.5 percentage points of APOR that can be originated as a safe harbor QM under the baseline can be originated as a safe harbor QM under the pricing conditions of this final rule. Similarly, the addition of the pricing conditions has no adverse impact on the ability of small creditors to originate rebuttable presumption QMs with APR between 1.5 percentage points and 2.25 percentage points over APOR. The addition of the pricing conditions will, however, prevent small creditors from originating rebuttable presumption QMs with APR 2.25 percentage points or more over APOR. In the SISNOSE analysis below, the Bureau conservatively assumes that none of these loans will be originated.

Type III: First-Liens That Are Small Loans

Under the baseline, small entities can originate these loans as General QMs if they have DTI ratios at or below the DTI limit of 43 percent. This final rule's amended General QM loan definition preserves QM status for some smaller, low-DTI loans priced 2.25 percentage points or more over APOR. Specifically, loans under $66,156 with APR less than 6.5 percentage points over APOR and loans under $110,260 with APR less than 3.5 percentage points over APOR can be originated as General QMs, assuming they meet all other General QM requirements.[389] This final rule will prevent small creditors from originating smaller, low-DTI loans with APR at or above these higher thresholds as General QMs. For the SISNOSE analysis below, the Bureau conservatively assumes that none of these loans will be originated.

Type IV: Closed-End Subordinate-Liens

Under the baseline, small entities can originate these loans as General QMs if they have DTI ratios at or below the DTI limit of 43 percent. This final rule's amended General QM loan definition creates new pricing thresholds for subordinate-lien originations. Subordinate-lien loans under $66,156 with APR less than 6.5 percentage points over APOR and larger subordinate-lien loans with APR less than 3.5 percentage points over APOR can be originated as General QMs, assuming they meet all other General QM requirements. The final rule will prevent small creditors from originating low-DTI, subordinate-lien loans with APR at or above these thresholds as General QMs. For the SISNOSE analysis below, the Bureau conservatively assumes that none of these loans will be originated.

Analysis

For purposes of this analysis, the Bureau assumes that average annual receipts for small entities is proportional to mortgage loan origination volume. The Bureau further assumes that a small entity experiences a significant negative effect from this final rule if it will cause a reduction in origination volume of over 2 percent. Using the 2018 HMDA data, the Bureau estimates that if none of the Type II, III, or IV loans adversely affected were originated, 97 small entities would experience a loss of over 2 percent in mortgage loan origination volume. Thus, there are at most 97 small entities that experience a significant adverse economic impact. The Bureau estimates that there are 2,027 small entities in the HMDA data. Ninety-seven is not a substantial number relative to 2,027.

The Bureau recognizes that there are small entities that originate mortgage credit that do not report HMDA data. The Bureau has no reason to expect, however, that small entities that originate mortgage credit that do not report HMDA data would be affected differently than small HMDA reporters by the final rule. In other words, the Bureau expects that including HMDA non-reporters in the analysis would increase the number of small entities that will experience a loss of over 2 percent in mortgage loan origination volume and the number of relevant small entities by the same proportion. Thus, the overall number of small entities that will experience a significant adverse economic impact will not be a substantial number of the overall number of small entities that originate mortgage credit.

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

X. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA),[390] Federal agencies are generally required to seek, prior to implementation, approval from the Office of Management and Budget (OMB) for information collection requirements. Under the PRA, the Bureau may not conduct or sponsor, and, notwithstanding any other provision of law, a person is not required to respond to, an information collection unless the information collection displays a valid control number assigned by OMB.

The Bureau has determined that this final rule does not contain any new or substantively revised information collection requirements other than those previously approved by OMB under OMB control number 3170–0015. This final rule amends 12 CFR part 1026 (Regulation Z), which implements TILA. OMB control number 3170–0015 is the Bureau's OMB control number for Regulation Z.

XI. Congressional Review Act

Pursuant to the Congressional Review Act,[391] the Bureau will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States at least 60 days prior to the rule's published effective date. The Office of Information and Regulatory Affairs has designated this rule as a ''major rule'' as defined by 5 U.S.C. 804(2).

XII. Signing Authority

The Director of the Bureau, Kathleen L. Kraninger, having reviewed and approved this document, is delegating the authority to electronically sign this document to Grace Feola, a Bureau Federal Register Liaison, for purposes of publication in the **Federal Register**.

HMDA data do not directly distinguish mortgage brokers from mortgage companies, so the more inclusive revenue threshold is used.

[389] In addition, all loans for manufactured housing under $110,260 with APR less than 6.5 percentage points over APOR can be originated as General QMs, assuming they meet all other General QM requirements.

[390] 44 U.S.C. 3501 *et seq.*

[391] 5 U.S.C. 801 *et seq.*

List of Subjects in 12 CFR Part 1026

Advertising, Banks, Banking, Consumer protection, Credit, Credit unions, Mortgages, National banks, Reporting and recordkeeping requirements, Savings associations, Truth-in-lending.

Authority and Issuance

For the reasons set forth above, the Bureau amends Regulation Z, 12 CFR part 1026, as set forth below:

PART 1026—TRUTH IN LENDING (REGULATION Z)

■ 1. The authority citation for part 1026 continues to read as follows:

Authority: 12 U.S.C. 2601, 2603–2605, 2607, 2609, 2617, 3353, 5511, 5512, 5532, 5581; 15 U.S.C. 1601 *et seq.*

Subpart E—Special Rules for Certain Home Mortgage Transactions

■ 2. Amend § 1026.43 by revising paragraphs (b)(4), (e)(2)(v) and (vi), (e)(4), (e)(5)(i)(A) and (B), and (f)(1)(i) and (iii) to read as follows:

§ 1026.43 Minimum standards for transactions secured by a dwelling.

* * * * *

(b) * * *

(4) *Higher-priced covered transaction* means a covered transaction with an annual percentage rate that exceeds the average prime offer rate for a comparable transaction as of the date the interest rate is set by 1.5 or more percentage points for a first-lien covered transaction, other than a qualified mortgage under paragraph (e)(5), (e)(6), or (f) of this section; by 3.5 or more percentage points for a first-lien covered transaction that is a qualified mortgage under paragraph (e)(5), (e)(6), or (f) of this section; or by 3.5 or more percentage points for a subordinate-lien covered transaction. For purposes of a qualified mortgage under paragraph (e)(2) of this section, for a loan for which the interest rate may or will change within the first five years after the date on which the first regular periodic payment will be due, the creditor must determine the annual percentage rate for purposes of this paragraph (b)(4) by treating the maximum interest rate that may apply during that five-year period as the interest rate for the full term of the loan.

* * * * *

(e) * * *

(2) * * *

(v) For which the creditor, at or before consummation:

(A) Considers the consumer's current or reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan, debt obligations, alimony, child support, and monthly debt-to-income ratio or residual income, using the amounts determined from paragraph (e)(2)(v)(B) of this section. For purposes of this paragraph (e)(2)(v)(A), the consumer's monthly debt-to-income ratio or residual income is determined in accordance with paragraph (c)(7) of this section, except that the consumer's monthly payment on the covered transaction, including the monthly payment for mortgage-related obligations, is calculated in accordance with paragraph (e)(2)(iv) of this section.

(B)(*1*) Verifies the consumer's current or reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan using third-party records that provide reasonably reliable evidence of the consumer's income or assets, in accordance with paragraph (c)(4) of this section; and

(*2*) Verifies the consumer's current debt obligations, alimony, and child support using reasonably reliable third-party records in accordance with paragraph (c)(3) of this section.

(vi) For which the annual percentage rate does not exceed the average prime offer rate for a comparable transaction as of the date the interest rate is set by the amounts specified in paragraphs (e)(2)(vi)(A) through (F) of this section. The amounts specified here shall be adjusted annually on January 1 by the annual percentage change in the Consumer Price Index for All Urban Consumers (CPI–U) that was reported on the preceding June 1. For purposes of this paragraph (e)(2)(vi), the creditor must determine the annual percentage rate for a loan for which the interest rate may or will change within the first five years after the date on which the first regular periodic payment will be due by treating the maximum interest rate that may apply during that five-year period as the interest rate for the full term of the loan.

(A) For a first-lien covered transaction with a loan amount greater than or equal to $110,260 (indexed for inflation), 2.25 or more percentage points;

(B) For a first-lien covered transaction with a loan amount greater than or equal to $66,156 (indexed for inflation) but less than $110,260 (indexed for inflation), 3.5 or more percentage points;

(C) For a first-lien covered transaction with a loan amount less than $66,156 (indexed for inflation), 6.5 or more percentage points;

(D) For a first-lien covered transaction secured by a manufactured home with a loan amount less than $110,260 (indexed for inflation), 6.5 or more percentage points;

(E) For a subordinate-lien covered transaction with a loan amount greater than or equal to $66,156 (indexed for inflation), 3.5 or more percentage points;

(F) For a subordinate-lien covered transaction with a loan amount less than $66,156 (indexed for inflation), 6.5 or more percentage points.

* * * * *

(4) *Qualified mortgage defined—other agencies.* Notwithstanding paragraph (e)(2) of this section, a qualified mortgage is a covered transaction that is defined as a qualified mortgage by the U.S. Department of Housing and Urban Development under 24 CFR 201.7 and 24 CFR 203.19, the U.S. Department of Veterans Affairs under 38 CFR 36.4300 and 38 CFR 36.4500, or the U.S. Department of Agriculture under 7 CFR 3555.109.

(5) * * *

(i) * * *

(A) That satisfies the requirements of paragraph (e)(2) of this section other than the requirements of paragraphs (e)(2)(v) and (vi) of this section;

(B) For which the creditor:

(*1*) Considers and verifies at or before consummation the consumer's current or reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan, in accordance with paragraphs (c)(2)(i) and (c)(4) of this section;

(*2*) Considers and verifies at or before consummation the consumer's current debt obligations, alimony, and child support in accordance with paragraphs (c)(2)(vi) and (c)(3) of this section;

(*3*) Considers at or before consummation the consumer's monthly debt-to-income ratio or residual income and verifies the debt obligations and income used to determine that ratio in accordance with paragraph (c)(7) of this section, except that the calculation of the payment on the covered transaction for purposes of determining the consumer's total monthly debt obligations in paragraph (c)(7)(i)(A) shall be determined in accordance with paragraph (e)(2)(iv) of this section instead of paragraph (c)(5) of this section;

* * * * *

(f) * * *

(1) * * *

(i) The loan satisfies the requirements for a qualified mortgage in paragraphs

(e)(2)(i)(A) and (e)(2)(ii) and (iii) of this section;

* * * * *

(iii) The creditor:

(A) Considers and verifies at or before consummation the consumer's current or reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan, in accordance with paragraphs (c)(2)(i) and (c)(4) of this section;

(B) Considers and verifies at or before consummation the consumer's current debt obligations, alimony, and child support in accordance with paragraphs (c)(2)(vi) and (c)(3) of this section;

(C) Considers at or before consummation the consumer's monthly debt-to-income ratio or residual income and verifies the debt obligations and income used to determine that ratio in accordance with paragraph (c)(7) of this section, except that the calculation of the payment on the covered transaction for purposes of determining the consumer's total monthly debt obligations in (c)(7)(i)(A) shall be determined in accordance with paragraph (f)(1)(iv)(A) of this section, together with the consumer's monthly payments for all mortgage-related obligations and excluding the balloon payment;

* * * * *

Appendix Q to Part 1026 [Removed]

■ 3. Remove appendix Q to part 1026.

■ 4. In supplement I to part 1026, under *Section 1026.43—Minimum Standards for Transactions Secured by a Dwelling:*

■ a. Under introductory paragraph 1, add introductory paragraph 2;

■ b. Revise sections *43(b)(4) Higher-priced covered transaction, 43(c)(4) Verification of income or assets,* and *43(c)(7) Monthly debt-to-income ratio or residual income;*

■ c. Revise *Paragraph 43(e)(2)(v);*

■ d. Add *Paragraphs 43(e)(2)(v)(A) and 43(e)(2)(v)(B)* after *Paragraph 43(e)(2)(v);*

■ e. Revise *Paragraph 43(e)(2)(vi);*

■ f. Revise section *43(e)(4);* and

■ g. Revise *Paragraph 43(e)(5)* and *Paragraphs 43(f)(1)(i), 43(f)(1)(ii), 43(f)(1)(iii), 43(f)(1)(iv), 43(f)(1)(v),* and *43(f)(1)(vi),.*

The additions and revisions read as follows:

Supplement I to Part 1026—Official Interpretations

* * * * *

Section 1026.43—Minimum Standards for Transactions Secured by a Dwelling

* * * * *

2. *General QM Amendments Effective on March 1, 2021.* The Bureau's revisions to Regulation Z contained in Qualified Mortgage Definition Under the Truth in Lending Act (Regulation Z): General QM Loan Definition published on December 29, 2020 (2021 General QM Amendments) apply with respect to transactions for which a creditor received an application on or after March 1, 2021 (effective date). Compliance with the 2021 General QM Amendments is mandatory with respect to transactions for which a creditor received an application on or after July 1, 2021 (mandatory compliance date). For a given transaction for which a creditor received an application on or after March 1, 2021 but prior to July 1, 2021, a person has the option of complying either: With 12 CFR part 1026 as it is in effect; or with 12 CFR part 1026 as it was in effect on February 26, 2021, together with any amendments to 12 CFR part 1026 that become effective after February 26, 2021, other than the 2021 General QM Amendments. For transactions subject to § 1026.19(e), (f), or (g), creditors determine the date the creditor received the consumer's application, for purposes of this comment, in accordance with § 1026.2(a)(3)(ii). For transactions that are not subject to § 1026.19(e), (f), or (g), creditors can determine the date the creditor received the consumer's application, for purposes of this comment, in accordance with either § 1026.2(a)(3)(i) or (ii).

* * * * *

43(b)(4) Higher-Priced Covered Transaction

1. *Average prime offer rate.* The average prime offer rate is defined in § 1026.35(a)(2). For further explanation of the meaning of ''average prime offer rate,'' and additional guidance on determining the average prime offer rate, *see* comments 35(a)(2)–1 through –4.

2. *Comparable transaction.* A higher-priced covered transaction is a consumer credit transaction that is secured by the consumer's dwelling with an annual percentage rate that exceeds by the specified amount the average prime offer rate for a comparable transaction as of the date the interest rate is set. The published tables of average prime offer rates indicate how to identify a comparable transaction. *See* comment 35(a)(2)–2.

3. *Rate set.* A transaction's annual percentage rate is compared to the average prime offer rate as of the date the transaction's interest rate is set (or ''locked'') before consummation. Sometimes a creditor sets the interest rate initially and then re-sets it at a different level before consummation. The creditor should use the last date the interest rate is set before consummation.

4. *Determining the annual percentage rate for certain loans for which the interest rate may or will change.* Provisions in subpart C of this part, including the commentary to § 1026.17(c)(1), address how to determine the annual percentage rate disclosures for closed-end credit transactions. Provisions in § 1026.32(a)(3) address how to determine the annual percentage rate to determine coverage under § 1026.32(a)(1)(i). Section 1026.43(b)(4) requires, only for the purposes of a qualified mortgage under § 1026.43(e)(2), a different determination of the annual percentage rate for purposes of § 1026.43(b)(4) for a loan for which the interest rate may or will change within the first five years after the date on which the first regular periodic payment will be due. *See* comment 43(e)(2)(vi)–4 for how to determine the annual percentage rate of such a loan.

* * * * *

43(c)(4) Verification of Income or Assets

1. *Income or assets relied on.* A creditor need consider, and therefore need verify, only the income or assets the creditor relies on to evaluate the consumer's repayment ability. *See* comment 43(c)(2)(i)–2. For example, if a consumer's application states that the consumer earns a salary and is paid an annual bonus and the creditor relies on only the consumer's salary to evaluate the consumer's repayment ability, the creditor need verify only the salary. *See also* comments 43(c)(3)–1 and –2.

2. *Multiple applicants.* If multiple consumers jointly apply for a loan and each lists income or assets on the application, the creditor need verify only the income or assets the creditor relies on in determining repayment ability. *See* comment 43(c)(2)(i)–5.

3. *Tax-return transcript.* Under § 1026.43(c)(4), a creditor may verify a consumer's income using an Internal Revenue Service (IRS) tax-return transcript, which summarizes the information in a consumer's filed tax return, another record that provides reasonably reliable evidence of the consumer's income, or both. A creditor may obtain a copy of a tax-return transcript or a filed tax return directly from the consumer or from a service provider. A creditor need not obtain the copy directly from the IRS or other taxing authority. *See* comment 43(c)(3)–2.

4. *Unidentified funds.* A creditor does not meet the requirements of § 1026.43(c)(4) if it observes an inflow of funds into the consumer's account without confirming that the funds are income. For example, a creditor would not meet the requirements of § 1026.43(c)(4) where it observes an unidentified $5,000 deposit in the consumer's account but fails to take any measures to confirm or lacks any basis to conclude that the deposit represents the consumer's personal income and not, for example, proceeds from the disbursement of a loan.

* * * * *

43(c)(7) Monthly Debt-to-Income Ratio or Residual Income

1. *Monthly debt-to-income ratio or monthly residual income.* Under § 1026.43(c)(2)(vii), the creditor must consider the consumer's monthly debt-to-income ratio, or the consumer's monthly residual income, in accordance with the requirements in § 1026.43(c)(7). Section 1026.43(c) does not prescribe a specific monthly debt-to-income ratio with which creditors must comply. Instead, an appropriate threshold for a consumer's monthly debt-to-income ratio or monthly residual income is for the creditor to determine in making a reasonable and

good faith determination of a consumer's ability to repay.

2. *Use of both monthly debt-to-income ratio and monthly residual income.* If a creditor considers the consumer's monthly debt-to-income ratio, the creditor may also consider the consumer's residual income as further validation of the assessment made using the consumer's monthly debt-to-income ratio.

3. *Compensating factors.* The creditor may consider factors in addition to the monthly debt-to-income ratio or residual income in assessing a consumer's repayment ability. For example, the creditor may reasonably and in good faith determine that a consumer has the ability to repay despite a higher debt-to-income ratio or lower residual income in light of the consumer's assets other than the dwelling, including any real property attached to the dwelling, securing the covered transaction, such as a savings account. The creditor may also reasonably and in good faith determine that a consumer has the ability to repay despite a higher debt-to-income ratio in light of the consumer's residual income.

* * * * *

Paragraph 43(e)(2)(v)

1. *General.* For guidance on satisfying § 1026.43(e)(2)(v), a creditor may rely on commentary to § 1026.43(c)(2)(i) and (vi), (c)(3), and (c)(4).

Paragraph 43(e)(2)(v)(A)

Consider. In order to comply with the requirement to consider under § 1026.43(e)(2)(v)(A), a creditor must take into account current or reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan, debt obligations, alimony, child support, and monthly debt-to-income ratio or residual income in its ability-to-repay determination. A creditor must maintain written policies and procedures for how it takes into account, pursuant to its underwriting standards, income or assets, debt obligations, alimony, child support, and monthly debt-to-income ratio or residual income in its ability-to-repay determination. A creditor must also retain documentation showing how it took into account income or assets, debt obligations, alimony, child support, and monthly debt-to-income ratio or residual income in its ability-to-repay determination, including how it applied its policies and procedures, in order to meet this requirement to consider and thereby meet the requirements for a qualified mortgage under § 1026.43(e)(2). This documentation may include, for example, an underwriter worksheet or a final automated underwriting system certification, in combination with the creditor's applicable underwriting standards and any applicable exceptions described in its policies and procedures, that shows how these required factors were taken into account in the creditor's ability-to-repay determination.

2. *Requirement to consider monthly debt-to-income ratio or residual income.* Section 1026.43(e)(2)(v)(A) does not prescribe specifically how a creditor must consider monthly debt-to-income ratio or residual income. Section 1026.43(e)(2)(v)(A) also does not prescribe a particular monthly debt-to-income ratio or residual income threshold with which a creditor must comply. A creditor may, for example, consider monthly debt-to-income ratio or residual income by establishing monthly debt-to-income or residual income thresholds for its own underwriting standards and documenting how it applied those thresholds to determine the consumer's ability to repay. A creditor may also consider these factors by establishing monthly debt-to-income or residual income thresholds and exceptions to those thresholds based on other compensating factors, and documenting application of the thresholds along with any applicable exceptions.

3. *Flexibility to consider additional factors related to a consumer's ability to repay.* The requirement to consider income or assets, debt obligations, alimony, child support, and monthly debt-to-income ratio or residual income does not preclude the creditor from taking into account additional factors that are relevant in determining a consumer's ability to repay the loan. For guidance on considering additional factors in determining the consumer's ability to repay, see comment 43(c)(7)–3.

Paragraph 43(e)(2)(v)(B)

1. *Verification of income, assets, debt obligations, alimony, and child support.* Section 1026.43(e)(2)(v)(B) does not prescribe specific methods of underwriting that creditors must use. Section 1026.43(e)(2)(v)(B)(*1*) requires a creditor to verify the consumer's current or reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan in accordance with § 1026.43(c)(4), which states that a creditor must verify such amounts using third-party records that provide reasonably reliable evidence of the consumer's income or assets. Section 1026.43(e)(2)(v)(B)(*2*) requires a creditor to verify the consumer's current debt obligations, alimony, and child support in accordance with § 1026.43(c)(3), which states that a creditor must verify such amounts using reasonably reliable third-party records. So long as a creditor complies with the provisions of § 1026.43(c)(3) with respect to debt obligations, alimony, and child support and § 1026.43(c)(4) with respect to income and assets, the creditor is permitted to use any reasonable verification methods and criteria.

2. *Classifying and counting income, assets, debt obligations, alimony, and child support.* ''Current and reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan'' is determined in accordance with § 1026.43(c)(2)(i) and its commentary. ''Current debt obligations, alimony, and child support'' has the same meaning as under § 1026.43(c)(2)(vi) and its commentary. Section 1026.43(c)(2)(i) and (vi) and the associated commentary apply to a creditor's determination with respect to what inflows and property it may classify and count as income or assets and what obligations it must classify and count as debt obligations, alimony, and child support, pursuant to its compliance with § 1026.43(e)(2)(v)(B).

3. *Safe harbor for compliance with specified external standards.*

i. Meeting the standards in the following manuals for verifying current or reasonably expected income or assets using third-party records provides a creditor with reasonably reliable evidence of the consumer's income or assets. Meeting the standards in the following manuals for verifying current debt obligations, alimony, and child support using third-party records provides a creditor with reasonably reliable evidence of the consumer's debt obligations, alimony, and child support obligations. Accordingly, a creditor complies with § 1026.43(e)(2)(v)(B) if it complies with verification standards in one or more of the following manuals:

A. Chapters B3–3 through B3–6 of the Fannie Mae Single Family Selling Guide, published June 3, 2020;

B. Sections 5102 through 5500 of the Freddie Mac Single-Family Seller/Servicer Guide, published June 10, 2020;

C. Sections II.A.1 and II.A.4–5 of the Federal Housing Administration's Single Family Housing Policy Handbook, issued October 24, 2019;

D. Chapter 4 of the U.S. Department of Veterans Affairs' Lenders Handbook, revised February 22, 2019;

E. Chapter 4 of the U.S. Department of Agriculture's Field Office Handbook for the Direct Single Family Housing Program, revised March 15, 2019; and

F. Chapters 9 through 11 of the U.S. Department of Agriculture's Handbook for the Single Family Guaranteed Loan Program, revised March 19, 2020.

ii. *Applicable provisions in manuals.* A creditor complies with § 1026.43(e)(2)(v)(B) if it complies with requirements in the manuals listed in comment 43(e)(2)(v)(B)–3 for creditors to verify income, assets, debt obligations, alimony and child support using specified reasonably reliable third-party documents or to include or exclude particular inflows, property, and obligations as income, assets, debt obligations, alimony, and child support.

iii. *Inapplicable provisions in manuals.* For purposes of compliance with § 1026.43(e)(2)(v)(B), a creditor need not comply with requirements in the manuals listed in comment 43(e)(2)(v)(B)–3 other than those that require creditors to verify income, assets, debt obligations, alimony and child support using specified documents or to classify and count particular inflows, property, and obligations as income, assets, debt obligations, alimony, and child support.

iv. *Revised versions of manuals.* A creditor also complies with § 1026.43(e)(2)(v)(B) where it complies with revised versions of the manuals listed in comment 43(e)(2)(v)(B)–3.i, provided that the two versions are substantially similar.

v. *Use of standards from more than one manual.* A creditor complies with § 1026.43(e)(2)(v)(B) if it complies with the verification standards in one or more of the manuals specified in comment 43(e)(2)(v)(B)–3.i. Accordingly, a creditor may, but need

not, comply with § 1026.43(e)(2)(v)(B) by complying with the verification standards from more than one manual (in other words, by ''mixing and matching'' verification standards).

Paragraph 43(e)(2)(vi)

1. *Determining the average prime offer rate for a comparable transaction as of the date the interest rate is set.* For guidance on determining the average prime offer rate for a comparable transaction as of the date the interest rate is set, see comments 43(b)(4)–1 through –3.

2. *Determination of applicable threshold.* A creditor must determine the applicable threshold by determining which category the loan falls into based on the face amount of the note (the ''loan amount'' as defined in § 1026.43(b)(5)). For example, for a first-lien covered transaction with a loan amount of $75,000, the loan would fall into the tier for loans greater than or equal to $66,156 (indexed for inflation) but less than $110,260 (indexed for inflation), for which the applicable threshold is 3.5 or more percentage points.

3. *Annual adjustment for inflation.* The dollar amounts in § 1026.43(e)(2)(vi) will be adjusted annually on January 1 by the annual percentage change in the CPI–U that was in effect on the preceding June 1. The Bureau will publish adjustments after the June figures become available each year.

4. *Determining the annual percentage rate for certain loans for which the interest rate may or will change.*

i. *In general.* The commentary to § 1026.17(c)(1) and other provisions in subpart C address how to determine the annual percentage rate disclosures for closed-end credit transactions. Provisions in § 1026.32(a)(3) address how to determine the annual percentage rate to determine coverage under § 1026.32(a)(1)(i). Section 1026.43(e)(2)(vi) requires, for the purposes of § 1026.43(e)(2)(vi), a different determination of the annual percentage rate for a qualified mortgage under § 1026.43(e)(2) for which the interest rate may or will change within the first five years after the date on which the first regular periodic payment will be due. An identical special rule for determining the annual percentage rate for such a loan also applies for purposes of § 1026.43(b)(4).

ii. *Loans for which the interest rate may or will change.* Section 1026.43(e)(2)(vi) includes a special rule for determining the annual percentage rate for a loan for which the interest rate may or will change within the first five years after the date on which the first regular periodic payment will be due. This rule applies to adjustable-rate mortgages that have a fixed-rate period of five years or less and to step-rate mortgages for which the interest rate changes within that five-year period.

iii. *Maximum interest rate during the first five years.* For a loan for which the interest rate may or will change within the first five years after the date on which the first regular periodic payment will be due, a creditor must treat the maximum interest rate that could apply at any time during that five-year period as the interest rate for the full term of the loan to determine the annual percentage rate for purposes of § 1026.43(e)(2)(vi), regardless of whether the maximum interest rate is reached at the first or subsequent adjustment during the five-year period. For additional instruction on how to determine the maximum interest rate during the first five years after the date on which the first regular periodic payment will be due, *see* comments 43(e)(2)(iv)–3 and –4.

iv. *Treatment of the maximum interest rate in determining the annual percentage rate.* For a loan for which the interest rate may or will change within the first five years after the date on which the first regular periodic payment will be due, the creditor must determine the annual percentage rate for purposes of § 1026.43(e)(2)(vi) by treating the maximum interest rate that may apply within the first five years as the interest rate for the full term of the loan. For example, assume an adjustable-rate mortgage with a loan term of 30 years and an initial discounted rate of 5.0 percent that is fixed for the first three years. Assume that the maximum interest rate during the first five years after the date on which the first regular periodic payment will be due is 7.0 percent. Pursuant to § 1026.43(e)(2)(vi), the creditor must determine the annual percentage rate based on an interest rate of 7.0 percent applied for the full 30-year loan term.

5. *Meaning of a manufactured home.* For purposes of § 1026.43(e)(2)(vi)(D), manufactured home means any residential structure as defined under regulations of the U.S. Department of Housing and Urban Development (HUD) establishing manufactured home construction and safety standards (24 CFR 3280.2). Modular or other factory-built homes that do not meet the HUD code standards are not manufactured homes for purposes of § 1026.43(e)(2)(vi)(D).

6. *Scope of threshold for transactions secured by a manufactured home.* The threshold in § 1026.43(e)(2)(vi)(D) applies to first-lien covered transactions less than $110,260 (indexed for inflation) that are secured by a manufactured home and land, or by a manufactured home only.

* * * * *

43(e)(4) Qualified Mortgage Defined—Other Agencies

1. *General.* The Department of Housing and Urban Development, Department of Veterans Affairs, and the Department of Agriculture have promulgated definitions for qualified mortgages under mortgage programs they insure, guarantee, or provide under applicable law. Cross-references to those definitions are listed in § 1026.43(e)(4) to acknowledge the covered transactions covered by those definitions are qualified mortgages for purposes of this section.

2. *Mortgages for which the creditor received the consumer's application prior to July 1, 2021.* Covered transactions that met the requirements of § 1026.43(e)(2)(i) thorough (iii), were eligible for purchase or guarantee by the Federal National Mortgage Association (Fannie Mae) or the Federal Home Loan Mortgage Corporation (Freddie Mac) (or any limited-life regulatory entity succeeding the charter of either) operating under the conservatorship or receivership of the Federal Housing Finance Agency pursuant to section 1367 of the Federal Housing Enterprises Financial Safety and Soundness Act of 1992 (12 U.S.C. 4617), and for which the creditor received the consumer's application prior to the mandatory compliance date of July 1, 2021 continue to be qualified mortgages for the purposes of this section, including those covered transactions that were consummated on or after July 1, 2021.

3. *Mortgages for which the creditor received the consumer's application on or after March 1, 2021 and prior to July 1, 2021.* For a discussion of the optional early compliance period for the 2021 General QM Amendments, please see comment 43–2.

4. [Reserved].

5. [Reserved].

* * * * *

Paragraph 43(e)(5)

1. *Satisfaction of qualified mortgage requirements.* For a covered transaction to be a qualified mortgage under § 1026.43(e)(5), the mortgage must satisfy the requirements for a qualified mortgage under § 1026.43(e)(2), other than the requirements in § 1026.43(e)(2)(v) and (vi). For example, a qualified mortgage under § 1026.43(e)(5) may not have a loan term in excess of 30 years because longer terms are prohibited for qualified mortgages under § 1026.43(e)(2)(ii). Similarly, a qualified mortgage under § 1026.43(e)(5) may not result in a balloon payment because § 1026.43(e)(2)(i)(C) provides that qualified mortgages may not have balloon payments except as provided under § 1026.43(f). However, a covered transaction need not comply with § 1026.43(e)(2)(v) and (vi).

2. *Debt-to-income ratio or residual income.* Section 1026.43(e)(5) does not prescribe a specific monthly debt-to-income ratio with which creditors must comply. Instead, creditors must consider a consumer's debt-to-income ratio or residual income calculated generally in accordance with § 1026.43(c)(7) and verify the information used to calculate the debt-to-income ratio or residual income in accordance with § 1026.43(c)(3) and (4). However, § 1026.43(c)(7) refers creditors to § 1026.43(c)(5) for instructions on calculating the payment on the covered transaction. Section 1026.43(c)(5) requires creditors to calculate the payment differently than § 1026.43(e)(2)(iv). For purposes of the qualified mortgage definition in § 1026.43(e)(5), creditors must base their calculation of the consumer's debt-to-income ratio or residual income on the payment on the covered transaction calculated according to § 1026.43(e)(2)(iv) instead of according to § 1026.43(c)(5).

3. *Forward commitments.* A creditor may make a mortgage loan that will be transferred or sold to a purchaser pursuant to an agreement that has been entered into at or before the time the transaction is consummated. Such an agreement is sometimes known as a ''forward commitment.'' A mortgage that will be acquired by a purchaser pursuant to a forward commitment does not satisfy the requirements of § 1026.43(e)(5), whether the forward commitment provides for the purchase and sale of the specific transaction

or for the purchase and sale of transactions with certain prescribed criteria that the transaction meets. However, a forward commitment to another person that also meets the requirements of § 1026.43(e)(5)(i)(D) is permitted. For example, assume a creditor that is eligible to make qualified mortgages under § 1026.43(e)(5) makes a mortgage. If that mortgage meets the purchase criteria of an investor with which the creditor has an agreement to sell loans after consummation, then the loan does not meet the definition of a qualified mortgage under § 1026.43(e)(5). However, if the investor meets the requirements of § 1026.43(e)(5)(i)(D), the mortgage will be a qualified mortgage if all other applicable criteria also are satisfied.

4. *Creditor qualifications.* To be eligible to make qualified mortgages under § 1026.43(e)(5), a creditor must satisfy the requirements stated in § 1026.35(b)(2)(iii)(B) and (C). Section 1026.35(b)(2)(iii)(B) requires that, during the preceding calendar year, or, if the application for the transaction was received before April 1 of the current calendar year, during either of the two preceding calendar years, the creditor and its affiliates together extended no more than 2,000 covered transactions, as defined by § 1026.43(b)(1), secured by first liens, that were sold, assigned, or otherwise transferred to another person, or that were subject at the time of consummation to a commitment to be acquired by another person. Section 1026.35(b)(2)(iii)(C) requires that, as of the preceding December 31st, or, if the application for the transaction was received before April 1 of the current calendar year, as of either of the two preceding December 31sts, the creditor and its affiliates that regularly extended, during the applicable period, covered transactions, as defined by § 1026.43(b)(1), secured by first liens, together, had total assets of less than $2 billion, adjusted annually by the Bureau for inflation.

5. *Requirement to hold in portfolio.* Creditors generally must hold a loan in portfolio to maintain the transaction's status as a qualified mortgage under § 1026.43(e)(5), subject to four exceptions. Unless one of these exceptions applies, a loan is no longer a qualified mortgage under § 1026.43(e)(5) once legal title to the debt obligation is sold, assigned, or otherwise transferred to another person. Accordingly, unless one of the exceptions applies, the transferee could not benefit from the presumption of compliance for qualified mortgages under § 1026.43(e)(1) unless the loan also met the requirements of another qualified mortgage definition.

6. *Application to subsequent transferees.* The exceptions contained in § 1026.43(e)(5)(ii) apply not only to an initial sale, assignment, or other transfer by the originating creditor but to subsequent sales, assignments, and other transfers as well. For example, assume Creditor A originates a qualified mortgage under § 1026.43(e)(5). Six months after consummation, Creditor A sells the qualified mortgage to Creditor B pursuant to § 1026.43(e)(5)(ii)(B) and the loan retains its qualified mortgage status because Creditor B complies with the limits on asset size and number of transactions. If Creditor B sells the qualified mortgage, it will lose its qualified mortgage status under § 1026.43(e)(5) unless the sale qualifies for one of the § 1026.43(e)(5)(ii) exceptions for sales three or more years after consummation, to another qualifying institution, as required by supervisory action, or pursuant to a merger or acquisition.

7. *Transfer three years after consummation.* Under § 1026.43(e)(5)(ii)(A), if a qualified mortgage under § 1026.43(e)(5) is sold, assigned, or otherwise transferred three years or more after consummation, the loan retains its status as a qualified mortgage under § 1026.43(e)(5) following the transfer. The transferee need not be eligible to originate qualified mortgages under § 1026.43(e)(5). The loan will continue to be a qualified mortgage throughout its life, and the transferee, and any subsequent transferees, may invoke the presumption of compliance for qualified mortgages under § 1026.43(e)(1).

8. *Transfer to another qualifying creditor.* Under § 1026.43(e)(5)(ii)(B), a qualified mortgage under § 1026.43(e)(5) may be sold, assigned, or otherwise transferred at any time to another creditor that meets the requirements of § 1026.43(e)(5)(i)(D). That section requires that a creditor together with all its affiliates, extended no more than 2,000 first-lien covered transactions that were sold, assigned, or otherwise transferred by the creditor or its affiliates to another person, or that were subject at the time of consummation to a commitment to be acquired by another person; and have, together with its affiliates that regularly extended covered transactions secured by first liens, total assets less than $2 billion (as adjusted for inflation). These tests are assessed based on transactions and assets from the calendar year preceding the current calendar year or from either of the two calendar years preceding the current calendar year if the application for the transaction was received before April 1 of the current calendar year. A qualified mortgage under § 1026.43(e)(5) transferred to a creditor that meets these criteria would retain its qualified mortgage status even if it is transferred less than three years after consummation.

9. *Supervisory sales.* Section 1026.43(e)(5)(ii)(C) facilitates sales that are deemed necessary by supervisory agencies to revive troubled creditors and resolve failed creditors. A qualified mortgage under § 1026.43(e)(5) retains its qualified mortgage status if it is sold, assigned, or otherwise transferred to another person pursuant to: A capital restoration plan or other action under 12 U.S.C. 1831o; the actions or instructions of any person acting as conservator, receiver or bankruptcy trustee; an order of a State or Federal government agency with jurisdiction to examine the creditor pursuant to State or Federal law; or an agreement between the creditor and such an agency. A qualified mortgage under § 1026.43(e)(5) that is sold, assigned, or otherwise transferred under these circumstances retains its qualified mortgage status regardless of how long after consummation it is sold and regardless of the size or other characteristics of the transferee. Section 1026.43(e)(5)(ii)(C) does not apply to transfers done to comply with a generally applicable regulation with future effect designed to implement, interpret, or prescribe law or policy in the absence of a specific order by or a specific agreement with a governmental agency described in § 1026.43(e)(5)(ii)(C) directing the sale of one or more qualified mortgages under § 1026.43(e)(5) held by the creditor or one of the other circumstances listed in § 1026.43(e)(5)(ii)(C). For example, a qualified mortgage under § 1026.43(e)(5) that is sold pursuant to a capital restoration plan under 12 U.S.C. 1831o would retain its status as a qualified mortgage following the sale. However, if the creditor simply chose to sell the same qualified mortgage as one way to comply with general regulatory capital requirements in the absence of supervisory action or agreement it would lose its status as a qualified mortgage following the sale unless it qualifies under another definition of qualified mortgage.

10. *Mergers and acquisitions.* A qualified mortgage under § 1026.43(e)(5) retains its qualified mortgage status if a creditor merges with, is acquired by, or acquires another person regardless of whether the creditor or its successor is eligible to originate new qualified mortgages under § 1026.43(e)(5) after the merger or acquisition. However, the creditor or its successor can originate new qualified mortgages under § 1026.43(e)(5) only if it complies with all of the requirements of § 1026.43(e)(5) after the merger or acquisition. For example, assume a creditor that originates 250 covered transactions each year and originates qualified mortgages under § 1026.43(e)(5) is acquired by a larger creditor that originates 10,000 covered transactions each year. Following the acquisition, the small creditor would no longer be able to originate § 1026.43(e)(5) qualified mortgages because, together with its affiliates, it would originate more than 500 covered transactions each year. However, the § 1026.43(e)(5) qualified mortgages originated by the small creditor before the acquisition would retain their qualified mortgage status.

* * * * *

43(f)(1) Exemption

Paragraph 43(f)(1)(i)

1. *Satisfaction of qualified mortgage requirements.* Under § 1026.43(f)(1)(i), for a mortgage that provides for a balloon payment to be a qualified mortgage, the mortgage must satisfy the requirements for a qualified mortgage in paragraphs (e)(2)(i)(A), (e)(2)(ii), and (e)(2)(iii). Therefore, a covered transaction with balloon payment terms must provide for regular periodic payments that do not result in an increase of the principal balance, pursuant to § 1026.43(e)(2)(i)(A); must have a loan term that does not exceed 30 years, pursuant to § 1026.43(e)(2)(ii); and must have total points and fees that do not exceed specified thresholds pursuant to § 1026.43(e)(2)(iii).

Paragraph 43(f)(1)(ii)

1. *Example.* Under § 1026.43(f)(1)(ii), if a qualified mortgage provides for a balloon payment, the creditor must determine that the consumer is able to make all scheduled payments under the legal obligation other

than the balloon payment. For example, assume a loan in an amount of $200,000 that has a five-year loan term, but is amortized over 30 years. The loan agreement provides for a fixed interest rate of 6 percent. The loan consummates on March 3, 2014, and the monthly payment of principal and interest scheduled for the first five years is $1,199, with the first monthly payment due on April 1, 2014. The balloon payment of $187,308 is required on the due date of the 60th monthly payment, which is April 1, 2019. The loan can be a qualified mortgage if the creditor underwrites the loan using the scheduled principal and interest payment of $1,199, plus the consumer's monthly payment for all mortgage-related obligations, and satisfies the other criteria set forth in § 1026.43(f).

2. *Creditor's determination.* A creditor must determine that the consumer is able to make all scheduled payments other than the balloon payment to satisfy § 1026.43(f)(1)(ii), in accordance with the legal obligation, together with the consumer's monthly payments for all mortgage-related obligations and excluding the balloon payment, to meet the repayment ability requirements of § 1026.43(f)(1)(ii). A creditor satisfies § 1026.43(f)(1)(ii) if it uses the maximum payment in the payment schedule, excluding any balloon payment, to determine if the consumer has the ability to make the scheduled payments.

Paragraph 43(f)(1)(iii)

1. *Debt-to-income or residual income.* A creditor must consider and verify the consumer's monthly debt-to-income ratio or residual income to meet the requirements of § 1026.43(f)(1)(iii)(C). To calculate the consumer's monthly debt-to-income or residual income for purposes of § 1026.43(f)(1)(iii)(C), the creditor may rely on the definitions and calculation rules in § 1026.43(c)(7) and its accompanying commentary, except for the calculation rules for a consumer's total monthly debt obligations (which is a component of debt-to-income and residual income under § 1026.43(c)(7)). For purposes of calculating the consumer's total monthly debt obligations under § 1026.43(f)(1)(iii), the creditor must calculate the monthly payment on the covered transaction using the payment calculation rules in § 1026.43(f)(1)(iv)(A), together with all mortgage-related obligations and excluding the balloon payment.

Paragraph 43(f)(1)(iv)

1. *Scheduled payments.* Under § 1026.43(f)(1)(iv)(A), the legal obligation must provide that scheduled payments must be substantially equal and determined using an amortization period that does not exceed 30 years. Balloon payments often result when the periodic payment would fully repay the loan amount only if made over some period that is longer than the loan term. For example, a loan term of 10 years with periodic payments based on an amortization period of 20 years would result in a balloon payment being due at the end of the loan term. Whatever the loan term, the amortization period used to determine the scheduled periodic payments that the consumer must pay under the terms of the legal obligation may not exceed 30 years.

2. *Substantially equal.* The calculation of payments scheduled by the legal obligation under § 1026.43(f)(1)(iv)(A) are required to result in substantially equal amounts. This means that the scheduled payments need to be similar, but need not be equal. For further guidance on substantially equal payments, see comment 43(c)(5)(i)–4.

3. *Interest-only payments.* A mortgage that only requires the payment of accrued interest each month does not meet the requirements of § 1026.43(f)(1)(iv)(A).

Paragraph 43(f)(1)(v)

1. *Forward commitments.* A creditor may make a mortgage loan that will be transferred or sold to a purchaser pursuant to an agreement that has been entered into at or before the time the transaction is consummated. Such an agreement is sometimes known as a ''forward commitment.'' A balloon-payment mortgage that will be acquired by a purchaser pursuant to a forward commitment does not satisfy the requirements of § 1026.43(f)(1)(v), whether the forward commitment provides for the purchase and sale of the specific transaction or for the purchase and sale of transactions with certain prescribed criteria that the transaction meets. However, a purchase and sale of a balloon-payment qualified mortgage to another person that separately meets the requirements of § 1026.43(f)(1)(vi) is permitted. For example: Assume a creditor that meets the requirements of § 1026.43(f)(1)(vi) makes a balloon-payment mortgage that meets the requirements of § 1026.43(f)(1)(i) through (iv); if the balloon-payment mortgage meets the purchase criteria of an investor with which the creditor has an agreement to sell such loans after consummation, then the balloon-payment mortgage does not meet the definition of a qualified mortgage in accordance with § 1026.43(f)(1)(v). However, if the investor meets the requirement of § 1026.43(f)(1)(vi), the balloon-payment qualified mortgage retains its qualified mortgage status.

Paragraph 43(f)(1)(vi)

1. *Creditor qualifications.* Under § 1026.43(f)(1)(vi), to make a qualified mortgage that provides for a balloon payment, the creditor must satisfy three criteria that are also required under § 1026.35(b)(2)(iii)(A), (B) and (C), which require:

i. During the preceding calendar year or during either of the two preceding calendar years if the application for the transaction was received before April 1 of the current calendar year, the creditor extended a first-lien covered transaction, as defined in § 1026.43(b)(1), on a property that is located in an area that is designated either ''rural'' or ''underserved,'' as defined in § 1026.35(b)(2)(iv), to satisfy the requirement of § 1026.35(b)(2)(iii)(A) (the rural-or-underserved test). Pursuant to § 1026.35(b)(2)(iv), an area is considered to be rural if it is: A county that is neither in a metropolitan statistical area, nor a micropolitan statistical area adjacent to a metropolitan statistical area, as those terms are defined by the U.S. Office of Management and Budget; a census block that is not in an urban area, as defined by the U.S. Census Bureau using the latest decennial census of the United States; or a county or a census block that has been designated as ''rural'' by the Bureau pursuant to the application process established in 2016. *See* Application Process for Designation of Rural Area under Federal Consumer Financial Law; Procedural Rule, 81 FR 11099 (Mar. 3, 2016). An area is considered to be underserved during a calendar year if, according to HMDA data for the preceding calendar year, it is a county in which no more than two creditors extended covered transactions secured by first liens on properties in the county five or more times.

A. The Bureau determines annually which counties in the United States are rural or underserved as defined by § 1026.35(b)(2)(iv)(A)(1) or § 1026.35(b)(2)(iv)(B) and publishes on its public website lists of those counties to assist creditors in determining whether they meet the criterion at § 1026.35(b)(2)(iii)(A). Creditors may also use an automated tool provided on the Bureau's public website to determine whether specific properties are located in areas that qualify as ''rural'' or ''underserved'' according to the definitions in § 1026.35(b)(2)(iv) for a particular calendar year. In addition, the U.S. Census Bureau may also provide on its public website an automated address search tool that specifically indicates if a property address is located in an urban area for purposes of the Census Bureau's most recent delineation of urban areas. For any calendar year that begins after the date on which the Census Bureau announced its most recent delineation of urban areas, a property is located in an area that qualifies as ''rural'' according to the definitions in § 1026.35(b)(2)(iv) if the search results provided for the property by any such automated address search tool available on the Census Bureau's public website do not identify the property as being in an urban area. A property is also located in an area that qualifies as ''rural,'' if the Bureau has designated that area as rural under § 1026.35(b)(2)(iv)(A)(3) and published that determination in the **Federal Register**. *See* Application Process for Designation of Rural Area under Federal Consumer Financial Law; Procedural Rule, 81 FR 11099 (Mar. 3, 2016).

B. For example, if a creditor extended during 2017 a first-lien covered transaction that is secured by a property that is located in an area that meets the definition of rural or underserved under § 1026.35(b)(2)(iv), the creditor meets this element of the exception for any transaction consummated during 2018.

C. Alternatively, if the creditor did not extend in 2017 a transaction that meets the definition of rural or underserved test under § 1026.35(b)(2)(iv), the creditor satisfies this criterion for any transaction consummated during 2018 for which it received the application before April 1, 2018, if it extended during 2016 a first-lien covered transaction that is secured by a property that is located in an area that meets the definition of rural or underserved under § 1026.35(b)(2)(iv).

ii. During the preceding calendar year, or, if the application for the transaction was

received before April 1 of the current calendar year, during either of the two preceding calendar years, the creditor together with its affiliates extended no more than 2,000 covered transactions, as defined by § 1026.43(b)(1), secured by first liens, that were sold, assigned, or otherwise transferred to another person, or that were subject at the time of consummation to a commitment to be acquired by another person, to satisfy the requirement of § 1026.35(b)(2)(iii)(B).

iii. As of the preceding December 31st, or, if the application for the transaction was received before April 1 of the current calendar year, as of either of the two preceding December 31sts, the creditor and its affiliates that regularly extended covered transactions secured by first liens, together, had total assets that do not exceed the applicable asset threshold established by the Bureau, to satisfy the requirement of § 1026.35(b)(2)(iii)(C). The Bureau publishes notice of the asset threshold each year by amending comment 35(b)(2)(iii)–1.iii.

Dated: December 10, 2020.

Grace Feola,

Federal Register Liaison, Bureau of Consumer Financial Protection.

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Part IV

Bureau of Consumer Financial Protection

12 CFR Part 1026

Qualified Mortgage Definition Under the Truth in Lending Act (Regulation Z): Seasoned QM Loan Definition; Final Rule

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1026

[Docket No. CFPB–2020–0028]

RIN 3170–AA98

Qualified Mortgage Definition Under the Truth in Lending Act (Regulation Z): Seasoned QM Loan Definition

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Final rule; official interpretation.

SUMMARY: With certain exceptions, Regulation Z requires creditors to make a reasonable, good faith determination of a consumer's ability to repay any residential mortgage loan, and loans that meet Regulation Z's requirements for ''qualified mortgages'' (QMs) obtain certain protections from liability. Regulation Z contains several categories of QMs, including the General QM category and a temporary category (Temporary GSE QMs) of loans that are eligible for purchase or guarantee by government-sponsored enterprises (GSEs) while they are operating under the conservatorship or receivership of the Federal Housing Finance Agency (FHFA). The Bureau of Consumer Financial Protection (Bureau) is issuing this final rule to create a new category of QMs (Seasoned QMs) for first-lien, fixed-rate covered transactions that have met certain performance requirements, are held in portfolio by the originating creditor or first purchaser for a 36-month period, comply with general restrictions on product features and points and fees, and meet certain underwriting requirements. The Bureau's primary objective with this final rule is to ensure access to responsible, affordable mortgage credit by adding a Seasoned QM definition to the existing QM definitions.

DATES: This final rule is effective on March 1, 2021.

FOR FURTHER INFORMATION CONTACT: Eliott C. Ponte or Ruth Van Veldhuizen, Counsels, or Joan Kayagil, Amanda Quester, or Jane Raso, Senior Counsels, Office of Regulations, at 202–435–7700. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

SUPPLEMENTARY INFORMATION:

I. Summary of the Final Rule

The Ability-to-Repay/Qualified Mortgage Rule (ATR/QM Rule) requires a creditor to make a reasonable, good faith determination of a consumer's ability to repay a residential mortgage loan according to its terms. Loans that meet the ATR/QM Rule's requirements for QMs obtain certain protections from liability. The Bureau issued a proposal in August 2020 to create a new category of QMs, Seasoned QMs. The Bureau is now finalizing the proposal largely as proposed.[1] The final rule defines Seasoned QMs as first-lien, fixed-rate covered transactions that have met certain performance requirements over a seasoning period of at least 36 months, are held in portfolio until the end of the seasoning period by the originating creditor or first purchaser, comply with general restrictions on product features and points and fees, and meet certain underwriting requirements.

The Bureau concludes that a Seasoned QM definition will complement existing QM definitions and help ensure access to responsible, affordable mortgage credit. One QM category defined in the ATR/QM Rule is the General QM category. General QMs must comply with the ATR/QM Rule's prohibitions on certain loan features, its points-and-fees limits, and its underwriting requirements. Under the definition for General QMs currently in effect, the ratio of the consumer's total monthly debt to total monthly income (DTI) must not exceed 43 percent. In a separate final rule released simultaneously with this final rule, the Bureau is amending the General QM loan definition to, among other things, replace the existing General QM loan definition that includes the 43 percent DTI limit with a price-based General QM loan definition (General QM Final Rule).

A second, temporary category of QMs defined in the ATR/QM Rule is the Temporary GSE QM category, which consists of mortgages that (1) comply with the same loan-feature prohibitions and points-and-fees limits as General QMs and (2) are eligible to be purchased or guaranteed by the GSEs while under the conservatorship of the FHFA. The Temporary GSE QM loan definition was previously set to expire with respect to each GSE when that GSE ceases to operate under conservatorship or on January 10, 2021, whichever comes first. In a final rule issued on October 20, 2020 and published in the **Federal Register** on October 26, 2020, the Bureau extended the Temporary GSE QM loan definition until the earlier of the mandatory compliance date of final amendments to the General QM loan definition or the date the GSEs cease to operate under conservatorship or receivership (Extension Final Rule).[2]

The Bureau is issuing this final rule to create a new category of QMs because it seeks to encourage safe and responsible innovation in the mortgage origination market, including for certain loans that are not QMs or are rebuttable presumption QMs under the existing QM categories. The Bureau presumes compliance with the ability-to-repay (ATR) requirements if such loans season in the manner set forth in this final rule. Under this final rule, a covered transaction receives a safe harbor from ATR liability at the end of a seasoning period of at least 36 months as a Seasoned QM if it satisfies certain product restrictions, points-and-fees limits, and underwriting requirements, and it meets performance and portfolio requirements during the seasoning period. Specifically, a covered transaction has to meet the following product restrictions to be eligible to become a Seasoned QM:

1. The loan is secured by a first lien;
2. The loan has a fixed rate, with regular, substantially equal periodic payments that are fully amortizing and no balloon payments;
3. The loan term does not exceed 30 years; and
4. The loan is not a high-cost mortgage as defined in § 1026.32(a).

In order to become a Seasoned QM, the loan's total points and fees also must not exceed specified limits.

For a loan to be eligible to become a Seasoned QM, this final rule requires that the creditor consider the consumer's DTI ratio or residual income, income or assets other than the value of the dwelling, and debts and verify the consumer's income or assets other than the value of the dwelling and the consumer's debts, using the same consider and verify requirements established for General QMs in the General QM Final Rule.

Under this final rule, a loan generally is eligible to season only if the creditor holds it in portfolio until the end of the seasoning period. There are several exceptions to this portfolio requirement that are similar to the exceptions to the Small Creditor QM portfolio requirement under the ATR/QM Rule. This final rule also includes an additional exception for a single transfer of a loan during the seasoning period. In the event of such a transfer, the final rule requires the purchaser to hold the

[1] As explained in more detail in part VI below, the final rule differs from the proposal in certain limited respects, including by adding a new exception to the portfolio requirement that allows loans to be transferred once during the seasoning period, excluding high-cost mortgages as defined in 12 CFR 1026.32(a), and applying the same consider and verify requirements that will apply to General QM loans.

[2] 85 FR 67938 (Oct. 26, 2020).

loan in portfolio after the transfer until the end of the seasoning period.

In order to become a Seasoned QM, a loan must meet certain performance requirements at the end of the seasoning period. Specifically, seasoning is available only for covered transactions that have no more than two delinquencies of 30 or more days and no delinquencies of 60 or more days at the end of the seasoning period. Funds taken from escrow in connection with the covered transaction and funds paid on behalf of the consumer by the creditor, servicer, or assignee of the covered transaction (or any other person acting on their behalf) are not considered in assessing whether a periodic payment has been made or is delinquent for purposes of this final rule. Creditors can, however, generally accept deficient payments, within a payment tolerance of $50, on up to three occasions during the seasoning period without triggering a delinquency for purposes of this final rule.

This final rule generally defines the seasoning period as a period of 36 months beginning on the date on which the first periodic payment is due after consummation. Failure to make full contractual payments does not disqualify a loan from eligibility to become a Seasoned QM if the consumer is in a temporary payment accommodation extended in connection with a disaster or pandemic-related national emergency, as long as certain conditions are met. However, time spent in such a temporary accommodation does not count towards the 36-month seasoning period, and the seasoning period can only resume after the temporary accommodation if any delinquency is cured either pursuant to the loan's original terms or through a qualifying change as defined in this final rule. This final rule defines a qualifying change as an agreement entered into during or after a temporary payment accommodation extended in connection with a disaster or pandemic-related national emergency that ends any preexisting delinquency and meets certain other conditions to ensure the loan remains affordable (such as a restriction on increasing the amount of interest charged over the full term of the loan as a result of the agreement).

This final rule will take effect 60 days after publication in the **Federal Register**, which aligns with the effective date provided in the General QM Final Rule. For this final rule, the revised regulations apply to covered transactions for which creditors receive an application on or after the effective date.

II. Background

A. Dodd-Frank Act Amendments to the Truth in Lending Act

The Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) [3] amended the Truth in Lending Act (TILA) [4] to establish, among other things, ATR requirements in connection with the origination of most residential mortgage loans.[5] The amendments were intended ''to assure that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loans and that are understandable and not unfair, deceptive or abusive.'' [6] As amended, TILA prohibits a creditor from making a residential mortgage loan unless the creditor makes a reasonable and good faith determination based on verified and documented information that the consumer has a reasonable ability to repay the loan.[7]

TILA identifies the factors a creditor must consider in making a reasonable and good faith assessment of a consumer's ability to repay. These factors are the consumer's credit history, current and expected income, current obligations, DTI ratio or residual income after paying non-mortgage debt and mortgage-related obligations, employment status, and other financial resources other than equity in the dwelling or real property that secures the repayment of the loan.[8] A creditor, however, may not be certain whether its ATR determination is reasonable in a particular case.[9]

TILA addresses this potential uncertainty by defining a category of loans—called QMs—for which a creditor ''may presume that the loan has met'' the ATR requirements.[10] The statute generally defines a QM to mean any residential mortgage loan for which:

- The loan does not have negative amortization, interest-only payments, or balloon payments;
- The loan term does not exceed 30 years;
- The total points and fees generally do not exceed 3 percent of the loan amount;
- The income and assets relied upon for repayment are verified and documented;
- The underwriting uses a monthly payment based on the maximum rate during the first five years, uses a payment schedule that fully amortizes the loan over the loan term, and takes into account all mortgage-related obligations; and
- The loan complies with any guidelines or regulations established by the Bureau relating to the ratio of total monthly debt to monthly income or alternative measures of ability to pay regular expenses after payment of total monthly debt.[11]

The ATR/QM Rule

In January 2013, the Bureau issued a final rule amending Regulation Z to implement TILA's ATR requirements (January 2013 Final Rule).[12] The January 2013 Final Rule became effective on January 10, 2014, and the Bureau has amended it several times since January 2013.[13] This final rule refers to the January 2013 Final Rule and later amendments to it collectively as the ATR/QM Rule. The ATR/QM Rule implements the statutory ATR provisions discussed above and defines several categories of QMs.[14]

1. General QMs

One category of QMs defined by the ATR/QM Rule consists of General QMs. Under the definition for General QMs currently in effect, a loan is a General QM if:

- The loan does not have negative-amortization, interest-only, or balloon-payment features, a term that exceeds 30 years, or points and fees that exceed specified limits; [15]
- The creditor underwrites the loan based on a fully amortizing schedule

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

[4] 15 U.S.C. 1601 *et seq.*

[5] Dodd-Frank Act sections 1411–12, 1414, 124 Stat. 2142–49; 15 U.S.C. 1639c.

[6] 15 U.S.C. 1639b(a)(2).

[7] 15 U.S.C. 1639c(a)(1). TILA section 103 defines ''residential mortgage loan'' to mean, with some exceptions including open-end credit plans, ''any consumer credit transaction that is secured by a mortgage, deed of trust, or other equivalent consensual security interest on a dwelling or on residential real property that includes a dwelling.'' 15 U.S.C. 1602(dd)(5). TILA section 129C also exempts certain residential mortgage loans from the ATR requirements. *See, e.g.,* 15 U.S.C. 1639c(a)(8) (exempting reverse mortgages and temporary or bridge loans with a term of 12 months or less).

[8] 15 U.S.C. 1639c(a)(3).

[9] A creditor that violates this ATR requirement may be subject to government enforcement and private actions. Generally, the statute of limitations for a private action for damages for a violation of the ATR requirement is three years from the date of the occurrence of the violation. 15 U.S.C. 1640(e). TILA also provides that if a creditor, an assignee, other holder, or their agent initiates a foreclosure action, a consumer may assert a violation by the creditor of the ATR requirement as a matter of defense by recoupment or set off without regard for the time limit on a private action for damages. 15 U.S.C. 1640(k).

[10] 15 U.S.C. 1639c(b)(1).

[11] 15 U.S.C. 1639c(b)(2)(A).

[12] 78 FR 6408 (Jan. 30, 2013).

[13] *See* 78 FR 35429 (June 12, 2013); 78 FR 44686 (July 24, 2013); 78 FR 60382 (Oct. 1, 2013); 79 FR 65300 (Nov. 3, 2014); 80 FR 59944 (Oct. 2, 2015); 81 FR 16074 (Mar. 25, 2016); 85 FR 67938 (Oct. 26, 2020).

[14] 12 CFR 1026.43(c), (e).

[15] 12 CFR 1026.43(e)(2)(i) through (iii).

using the maximum rate permitted during the first five years;[16]

- The creditor considers and verifies the consumer's income and debt obligations in accordance with appendix Q;[17] and
- The consumer's DTI ratio is no more than 43 percent, determined in accordance with appendix Q.[18]

Appendix Q contains standards for calculating and verifying debt and income for purposes of determining whether a mortgage satisfies the 43 percent DTI limit for General QMs. Appendix Q addresses how to determine a consumer's employment-related income (*e.g.,* income from wages, commissions, and retirement plans); non-employment-related income (*e.g.,* income from alimony and child support payments, investments, and property rentals); and liabilities, including recurring and contingent liabilities and projected obligations.[19]

On June 22, 2020, the Bureau proposed amendments to the General QM loan definition, which would, among other things, replace the General QM loan definition's 43 percent DTI limit with a price-based approach and remove appendix Q.[20] In addition to soliciting comment on the Bureau's proposed price-based approach, the Bureau requested comment on certain alternative approaches that would retain a DTI limit but would raise it above the current limit of 43 percent and provide a more flexible set of standards for verifying debt and income in place of appendix Q. Simultaneously with issuing this final rule, the Bureau is issuing the General QM Final Rule, which is discussed in part II.D below.

2. Temporary GSE QMs

A second, temporary category of QMs defined by the ATR/QM Rule, Temporary GSE QMs, consists of mortgages that (1) comply with the ATR/QM Rule's prohibitions on certain loan features and its limitations on points and fees;[21] and (2) are eligible to be purchased or guaranteed by either GSE while under the conservatorship of the FHFA.[22] Regulation Z does not prescribe a DTI limit for Temporary GSE QMs. Thus, a loan can qualify as a Temporary GSE QM even if the DTI ratio exceeds 43 percent, as long as the DTI ratio meets the applicable GSE's DTI requirements and other underwriting criteria, and the loan satisfies the other Temporary GSE QM requirements. In addition, income, debt, and DTI ratios for such loans generally are verified and calculated using GSE standards, rather than appendix Q. The January 2013 Final Rule provided that the Temporary GSE QM loan definition—also known as the GSE Patch—would expire with respect to each GSE when that GSE ceases to operate under conservatorship or on January 10, 2021, whichever comes first.[23] On June 22, 2020, the Bureau proposed to extend the Temporary GSE QM category until the effective date of final amendments to the General QM loan definition or the date the GSEs cease to operate under conservatorship or receivership, whichever comes first.[24] In a final rule issued on October 20, 2020, the Bureau extended the Temporary GSE QM category until the earlier of the mandatory compliance date of final amendments to the General QM loan definition or the date the GSEs cease to operate under conservatorship or receivership.[25]

3. Small Creditor QMs

In a May 2013 final rule, the Bureau amended the ATR/QM Rule to add, among other things, a new QM category—the Small Creditor QM—for covered transactions that are originated by creditors that meet certain size criteria and that satisfy certain other requirements.[26] Those requirements include many that apply to General QMs, with some exceptions. Specifically, the threshold for determining whether Small Creditor QMs are higher-priced covered transactions, and thus qualify for the QM safe harbor or rebuttable presumption, is higher than the threshold for General QMs.[27] Small Creditor QMs also are not subject to the General QM loan definition's 43 percent DTI limit, and the creditor is not required to use appendix Q to calculate debt and income.[28] In addition, Small Creditor QMs must be held in portfolio for three years (a requirement that does not apply to General QMs).[29] The Bureau made several amendments to the Small Creditor QM provisions in 2015.[30] These included: Amending the small creditor definition to increase the number of loans a small creditor can originate each year to 2,000; exempting from the 2,000-loan limit any loans held in the creditor's portfolio; and revising the small creditor definition's asset threshold to include the assets of any of the creditor's affiliates.[31]

The Bureau created the Small Creditor QM category based on its determination that the characteristics of a small creditor—its small size, community-based focus, and commitment to relationship lending—and the inherent incentives associated with portfolio lending together justify extending QM status to loans that do not meet all of the ordinary QM criteria.[32] With respect to the role of portfolio lending, the Bureau stated that the discipline imposed when small creditors make loans that they will hold in portfolio is important to protect consumers' interests and to prevent evasion of the ATR requirements.[33] The Bureau noted that by retaining mortgage loans in portfolio, creditors retain the risk of delinquency

[16] 12 CFR 1026.43(e)(2)(iv).

[17] 12 CFR 1026.43(e)(2)(v).

[18] 12 CFR 1026.43(e)(2)(vi).

[19] 12 CFR 1026, appendix Q.

[20] 85 FR 41716 (July 10, 2020).

[21] 12 CFR 1026.43(e)(2)(i) through (iii).

[22] 12 CFR 1026.43(e)(4).

[23] 12 CFR 1026.43(e)(4)(iii)(B). The ATR/QM Rule created several additional categories of QMs. The first additional category consisted of mortgages eligible to be insured or guaranteed (as applicable) by the U.S. Department of Housing and Urban Development, the U.S. Department of Veterans Affairs, the U.S. Department of Agriculture, and the Rural Housing Service. 12 CFR 1026.43(e)(4)(ii)(B) through (E). This temporary category of QMs no longer exists because the relevant Federal agencies have since issued their own QM rules. *See, e.g.,* 24 CFR 203.19. Other categories of QMs provide more flexible standards for certain loans originated by certain small creditors. 12 CFR 1026.43(e)(5), (f); *cf.* 12 CFR 1026.43(e)(6) (applicable only to covered transactions for which the application was received before April 1, 2016).

[24] 85 FR 41448 (July 10, 2020).

[25] 85 FR 67938 (Oct. 26, 2020).

[26] 78 FR 35430 (June 12, 2013).

[27] QMs are generally considered to be higher priced if they have an annual percentage rate (APR) that exceeds the applicable average prime offer rate (APOR) by at least 1.5 percentage points for first-lien loans and at least 3.5 percentage points for subordinate-lien loans. In contrast, Small Creditor QMs are only considered higher priced if the APR exceeds APOR by at least 3.5 percentage points for either a first- or subordinate-lien loan. 12 CFR 1026.43(b)(4). The same is true for another QM definition that permits certain creditors operating in rural or underserved areas to originate QMs with a balloon payment provided that the loans meet certain other criteria (Balloon Payment QM loans). QMs that are higher priced enjoy only a rebuttable presumption of compliance with the ATR requirements, whereas QMs that are not higher priced enjoy a safe harbor.

[28] 12 CFR 1026.43(e)(5)(i)(A).

[29] 12 CFR 1026.43(e)(5)(ii), (f)(2).

[30] 80 FR 59944 (Oct. 2, 2015).

[31] As with Small Creditor QMs, Balloon Payment QMs must be held in portfolio for three years. In addition, Balloon Payment QMs may not have negative-amortization or interest-only features and must comply with the points-and-fees limits that apply to other QM loans. Also, Balloon Payment QMs must carry a fixed interest rate, payments other than the balloon must fully amortize the loan over 30 years or less, and the loan term must be at least five years. The creditor must also determine the consumer's ability to make periodic payments other than the balloon and verify income and assets. 12 CFR 1026.43(f).

[32] 78 FR 35430, 35485 (June 12, 2013) (''The Bureau believes that § 1026.43(e)(5) will preserve consumers' access to credit and, because of the characteristics of small creditors and portfolio lending described above, the credit provided generally will be responsible and affordable.'').

[33] *Id.* at 35486.

or default on those loans, and as such the presence of portfolio lending within the small creditor market is an important influence on such creditors' underwriting practices.[34]

C. Economic Growth, Regulatory Relief, and Consumer Protection Act

The Economic Growth, Regulatory Relief, and Consumer Protection Act (EGRRCPA) was signed into law on May 24, 2018.[35] Section 101 of the EGRRCPA amended TILA to provide protection from liability for insured depository institutions and insured credit unions with assets below $10 billion with respect to certain ATR requirements regarding residential mortgage loans.[36] Specifically, the protection from liability is available if a loan: (1) Is originated by and retained in portfolio by the institution, (2) complies with requirements regarding prepayment penalties and points and fees, and (3) does not have any negative amortization or interest-only features. Further, for the protection from liability to apply, the institution must consider and document the debt, income, and financial resources of the consumer. Section 101 of the EGRRCPA also provides that the protection from liability is not available in the event of legal transfer except for transfers: (1) To another person by reason of bankruptcy or failure of a covered institution; (2) to a covered institution that retains the loan in portfolio; (3) in the event of a merger or acquisition as long as the loan is still retained in portfolio by the person to whom the loan is sold, assigned, or transferred; or (4) to a wholly owned subsidiary of a covered institution, provided that, after the sale, assignment, or transfer, the loan is considered to be an asset of the covered institution for regulatory accounting purposes.

D. General QM Final Rule

Simultaneously with this final rule, the Bureau is issuing a final rule to amend the General QM loan definition because retaining the existing General QM loan definition with the 43 percent DTI limit after the Temporary GSE QM loan definition expires would significantly reduce the size of the QM market and could significantly reduce access to responsible, affordable credit.[37] Readers should refer to the General QM Final Rule for a full discussion of the amendments and the Bureau's rationale for them.

In the General QM Final Rule, the Bureau is establishing a price-based General QM loan definition to replace the DTI-based approach. Under the General QM Final Rule, a loan meets the General QM loan definition in § 1026.43(e)(2) only if the annual percentage rate (APR) exceeds the average prime offer rate (APOR) for a comparable transaction by less than 2.25 percentage points as of the date the interest rate is set. The General QM Final Rule provides higher thresholds for loans with smaller loan amounts, for certain manufactured housing loans, and for subordinate-lien transactions. It retains the existing product-feature and underwriting requirements and limits on points and fees. Although the General QM Final Rule removes the 43 percent DTI limit from the General QM loan definition, the General QM Final Rule requires that the creditor consider the consumer's monthly DTI ratio or residual income; current or reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan; and debt obligations, alimony, and child support, and verify the consumer's current or reasonably expected income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan and the consumer's current debt obligations, alimony, and child support. The General QM Final Rule removes appendix Q. To prevent uncertainty that may result from appendix Q's removal, the General QM Final Rule clarifies the consider and verify requirements. The General QM Final Rule preserves the current threshold separating safe harbor from rebuttable presumption QMs, under which a loan is a safe harbor QM if its APR does not exceed APOR for a comparable transaction by 1.5 percentage points or more as of the date the interest rate is set (or by 3.5 percentage points or more for subordinate-lien transactions).

E. Presumption of Compliance for Existing Categories of QMs Under the ATR/QM Rule

In the January 2013 Final Rule, the Bureau considered whether QMs should receive a conclusive presumption (*i.e.,* a safe harbor) or a rebuttable presumption of compliance with the ATR requirements.[38] The statute does not specify whether the presumption of compliance means that the creditor receives a conclusive presumption or a rebuttable presumption of compliance with the ATR provisions. The Bureau noted that its analysis of the statutory construction and policy implications demonstrated that there are sound reasons for adopting either interpretation.[39] The Bureau concluded that the statutory language is ambiguous and does not mandate either interpretation and that the presumptions should be tailored to promote the policy goals of the statute.[40] The Bureau ultimately interpreted the statute to provide for a rebuttable presumption of compliance with the ATR requirements but used its adjustment authority to establish a conclusive presumption of compliance for loans that are not ''higher priced.''[41]

Under the ATR/QM Rule, a creditor that makes a QM is protected from liability presumptively or conclusively, depending on whether the loan is ''higher priced.'' The ATR/QM Rule generally defines a ''higher-priced'' loan to mean a first-lien mortgage with an APR that exceeded APOR for a comparable transaction as of the date the interest rate was set by 1.5 or more percentage points; or a subordinate-lien mortgage with an APR that exceeded APOR for a comparable transaction as of the date the interest rate was set by 3.5 or more percentage points.[42] A creditor that makes a QM that is not ''higher priced'' is entitled to a conclusive presumption that it has complied with the ATR/QM Rule—*i.e.,* the creditor receives a safe harbor from liability.[43] A creditor that makes a loan that meets the standards for a QM but is ''higher priced'' is entitled to a rebuttable presumption that it has complied with the ATR/QM Rule.[44]

F. The Bureau's Assessment of the ATR/QM Rule

Section 1022(d) of the Dodd-Frank Act requires the Bureau to assess each of its significant rules and orders and to publish a report of each assessment within five years of the effective date of the rule or order.[45] In June 2017, the Bureau published a request for information in connection with its assessment of the ATR/QM Rule (Assessment RFI).[46] These comments are summarized in general terms in part III below.

In January 2019, the Bureau published its ATR/QM Rule Assessment Report

[34] *Id.* at 35437.

[35] Public Law 115–174, 132 Stat. 1296 (2018).

[36] EGRRCPA section 101, 15 U.S.C. 1639c(b)(2)(F).

[37] 85 FR 41716 (July 10, 2020).

[38] 78 FR 6408, 6511 (Jan. 30, 2013).

[39] *Id.* at 6507.

[40] *Id.* at 6511.

[41] *Id.* at 6514.

[42] 12 CFR 1026.43(b)(4).

[43] 12 CFR 1026.43(e)(1)(i).

[44] 12 CFR 1026.43(e)(1)(ii).

[45] 12 U.S.C. 5512(d).

[46] 82 FR 25246 (June 1, 2017).

(Assessment Report).[47] The Assessment Report included findings about the effects of the ATR/QM Rule on the mortgage market generally, as well as specific findings about Temporary GSE QM originations.

The Assessment Report found that the ATR/QM Rule did not eliminate access to credit for consumers with DTI ratios above 43 percent who qualify for loans eligible for purchase or guarantee by either of the GSEs, that is, Temporary GSE QMs.[48] On the other hand, based on application-level data obtained from nine large creditors, the Assessment Report found that the ATR/QM Rule eliminated between 63 and 70 percent of home purchase loans with DTI ratios above 43 percent that were not Temporary GSE QMs.[49]

One main finding about Temporary GSE QMs was that such loans continued to represent ''a large and persistent'' share of originations in the conforming segment of the mortgage market, and a robust and sizable market to support non-QM lending has not emerged.[50] As discussed, the GSEs' share of the conventional, conforming purchase-mortgage market was 69 percent in 2013 before the ATR/QM Rule took effect, and the Assessment Report found a small increase in that share since the ATR/QM Rule's effective date, reaching 71 percent in 2017.[51]

The Assessment Report discussed several possible reasons for the continued prevalence of Temporary GSE QM originations, including the structure of the secondary market.[52] If creditors adhere to the GSEs' guidelines, they gain access to a robust, highly liquid secondary market.[53] In contrast, while private-label securitizations have grown somewhat in recent years, they are still a fraction of their pre-crisis levels.[54] There were less than $20 billion in new origination private-label securities (PLS) issuances in 2017, compared with $1 trillion in 2005,[55] and only 21 percent of new origination PLS issuances in 2017 were non-QM issuances.[56] To the extent that private-label securitizations have occurred since the ATR/QM Rule took effect in 2014, the majority of new origination PLS issuances have consisted of prime jumbo loans made to consumers with strong credit characteristics, and these securities include a small share of non-QM loans.[57] The Assessment Report noted that the Temporary GSE QM loan definition may be inhibiting the growth of the non-QM market.[58] However, the Assessment Report also noted that it is possible that this market might not exist even with a narrower Temporary GSE QM loan definition, if consumers were unwilling to pay the premium charged to cover the potential litigation risk associated with non-QM loans (which do not have a presumption of compliance with the ATR requirements) or if creditors were unwilling or lack the funding to make the loans as a result of the potential litigation risk.[59]

G. Effects of the COVID–19 Pandemic on Mortgage Markets

The COVID–19 pandemic has had a significant effect on the U.S. economy. In the early months of the pandemic, economic activity contracted, millions of workers became unemployed, and mortgage markets were affected. In recent months, the unemployment rate has declined, and there has been a significant rebound in mortgage origination activity, buoyed by historically low interest rates and by an increasingly large share of government and GSE-backed loans. However, origination activity outside the government and GSE-backed origination channels has declined, and mortgage-credit availability for many consumers—including those who would be dependent on the non-QM market for financing—remains tight relative to pre-pandemic levels. While nearly all major non-QM creditors ceased making loans in March and April 2020, the market has begun to recover and many non-QM creditors—which largely depend on the ability to sell loans in the secondary market to fund new loans—have begun to resume originations, albeit with tighter underwriting requirements.[60]

In March 2020, Congress passed and the President signed into law the Coronavirus Aid, Relief, and Economic Security Act (CARES Act).[61] The CARES Act provides additional protections for borrowers with federally backed mortgages, such as those whose mortgages are purchased or securitized by a GSE or insured or guaranteed by the Federal Housing Administration (FHA), U.S. Department of Veterans Affairs (VA), or U.S. Department of Agriculture (USDA). The CARES Act mandated a 60-day foreclosure moratorium for such mortgages, which has since been extended by the agencies until the end of 2020 or January 31, 2021 in the case of the GSEs.[62] The CARES Act also allows borrowers with federally backed mortgages to request up to 180 days of forbearance due to a COVID–19-related financial hardship, with an option to extend the forbearance period for an additional 180 days. While forbearance rates remain elevated at 5.54 percent for the week ending November 22, 2020, they have decreased since reaching their high of 8.55 percent on June 7, 2020.[63]

For further discussion of the effect of the COVID–19 pandemic on mortgage origination and servicing markets, see part II.D of the General QM Final Rule.

III. Summary of the Rulemaking Process

The Bureau has solicited and received substantial public and stakeholder input on issues related to the ATR/QM Rule generally and the substance of this final rule. In addition to the Bureau's discussions with and communications from industry stakeholders, consumer advocates, other Federal agencies,[64] and members of Congress, the Bureau issued requests for information (RFIs) in 2017

[47] Bureau of Consumer Fin. Prot., *Ability to Repay and Qualified Mortgage Assessment Report* (Jan. 2019), *https://files.consumerfinance.gov/f/documents/cfpb_ability-to-repay-qualified-mortgage_assessment-report.pdf* (Assessment Report).

[48] *See, e.g., id.* at 10, 194–96.

[49] *See, e.g., id.* at 10–11, 117, 131–47.

[50] *Id.* at 188, 198.

[51] *Id.* at 191.

[52] *Id.* at 196.

[53] *Id.*

[54] *Id.*

[55] *Id.*

[56] *Id.* at 197.

[57] *Id.* at 196.

[58] *Id.* at 205.

[59] *Id.*

[60] Brandon Ivey, *Expanded Credit Lending Inches Up in Third Quarter,* Inside Mortg. Fin. (Nov. 25, 2020), *https://www.insidemortgagefinance.com/articles/219861-expanded-credit-lending-ticks-up-in-3q-amid-slow-recovery* (on file).

[61] Public Law 116–136, 134 Stat. 281 (2020) (includes loans backed by the U.S. Department of Housing and Urban Development, the U.S. Department of Agriculture, the U.S. Department of Veterans Affairs, Fannie Mae, and Freddie Mac).

[62] *See, e.g.,* Fed. Hous. Fin. Agency, *FHFA Extends Foreclosure and REO Eviction Moratoriums* (Dec. 2, 2020), *https://www.fhfa.gov/Media/PublicAffairs/Pages/FHFA-Extends-Foreclosure-and-REO-Eviction-Moratoriums-12022020.aspx;* Press Release, U.S. Dep't of Hous. & Urban Dev., *FHA Extends Foreclosure And Eviction Moratorium For Homeowners Through Year End* (Aug. 27, 2020), *https://www.hud.gov/press/press_releases_media_advisories/HUD_No_20_134;* Veterans Benefits Admin., *Extended Foreclosure Moratorium for Borrowers Affected by COVID–19* (Aug. 24, 2020), *https://www.benefits.va.gov/HOMELOANS/documents/circulars/26-20-30.pdf;* Rural Dev., U.S. Dep't of Agric., *Extension of Foreclosure and Eviction Moratorium for Single Family Housing Direct Loans* (Aug. 28, 2020), *https://content.govdelivery.com/accounts/USDARD/bulletins/29c3a9e.*

[63] Press Release, Mortg. Bankers Ass'n, *Share of Mortgage Loans in Forbearance Increases to 5.54%* (Dec. 1, 2020), *https://www.mba.org/2020-press-releases/december/share-of-mortgage-loans-in-forbearance-increases-to-554-percent.*

[64] The Bureau has consulted with agencies including the FHFA, the Board of Governors of the Federal Reserve System, the Federal Housing Administration, the Federal Deposit Insurance Corporation (FDIC), the Office of the Comptroller of the Currency (OCC), the Federal Trade Commission, the National Credit Union Administration, and the U.S. Department of the Treasury.

and 2018, and in July 2019, it issued an advance notice of proposed rulemaking regarding the ATR/QM Rule (ANPR).[65] The input from these RFIs and from the ANPR is briefly summarized in the General QM Final Rule and Extension Final Rule and below. The Bureau has also received substantial additional input through three ATR/QM rulemakings this year, as discussed below and in the General QM Final Rule and Extension Final Rule.

A. The Requests for Information

In June 2017, the Bureau published the Assessment RFI to gather information for its assessment of the ATR/QM Rule.[66] In response to the Assessment RFI, the Bureau received approximately 480 comments from creditors, industry groups, consumer advocate groups, and individuals.[67] The comments addressed a variety of topics, including the General QM loan definition and the 43 percent DTI limit; perceived problems with, and potential changes and alternatives to, appendix Q; and how the Bureau should address the expiration of the Temporary GSE QM loan definition. The comments expressed a range of ideas for addressing the expiration of the Temporary GSE QM loan definition. Some commenters recommended making the definition permanent or extending it for various periods of time. Other comments stated that the Temporary GSE QM loan definition should be eliminated or permitted to expire.

Beginning in January 2018, the Bureau issued a general call for evidence seeking comment on its enforcement, supervision, rulemaking, market monitoring, and financial education activities.[68] As part of the call for evidence, the Bureau published RFIs relating to, among other things, the Bureau's rulemaking process,[69] the Bureau's adopted regulations and new rulemaking authorities,[70] and the Bureau's inherited regulations and inherited rulemaking authorities.[71] In response to the call for evidence, the Bureau received comments on the ATR/QM Rule from stakeholders, including consumer advocate groups and industry groups. The comments addressed a variety of topics, including the General QM loan definition, appendix Q, and the Temporary GSE QM loan definition. The comments also raised concerns about, among other things, the risks of allowing the Temporary GSE QM loan definition to expire without any changes to the General QM loan definition or appendix Q. The concerns raised in these comments were similar to those raised in response to the Assessment RFI.

The Advance Notice of Proposed Rulemaking

As noted above, on July 25, 2019, the Bureau issued an ANPR.[72] The ANPR stated the Bureau's tentative plans to allow the Temporary GSE QM loan definition to expire in January 2021 or after a short extension, if necessary, to facilitate a smooth and orderly transition away from the Temporary GSE QM loan definition. The Bureau also stated that it was considering whether to propose revisions to the General QM loan definition in light of the potential expiration of the Temporary GSE QM loan definition and requested comments on several topics related to the General QM loan definition, including: Whether and how the Bureau should revise the DTI limit in the General QM loan definition; whether the Bureau should supplement or replace the DTI limit with another method for directly measuring a consumer's personal finances; whether the Bureau should revise appendix Q or replace it with other standards for calculating and verifying a consumer's debt and income; and whether, instead of a DTI limit, the Bureau should adopt standards that do not directly measure a consumer's personal finances.[73] Of relevance to this final rule, the ANPR noted that some stakeholders had suggested that the Bureau amend the ATR/QM Rule so that a performing loan, whether or not it qualified as a QM at consummation, would convert to, or season into, a QM if it performed for some period of time. The Bureau also requested comment on how much time industry would need to change its practices in response to any revisions the Bureau makes to the General QM loan definition.

The Bureau received 85 comments on the ANPR from businesses in the mortgage industry (including creditors and their trade associations), consumer advocate groups, elected officials, individuals, and research centers. The General QM Proposal contains an overview of these comments.[74] Of the 85 comments received, approximately 20 comments discussed whether the Bureau should permit a mortgage that was not a QM at consummation to season into a QM on the ground that a loan's performance over an extended period should be considered sufficient or conclusive evidence that the creditor adequately assessed a consumer's ability to repay at consummation. The discussion below provides a more detailed overview of comment letters that supported a seasoning approach to QM status and those that opposed such an approach.

1. Comments Supporting Seasoning

As discussed in the General QM Proposal, commenters from the mortgage industry and its trade associations, as well as several research centers, recommended that a mortgage that is originated as a non-QM or rebuttable presumption QM should be eligible to season into a QM safe harbor loan if a consumer makes timely payments for a predetermined length of time. According to these commenters, if a loan defaults after performing for some period of time, such as three or five years, it is reasonable to conclude that the default was not caused by the creditor's failure to reasonably determine the consumer had the ability to repay at the time of consummation. Rather, these commenters maintained that defaults in those cases are more likely to be caused by unexpected life events or other factors, such as general economic trends, rather than a creditor's poor underwriting or failure to make an ATR determination at consummation.

A few commenters pointed to the GSEs' representation and warranty framework.[75] Under this framework, after a loan meets certain payment requirements, the creditor obtains relief from the enforcement of representations and warranties it must make to a GSE regarding its underwriting. These commenters indicated that a creditor's legal exposure to the ATR requirements should sunset in a similar way. In addition, several commenters noted that the 2019 U.S. Department of the Treasury Housing Reform Plan report also suggested consideration of a seasoning approach to QM safe harbor loan status.[76] A few commenters

[65] 84 FR 37155 (July 31, 2019).

[66] 82 FR 25246 (June 1, 2017).

[67] *See* Assessment Report, *supra* note 47, appendix B (summarizing comments received in response to the Assessment RFI).

[68] *See* Bureau of Consumer Fin. Prot., *Call for Evidence, https://www.consumerfinance.gov/policy-compliance/notice-opportunities-comment/archive-closed/call-for-evidence* (last updated Apr. 17, 2018).

[69] 83 FR 10437 (Mar. 9, 2018).

[70] 83 FR 12286 (Mar. 21, 2018).

[71] 83 FR 12881 (Mar. 26, 2018).

[72] 84 FR 37155 (July 31, 2019).

[73] *Id.* at 37160–62.

[74] 85 FR 41716 (July 10, 2020).

[75] The GSEs' representation and warranty framework is discussed in greater detail in part V below.

[76] U.S. Dep't of the Treasury, *Housing Reform Plan* at 38 (Sept. 2019), *https://home.treasury.gov/system/files/136/Treasury-Housing-Finance-Reform-Plan.pdf?mod=article_inline.*

asserted that allowing mortgages to season into QMs is consistent with comment 43(c)(1)–1.ii.A.*1* in the current ATR/QM Rule.[77] A comment letter jointly submitted by two research centers suggested that a seasoning approach to portfolio-held mortgages build on the EGRRCPA's portfolio loan QM category.

Further, a number of commenters stated that a seasoning approach to QM status would benefit the mortgage market. Among other things, they stated that it could reduce compliance burden. Additionally, commenters in support of seasoning suggested that seasoning could improve investor confidence by addressing the issue of assignee liability and litigation risk with non-QM loans and rebuttable presumption QM loans. These commenters stated that this, in turn, could enhance capital liquidity in the market, which could expand access to credit. Several commenters suggested that a seasoning rule should apply to loans even if they were originated before the adoption of the rule.

Commenters supporting a seasoning approach offered differing views on the appropriate length of the seasoning period, varying from as brief as 12 months following consummation to as long as five years following consummation. Some opposed any restrictions on loan features, while others supported some restrictions, such as limiting the seasoning approach to mortgages that follow the statutory QM product prohibitions or to fixed-rate mortgage products. Several commenters supporting a seasoning approach also supported or did not oppose a requirement for creditors to hold loans in portfolio until the conclusion of the seasoning period. For example, some research center commenters noted that keeping loans in portfolio demonstrates creditors' acceptance of the default risk associated with the loan.

Some research center commenters suggested graduated or step approaches. Under one such approach, for example, a non-QM loan would first have to season into a rebuttable presumption QM loan and then either stay in that category or be allowed to season into a QM safe harbor loan if it meets certain conditions. Commenters supporting seasoning generally acknowledged that delinquencies during the seasoning period should disqualify a loan from seasoning into a QM, but most did not offer specific suggestions regarding what it means for a loan to be performing. A comment letter from a research center suggested the Bureau use the Mortgage Bankers Association's method for determining timely payments.

Several commenters supporting a seasoning approach also addressed the possibility of creditors engaging in gaming to minimize defaults during the seasoning period. Two commenters asserted that the Bureau could require consumers to use their own funds to make monthly payments but did not provide any suggestions on how to determine whether the funds used are the consumer's funds rather than the funds of another. A research center commenter suggested that a competitive guarantor market such as the one the U.S. Department of the Treasury envisions in the long term would serve as a check on gaming by creditors. The same commenter also argued that it would be hard for creditors to game a seasoning approach because they would not be able to easily time harmful mortgages to go delinquent only after a given period following consummation.

Comments Opposing Seasoning

Two coalitions of consumer advocate groups submitted separate comment letters opposing a seasoning approach to QM status. The General QM Proposal described some of their concerns, including the following: (1) A period of successful repayment is insufficient to presume conclusively that the creditor reasonably determined ability to repay at consummation; (2) creditors would engage in gaming to minimize defaults during the seasoning period; and (3) seasoning would inappropriately prevent consumers from raising lack of ability to repay as a defense to foreclosure. In addition, the consumer advocate groups asserted that, depending on the length of the seasoning period, seasoning could inappropriately prevent consumers from bringing affirmative claims against creditors for allegedly violating the ATR requirements. One coalition of consumer advocate groups stated that in providing a three-year statute of limitations for consumers to bring such claims, Congress had indicated that the seasoning period could not be less than three years for rebuttable presumption or non-QM loans. Another coalition of consumer advocate groups stated that the three-year statute of limitations may be extended if equitable tolling applies and, as such, consumers may pursue affirmative claims for alleged violations of the ATR requirements beyond the three-year period. Both coalitions of consumer advocate groups stated that non-QM loans and QM loans that only receive a rebuttable presumption of compliance with the ATR requirements at consummation should not be allowed to season into QM safe harbor loans because the right a consumer has to raise the lack of ability to repay as a defense to foreclosure is not subject to the three-year statute of limitations.

The consumer advocate groups also stated that certain types of mortgages should never be allowed to season into QMs, including adjustable-rate mortgages (ARMs) and mortgages with product features that disqualify them from being a QM loan currently (*e.g.,* interest-only and negative-amortization mortgages). With respect to adjustable-rate mortgages, consumer advocate groups expressed concern stating that just because a consumer can remain current during an initial teaser-rate period or during a low-interest rate environment does not mean that the consumer has the ability to repay the loan when the interest rate rises. One coalition of consumer advocate groups noted that consumers may not have the ability to repay interest-only or negative-amortization mortgages after the teaser rate payment period ends and stated that payment shock from higher future payments is inherent in the structure of these mortgage products.

In contrast to industry commenters who argued that allowing loans to season into QMs would promote access to credit and improve market liquidity, consumer advocate groups suggested that providing a QM seasoning definition would not benefit market liquidity and could hurt underserved communities. They asserted that a seasoning rule would prevent creditors from originating loans with certainty about who ultimately bears the credit and liquidity risk and what their litigation risk will eventually be. They further asserted that the uncertainty created by such risks has a greater, negative impact on independent mortgage bankers without large balance sheets that are an important source of credit for underserved communities. One coalition of consumer advocate groups also asserted that a heightened risk of put-backs with mortgages not originated as QMs would create significant liquidity and credit risks for creditors, particularly non-depository creditors important to fully serving the market.

Lastly, the consumer advocate groups challenged the Bureau's authority to amend the definition of QM to provide seasoning as a pathway to QM status, asserting that seasoning would facilitate,

[77] Comment 43(c)(1)–1.ii.A (''The following may be evidence that a creditor's ability-to-repay determination was reasonable and in good faith: *1.* The consumer demonstrated actual ability to repay the loan by making timely payments, without modification or accommodation, for a significant period of time after consummation or, for an adjustable-rate, interest-only, or negative-amortization mortgage, for a significant period of time after recast . . . .'').

not prevent, circumvention or evasion of the statute's ATR requirements. They stated that consumers can resort to extraordinary measures to stay current on mortgage payments to stay in their homes, such as foregoing spending on necessities; drawing down retirement accounts; borrowing money from family and friends; going without food, medicine, or utilities; or taking on other types of debt (such as credit card debt). These commenters stated that, as a result, even mortgages that were not affordable at consummation can perform for a long period of time. The consumer advocate groups further cited examples to show that mortgages can default due to unforeseen events. One coalition of consumer advocate groups noted that the timing of default often reflects broader economic conditions, given the procyclical nature of the mortgage market.

Extension Proposal, General QM Proposal, and Ensuing Final Rules

On June 22, 2020, the Bureau released the Extension Proposal, which would have extended the Temporary GSE QM loan definition to expire on the effective date of final amendments to the General QM loan definition or the date the GSEs cease to operate under conservatorship, whichever comes first.[78] On the same date, the Bureau separately released the General QM Proposal, which proposed amendments to the General QM loan definition.[79] In a final rule issued on October 20, 2020, the Bureau extended the Temporary GSE QM category until the earlier of the mandatory compliance date of final amendments to the General QM loan definition or the date the GSEs cease to operate under conservatorship.[80] In another final rule issued simultaneously with this final rule, the Bureau is amending the General QM loan definition. The General QM Final Rule is discussed in part II.D above.

Seasoned QM Proposal

On August 18, 2020, the Bureau issued a proposed rule to create a new category of QMs, Seasoned QMs, for first-lien, fixed-rate covered transactions that have met certain performance requirements over a 36-month seasoning period, are held in portfolio until the end of the seasoning period, comply with general restrictions on product features and points and fees, and meet certain underwriting requirements (Seasoned QM Proposal). The Seasoned QM Proposal was published in the **Federal Register** on August 28, 2020, with a 30-day comment period.[81] The comment period was later extended briefly and ended on October 1, 2020.[82]

Consumer advocate groups and an organization representing State regulators further asked the Bureau to provide an extension to the comment period of up to an additional 60 days. These commenters cited the complexity of the rule, the concurrent QM rulemakings, and the difficulties presented by the COVID–19 pandemic in support of their request. The Bureau concludes that the comment period (including the brief extension) provided interested stakeholders with sufficient opportunity to comment on the proposal. The Bureau has previously issued other rules of similar complexity pursuant to a 30-day comment period and concludes that the data and analysis supporting the proposal were relatively straightforward for commenters to understand and comment on.

In response to the Seasoned QM Proposal, the Bureau received around 40 comments from consumer advocate groups, industry participants, industry trade associations, other nonprofit organizations, a member of Congress, and others. As discussed in more detail below, the Bureau has considered these comments in adopting this final rule.[83]

IV. Legal Authority

The Bureau is issuing this final rule pursuant to its authority under TILA and the Dodd-Frank Act. Section 1061 of the Dodd-Frank Act transferred to the Bureau the ''consumer financial protection functions'' previously vested in certain other Federal agencies, including the Board of Governors of the Federal Reserve System (Board). The Dodd-Frank Act defines the term ''consumer financial protection function'' to include ''all authority to prescribe rules or issue orders or guidelines pursuant to any Federal consumer financial law, including performing appropriate functions to promulgate and review such rules, orders, and guidelines.'' [84] Title X of the Dodd-Frank Act (including section 1061), along with TILA and certain subtitles and provisions of title XIV of the Dodd-Frank Act, are Federal consumer financial laws.[85]

A. TILA

TILA section 105(a). Section 105(a) of TILA directs the Bureau to prescribe regulations to carry out the purposes of TILA and states that such regulations may contain such additional requirements, classifications, differentiations, or other provisions and may further provide for such adjustments and exceptions for all or any class of transactions that the Bureau judges are necessary or proper to effectuate the purposes of TILA, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.[86] A purpose of TILA is ''to assure a meaningful disclosure of credit terms so that the consumer will be able to compare more readily the various credit terms available to him and avoid the uninformed use of credit.'' [87] Additionally, a purpose of TILA sections 129B and 129C is to assure that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loans and that are understandable and not unfair, deceptive, or abusive.[88] As discussed in the section-by-section analysis below, the Bureau is issuing certain provisions of this final rule pursuant to its rulemaking, adjustment, and exception authority under TILA section 105(a).

TILA section 129C(b)(2)(A)(vi). TILA section 129C(b)(2)(A)(vi) provides the Bureau with authority to establish guidelines or regulations relating to ratios of total monthly debt to monthly income or alternative measures of ability to pay regular expenses after payment of total monthly debt, taking into account the income levels of the borrower and such other factors as the Bureau may determine relevant and consistent with the purposes described in TILA section 129C(b)(3)(B)(i).[89] As discussed in the section-by-section analysis below, the Bureau is issuing certain provisions of this final rule pursuant to its authority under TILA section 129C(b)(2)(A)(vi).

TILA section 129C(b)(3)(A) and (B)(i). TILA section 129C(b)(3)(B)(i) authorizes the Bureau to prescribe regulations that revise, add to, or subtract from the criteria that define a QM upon a finding that such regulations are necessary or proper to ensure that responsible, affordable mortgage credit remains

[78] 85 FR 41448 (July 10, 2020).

[79] 85 FR 41716 (July 10, 2020).

[80] 85 FR 67938 (Oct. 26, 2020).

[81] 85 FR 53568 (Aug. 28, 2020).

[82] 85 FR 60096 (Sept. 24, 2020).

[83] The Bureau also received a number of comments in response to the General QM Proposal that relate to the Seasoned QM Proposal. The Bureau has considered those comments as well in adopting this final rule.

[84] 12 U.S.C. 5581(a)(1)(A).

[85] Dodd-Frank Act section 1002(14), 12 U.S.C. 5481(14) (defining ''Federal consumer financial law'' to include the ''enumerated consumer laws'' and the provisions of title X of the Dodd-Frank Act), Dodd-Frank Act section 1002(12)(O), 12 U.S.C. 5481(12)(O) (defining ''enumerated consumer laws'' to include TILA).

[86] 15 U.S.C. 1604(a).

[87] 15 U.S.C. 1601(a).

[88] 15 U.S.C. 1639b(a)(2).

[89] 15 U.S.C. 1639c(b)(2)(A).

available to consumers in a manner consistent with the purposes of TILA section 129C; or are necessary and appropriate to effectuate the purposes of TILA sections 129B and 129C, to prevent circumvention or evasion thereof, or to facilitate compliance with such sections.[90] In addition, TILA section 129C(b)(3)(A) directs the Bureau to prescribe regulations to carry out the purposes of TILA section 129C(b).[91] As discussed in the section-by-section analysis below, the Bureau is issuing certain provisions of this final rule pursuant to its authority under TILA section 129C(b)(3)(B)(i).

B. Dodd-Frank Act

Dodd-Frank Act section 1022(b). Section 1022(b)(1) of the Dodd-Frank Act authorizes the Bureau to prescribe rules to enable the Bureau to administer and carry out the purposes and objectives of the Federal consumer financial laws, and to prevent evasions thereof.[92] TILA and title X of the Dodd-Frank Act are Federal consumer financial laws. Accordingly, in this final rule, the Bureau is exercising its authority under Dodd-Frank Act section 1022(b) to prescribe rules that carry out the purposes and objectives of TILA and title X and prevent evasion of those laws.

V. Why the Bureau Is Issuing This Final Rule

The Bureau is issuing this final rule to create an alternative pathway to a QM safe harbor to encourage safe and responsible innovation in the mortgage origination market, including for loans that may be originated as non-QM loans but meet certain underwriting conditions, product restrictions, and performance requirements. The Bureau is establishing this alternative definition because it concludes that many loans made to creditworthy consumers that do not fall within the existing QM loan definitions at consummation may be able to demonstrate through sustained loan performance compliance with the ATR requirements.

A. Considerations Related to Access to Responsible, Affordable Credit Discussed in the Proposal

As described in the proposal, a primary objective of the Seasoned QM alternative pathway to a QM safe harbor is to ensure the availability of responsible and affordable credit. Incentivizing the origination of non-QM loans that otherwise may not be made (or may be made at a significantly higher price) due to perceived litigation or other risks, even if a creditor has confidence that it can originate the loan in compliance with the ATR requirements, furthers the objective of ensuring the availability of responsible and affordable credit. The Bureau is concerned that, as discussed in the Assessment Report, the perceived risks associated with non-QM status at consummation may inhibit creditors' willingness to make such loans and thus could limit access to responsible, affordable credit for certain creditworthy consumers.[93] As noted in the proposal, an analysis of rejected applications in the Assessment Report suggested that the January 2013 Final Rule's impact on access to credit among particular categories of consumers did not correlate with traditional indicators of creditworthiness, such as credit score, income, and down payment amount. Moreover, the Assessment Report also found that there was significant variation in the extent to which creditors have tightened credit for non-GSE eligible high DTI loans following the publication of the January 2013 Final Rule. This variation and its persistence in the years following the ATR/QM Rule's issuance suggest that creditors have not developed a common approach to measuring and predicting risk of noncompliance with the ATR/QM Rule, as they have accomplished for other types of risks, such as prepayment and default.[94] For instance, cross-creditor differences in both the level and the change in approval rates of high DTI applications are much larger than, for example, differences in approval rates by FICO category.[95] The lack of uniformity is likely due in part to the difficulties associated with measuring and quantifying the litigation and compliance risk associated with originating non-QM loans. Thus, the Assessment Report concluded that some of the observed effect of the ATR/QM Rule on access to credit was likely driven by creditors' interest in avoiding litigation or other risks associated with non-QM status, rather than by rejections of consumers who were unlikely to repay the loan based on traditional indicators of creditworthiness.[96]

While the proposal acknowledged that the Assessment Report analyzed the impact of the January 2013 Final Rule and its 43 percent DTI limit on access to credit, the proposal noted that specific findings related to the uncertainty of compliance and litigation risk for non-QM loans—and the resulting impact on consumers' access to credit—remain relevant regardless of any amendments to the General QM loan definition.[97] Indeed, while the Bureau anticipated that its General QM Proposal to replace the current 43 percent DTI limit with a price-based approach would increase access to responsible and affordable mortgage credit among consumers with DTI ratios above 43 percent, the proposal expressed concern that compliance uncertainty and litigation risk would still persist for the remaining population of loans originated as non-QM loans at consummation. Furthermore, the proposal noted that the composition of the non-QM market has continued to grow and evolve since the period covered by the Assessment Report. In recent years, the share of non-QM securitizations comprised of loans with a DTI in excess of 43 percent has fallen, while loans based on alternative income documentation has grown to become the largest non-QM subsector, comprising approximately 50 percent of securitized pools in the first half of 2019.[98] As a result, the Bureau preliminarily concluded in the proposal that providing a QM safe harbor to non-QM loans that have demonstrated sustained and timely mortgage payment histories could have a meaningful impact on improving access to credit for creditworthy consumers whose loans fall outside the other QM definitions.

The Bureau proposed to adopt a Seasoned QM definition primarily to encourage creditors to originate more responsible, affordable loans that are not QMs at consummation, and to ensure that responsible, affordable credit is not lost because of legal uncertainty in non-QM status. The Bureau also stated that a Seasoned QM definition could provide incentives for making additional rebuttable presumption QM loans. As explained in the proposal, while the GSEs purchase rebuttable presumption QM loans, and nearly half of manufactured housing originations are rebuttable presumption QM loans, large

[90] 15 U.S.C. 1639c(b)(3)(B)(i).

[91] 15 U.S.C. 1639c(b)(3)(A).

[92] 12 U.S.C. 5512(b)(1).

[93] *See* Assessment Report, *supra* note 47, at 11, 118, 150.

[94] *Id.* at 118, 147, 150.

[95] *Id.* at 147.

[96] *Id.* at 118, 150.

[97] *See* 85 FR 41716 (July 10, 2020).

[98] S&P Global Ratings, *Non-QM's Meteoric Rise is Leading the Private-Label RMBS Comeback* (Sept. 20, 2019), *https://www.spglobal.com/ratings/en/research/articles/190920-non-qm-s-meteoric-rise-is-leading-the-private-label-rmbs-comeback-11159125.* Alternative income documentation includes alternative sources of income verification (*e.g.,* bank statements), which vary from traditional income underwriting forms/documents such as W–2 forms, paystubs, and tax returns. The variation is due to the use of non-traditional sources of documentation, such as for self-employed consumers.

banks tend to originate only safe harbor QM loans. A Seasoned QM definition may provide an additional incentive for large banks to originate rebuttable presumption QM loans that may not be eligible for sale to the GSEs and therefore may not otherwise have been made.

The proposal explained that based on feedback from external stakeholders, the Bureau expected that a Seasoned QM definition may encourage creditors to originate more responsible, affordable loans that are not QMs at consummation, and ensure that creditors do not decide not to make responsible, affordable loans because of legal uncertainty in non-QM status. Comments on the ANPR suggested that allowing performing loans to season into QM status would provide creditors with clarity and certainty by ensuring that creditors would not have to litigate their ATR compliance long after consummation when an extensive record of on-time payments demonstrates that compliance and when default is more likely due to a change in the consumer's circumstances. Not only would allowing performing loans to season into QM status clarify a creditor's litigation risk, but external feedback suggested this could help provide certainty for secondary market participants that might otherwise be unable or unwilling to accept the litigation risk associated with assignee liability for either rebuttable presumption QM or non-QM loans.

The proposal acknowledged that creditors may be uncertain about whether certain loans fall within the existing QM definitions. For example, the U.S. Department of Housing and Urban Development (HUD), the VA, and the USDA have each promulgated QM definitions pursuant to their authority under TILA section 129C(b)(3)(B)(ii), and they have largely set their QM criteria based on eligibility criteria they apply in their respective mortgage insurance or guarantee programs. The proposal noted that a creditor may be uncertain about whether a State court would interpret and apply those criteria to a particular loan in a consumer's TILA section 130(k)[99] foreclosure defense, if the loan's QM status were ever challenged, in the same way the agency would in administering its mortgage insurance or guarantee program. As discussed in the proposal, to the extent that there is ambiguity as to whether a given loan is eligible for a QM safe harbor through other QM definitions, a Seasoned QM definition will provide additional legal certainty by providing an alternative basis for a conclusive presumption of ATR compliance after the required seasoning period.

As discussed in the proposal, to the extent that additional legal certainty provided by a Seasoned QM definition makes creditors more comfortable extending these types of loans in the future, such an effect would not only promote continued access to responsible and affordable credit, but could result in increased access to such credit. While the rationale in the proposal was primarily focused on the non-agency and non-QM markets, the proposal noted that the agency (*i.e.,* GSE and government-insured) mortgage markets in the wake of the 2008 recession can serve as a useful illustration of the chilling effect legal risk and compliance uncertainty can have on origination markets. Access to responsible mortgage credit remained tight for years after the crisis, even in the agency mortgage market in which creditors typically do not bear the credit risk of default.[100] While there is no doubt that the size and scale of the 2008 crisis impacted creditors' willingness to take on credit risk, creditors also imposed additional, more stringent borrowing requirements due to their concerns that they could be forced to repurchase loans as a result of subsequent assertions of non-compliance. This occurred even though creditors believed the loans complied with FHA requirements for mortgage insurance and GSE standards for sale into the secondary markets without the more stringent borrowing requirements. Following GSE and FHA reforms, the proposal noted that access to responsible mortgage credit for GSE and government-insured loans has begun to rebound, with some of the biggest banks considering a return to FHA lending.[101] Similarly, the Bureau noted in the proposal that creditors may originate loans they believe to be QMs at origination, but to the extent any lingering ambiguity remains, the added compliance certainty provided by the Seasoned QM definition could further incentivize creditors to originate these loans at scale.

In addition, the Bureau preliminarily concluded in the proposal that, along with a possible increase in non-QM originations, a Seasoned QM definition might also encourage meaningful innovation and lending to broader groups of creditworthy consumers, especially those with less traditional credit profiles. As described in the proposal, the Bureau anticipates that innovations in technology and diversification of the overall economy will lead to changes in the composition of the job market and labor force, and the Bureau intends for the ATR/QM Rule to remain sufficiently flexible to accommodate and encourage developments in mortgage underwriting to reflect these changes. New technology allows creditors to assess financial information that may not be readily apparent through a traditional credit report, such as a consumer's ability to consistently make on-time rent payments. The use of new tools could broaden homeownership to consumers who may have lacked credit histories with major credit reporting bureaus and so may have been less likely to obtain mortgages at an affordable price or obtain a mortgage at all. Additionally, technology platforms have led to rapid growth in the ''gig economy,'' through which workers earn income by providing services such as ride-sharing and home delivery and through the ability to earn income on assets such as a home. Some workers participate in the gig economy for their sole source of income, while others may do so to supplement their income from more traditional employment. Creditors' methods of assessing consumers' ability to repay mortgages evolve to accommodate these changes, but creditors may be left with some uncertainty as to whether these methods constitute, or can be part of, a reasonable determination of a consumer's ability to repay under the ATR/QM Rule. Accordingly, the Bureau preliminarily concluded in the proposal that allowing an alternative pathway to a QM safe harbor may encourage creditors to lend to consumers with less traditional credit profiles at an affordable price based on an individualized determination of a consumer's ability to repay.

The proposal acknowledged that the extent to which a Seasoned QM definition may increase access to credit would be a function of the size of the eligible loan population that could benefit: The more loans that would be

[99] 15 U.S.C. 1640(k).

[100] Jim Parrot & Mark Zandi, *Opening the Credit Box,* Moody's Analytics & the Urban Inst. (Sept. 30, 2013), *https://www.urban.org/sites/default/files/publication/24001/412910-Opening-the-Credit-Box.PDF.* As an illustration of the tight underwriting requirements, in 2013, the average credit score in the agency market was over 750. This is 50 points higher than the average credit score across all loans at the time, and 50 points higher than the average score among those who purchased homes a decade prior, implying that mortgage origination markets may have over-corrected relative to the economic fundamentals at the time.

[101] *JPMorgan mulls return to FHA-backed mortgages after era of fines,* Am. Banker (Feb. 5, 2020), *https://www.americanbanker.com/articles/jpmorgan-mulls-return-to-fha-backed-mortgages-after-era-of-fines.*

eligible to become Seasoned QMs, the more loans might be made that would not otherwise be made. In determining the length of time that is the appropriate seasoning period, the Bureau considered the rate at which loans terminate, to assess the potential population of loans that would be eligible to benefit from a Seasoned QM definition and thus potentially affect access to credit. Based on the data and analysis presented in part VII of the proposal, the Bureau preliminarily concluded that the majority of eligible non-QM and rebuttable presumption mortgage loans would remain active and thus be eligible to benefit from the seasoning period, across the economic cycle.

B. Considerations Related to Ability To Repay Discussed in the Proposal

The Bureau proposed to introduce an alternative pathway to a QM safe harbor for a new category of Seasoned QMs because it preliminarily concluded that, when coupled with certain other factors, successful loan performance over a number of years appears to indicate with sufficient certainty creditor compliance with the ATR requirements at consummation.

The proposal first noted that the current ATR/QM Rule provides that loan performance can be a factor in evaluating a creditor's ATR determination. Specifically, it provides that evidence that a creditor's ATR determination was reasonable and in good faith may include the fact that the consumer demonstrated actual ability to repay the loan by making timely payments, without modification or accommodation, for a significant period of time after consummation.[102] It explains further that the longer a consumer successfully makes timely payments after consummation or recast,[103] the less likely it is that the creditor's determination of ability to repay was unreasonable or not in good faith. The current ATR/QM Rule also distinguishes between a failure to repay that can be evidence that a consumer lacked the ability to repay at loan consummation, versus a failure to repay due to a subsequent change in the consumer's circumstances that the creditor could not have reasonably anticipated at consummation. Specifically, it states that a change in the consumer's circumstances after consummation (for example, a significant reduction in income due to a job loss or a significant obligation arising from a major medical expense) that cannot be reasonably anticipated from the consumer's application or the records used to determine repayment ability is not relevant to determining a creditor's compliance with the ATR/QM Rule.[104] Thus, the existing regulatory framework supports the relevance of loan performance, particularly during the initial period following consummation, in evaluating a creditor's ATR determination at consummation.

Second, the proposal explained that an approach that takes loan performance into consideration in evaluating ATR compliance is consistent with the Bureau's prior analyses of repayment ability. Because the affordability of a given mortgage will vary from consumer to consumer based upon a range of factors, there is no single recognized metric, or set of metrics, that can directly measure whether the terms of mortgage loans are within consumers' ability to repay.[105] The Bureau's Assessment Report concluded that early borrower distress was an appropriate proxy for the lack of the consumer's ability to repay at consummation across a wide pool of loans. Likewise, in the General QM Proposal and General QM Final Rule, the Bureau focused on an analysis of delinquency rates in the first few years to evaluate whether a loan's price, as measured by the spread of APR over APOR (herein referred to as the loan's rate spread), may be an appropriate measure of whether a loan should be presumed to comply with the ATR provisions. The incorporation of loan performance requirements in a Seasoned QM definition in turn reflects the Bureau's view that across a wide pool of loans, early distress supports an inference that consumers lacked the ability to repay at consummation.

As discussed in the proposal, in general, the earlier a delinquency occurs, the more likely it is due to a lack of ability to repay at consummation than a change in circumstances after consummation that the creditor could not have reasonably anticipated from the consumer's application or the records used to determine repayment ability. However, there is neither an exact period of time after which all delinquencies can be attributed to a lack of ability to repay at consummation, nor an exact period after which no delinquencies can be attributed to a lack of ability to repay at consummation. The Bureau proposed a seasoning period of 36 months based on a range of policy considerations, rather than any singular measure of delinquency, as discussed in the section-by-section analysis of § 1026.43(e)(7)(iv)(C). The Bureau preliminarily decided in the proposal to grant a safe harbor to these loans because 36 months of loan performance, combined with the product restrictions and underwriting requirements as defined in the proposal, appeared to indicate with sufficient certainty creditor compliance with the ATR requirements at consummation. The Bureau acknowledged that some meaningful percentage of non-QM loans may end up delinquent in later years. But, given the increasing likelihood that intervening events meaningfully contributed to such delinquencies, the proposal noted the Bureau does not view delinquency at that point in the lifecycle of a loan product as undermining the presumption of creditor compliance with the ATR requirements at consummation.

The proposal also explained that the current practices of market participants with respect to remedies for deficiencies in underwriting practices also support the Bureau's adoption of a seasoning period to evaluate a creditor's ATR determination. Each GSE generally provides creditors relief from its enforcement with respect to representations and warranties a creditor must make to the GSE regarding its underwriting of a loan. The GSEs generally provide creditors that relief after the first 36 monthly payments if the consumer had no more than two 30-day delinquencies.[106] Similarly, the master policies of mortgage insurers generally provide that the mortgage insurer will not issue a rescission with respect to certain representations and warranties the originating lender made if the consumer had no more than two 30-day delinquencies in the 36 months following the consumer's first payment, among other requirements.[107] These practices, which extend to a significant portion of covered transactions, suggest that the GSEs and mortgage insurers have concluded, based on their experience, that after 36 months of loan performance, a default should not be attributed to underwriting, but rather a change in the consumer's circumstances that the creditor could not have reasonably anticipated from the consumer's application or the records.

[102] Comment 43(c)(1)–1.ii.A.*1*.

[103] Section 1026.43(b)(11) provides a definition of recast.

[104] Comment 43(c)(1)–2.

[105] Assessment Report, *supra* note 47, at 83.

[106] Fed. Hous. Fin. Agency, *Representation and Warranty Framework, https://www.fhfa.gov/PolicyProgramsResearch/Policy/Pages/Representation-and-Warranty-Framework.aspx* (last visited Nov. 30, 2020).

[107] Fannie Mae, *Amended and Restated GSE Rescission Relief Principles for Implementation of Master Policy Requirement #28 (Rescission Relief/Incontestability)* (Sept. 10, 2018), *https://singlefamily.fanniemae.com/media/16331/display.*

Based on these considerations, the Bureau preliminarily concluded in the proposal that a consumer's timely payments for 36 months, in combination with compliance with the product restrictions and underwriting and portfolio requirements in the proposal, indicate that the consumer had the ability to repay the loan at consummation, such that granting of safe harbor QM status to the loan is warranted subject to certain limitations. As discussed in the proposal, the Bureau focused on loans that would be eligible to be Seasoned QMs and that have an interest rate spread in excess of 150 basis points, and therefore would be outside the safe harbor threshold in the General QM Proposal and General QM Final Rule. These non-QMs and rebuttable presumption QMs are the population whose ATR compliance presumption status would be affected by becoming Seasoned QMs. The proposal noted that two-thirds (66 percent) of loans that experience a disqualifying event (*i.e.,* an event that would prevent a loan from becoming a Seasoned QM under the proposed criteria described in the section-by-section analysis of § 1026.43(e)(7)) do so within 36 months, and the rate at which loans disqualify diminishes beyond 36 months. The proposal explained that this may suggest that a failure to repay that occurs more than three years after consummation can generally be attributed to causes other than the consumer's ability to repay at loan consummation, such as a subsequent job loss or other change in the consumer's circumstances that could not reasonably be anticipated from the records used to determine repayment ability. Furthermore, while the proposal acknowledged that it is possible that a consumer could continue making on-time payments for some period of time despite lacking the ability to repay, such as by forgoing payments on other obligations, the Bureau noted that it believes it is unlikely that a consumer could continue doing so for more than three years following consummation, especially in the absence of circumstances that would be disqualifying under the proposal (such as a 60-day delinquency), as explained below in part VI.

Notwithstanding this evidence and these considerations, the proposal acknowledged that a consumer might lack an ability to repay at loan consummation and yet still make timely payments for three years. For example, a consumer could at consummation lack the ability to make a fully amortizing mortgage payment but manage to make interest-only payments in the first three years. The proposal noted that the prospect that at consummation a consumer may lack the ability to repay a loan yet still make timely payments for three years, as well as the potential benefits that a Seasoned QM definition might offer in terms of fostering access to responsible, affordable mortgage credit, would tend to vary depending on the loan characteristics. To address this, the proposal limited the Seasoned QM definition to first-lien, fixed-rate covered transactions that are held in the originating creditor's portfolio (with specified exceptions), satisfy the existing product-feature requirements and limits on points and fees under the General QM loan definition, and meet the underwriting requirements applicable to Small Creditor QMs.

C. Comments in Support of a Seasoned QM Definition

Numerous industry commenters supported the Bureau's proposal to create a pathway to a QM safe harbor for loans that demonstrate a satisfactory performance history, subject to certain product feature restrictions and underwriting requirements. Commenters who supported the Seasoned QM definition generally supported the Bureau's rationale for the proposal, which is described in parts V.A and V.B above. With respect to encouraging responsible innovation and expansion in the non-QM market, commenters supporting the proposal generally agreed that a Seasoned QM definition would provide an important incentive for industry to originate loans that are considered non-QMs at origination, while appropriately balancing access to credit with meaningful consumer protections. With respect to ability to repay, these commenters also generally agreed that a borrower's demonstrated ability to make three years of mortgage payments indicates that the creditor made a reasonable, good faith determination of the borrower's ability to repay at consummation and should therefore warrant a conclusive presumption of compliance.

Individual financial institutions as well as industry trade associations argued that a Seasoned QM definition would increase access to credit without undermining protections for consumers. Some of these commenters stated that a Seasoned QM definition would reduce non-QM litigation exposure and reward responsible underwriting. While industry commenters offered varying assessments of the extent to which this reduction in compliance uncertainty and litigation exposure would increase access to credit, many industry commenters indicated that the proposal would encourage origination of more loans that may be considered non-QM or rebuttable presumption QM at origination without weakening the rule's ability to protect consumers from unaffordable mortgage loans.

Several industry commenters agreed that the proposal would provide a meaningful incentive for creditors to use innovative underwriting techniques to increase access to credit and reduce the costs of credit for the substantial share of the broader population who may lack traditional credit profiles or income sources and therefore struggle to qualify for mortgage credit through GSE and government mortgage programs. These commenters also noted that because these borrowers are more likely to fall outside the GSE and government underwriting guidelines, their loans are also more likely to be higher priced and therefore fall outside of the Bureau's price-based thresholds for determining General QM status. An industry trade association noted that market data show creditors have a lower willingness to originate non-QM and rebuttable presumption QM loans. Examples provided by commenters of these credit-worthy borrowers who have limited credit history include younger consumers without a long credit history, elderly borrowers who have paid down their debts and pay their expenses with cash, and other consumers who may have used more informal means of borrowing in the past. Examples provided of borrowers with non-traditional income include those with income sources that are not reported on W–2 forms who have difficulty qualifying under standard underwriting guidelines due to variable amount and timing of their income, such as ''gig economy'' workers, seasonal employees, and self-employed borrowers.

Three industry commenters supported the proposal but suggested that its impact on access to credit may be marginal. One of these commenters described the proposal as a ''modest, but useful step'' that would bring incremental improvement. Generally, these commenters expressed concern that the risk of litigation would remain because the Seasoned QM definition would not confer safe harbor status at consummation. These commenters indicated that some creditors would be less willing to originate additional loans even if the proposal were finalized, and even if the borrower has the requisite ability to repay based on prudent underwriting practices, given that these loans would lack a QM safe harbor at consummation.

Several commenters stated that access to credit would increase because the proposal would increase marketability to the secondary market of loans that are originated as non-QM or rebuttable presumption QM loans but season into a QM safe harbor, thereby increasing the ability of creditors to access secondary market liquidity to originate new loans. These commenters noted that the secondary market for non-QM loans is less liquid due to litigation and compliance risks as well as the costs of additional due diligence that many secondary market investors require prior to purchase. According to these commenters, eliminating assignee liability and litigation risks related to the ATR/QM Rule for Seasoned QMs that are sold in the secondary market would improve the marketability of these loans and reduce the transaction costs associated with buying and selling Seasoned QMs. These commenters stated that this would have the effect of increasing the number of market participants, in both the primary and secondary markets.

Commenters in support of the proposal also agreed with the Bureau's rationale for proposing a conclusive presumption of compliance with the ATR/QM Rule after three years of demonstrated loan performance. These commenters stated that if a borrower makes timely payments for an extended period of time, any subsequent default cannot reasonably be attributed to a creditor's underwriting or ATR determination at consummation. Some commenters noted that because the legal standard for the ATR/QM Rule requires a creditor to make its ATR determination at consummation, subsequent defaults due to economic disruptions or a change in life circumstances that cannot be attributed to an underwriting or ATR deficiency at the time of consummation.

While these commenters agreed that performance over time is sufficient evidence of a creditor's ATR determination at consummation, they had varying opinions on the necessity of some of the additional consumer protections in the proposal, as discussed in greater detail in part VI below. While industry commenters generally supported maintaining the statutory product restrictions (such as the exclusion for loans with interest-only or negative amortization features, balloon payments, or terms that exceed 30 years), they expressed a range of views on whether ARMs and subordinate-lien loans should be eligible to season into QM status. They also expressed varying opinions on whether the proposed portfolio requirement is a necessary consumer protection or overly restrictive.

D. Comments in Opposition to a Seasoned QM Definition

A number of consumer advocates and other non-profit organizations as well as an academic commenter opposed the Bureau's proposed Seasoned QM definition. These commenters generally expressed concerns over the evidentiary support for the proposed Seasoned QM definition, the Bureau's legal authority, the concept that demonstrated loan performance over an extended period of time can warrant a conclusive presumption of compliance with the ATR/QM Rule, and the impact on minority borrowers. Most of these commenters stated that if the Bureau were to finalize a Seasoned QM definition, the Bureau should retain the underwriting requirements, product restrictions, portfolio requirement, and other consumer protections included in the proposal. A joint comment from a number of non-profit organizations suggested that if the Bureau were to finalize a Seasoned QM definition, the final rule should incorporate a two-tiered approach, such that non-QM loans at consummation could only season into rebuttable presumption QM loans and only loans originated as rebuttable presumption QM loans could season into safe harbor QM loans.

Nearly all commenters that opposed the Seasoned QM definition questioned the Bureau's legal authority to issue a rule that would limit a consumer's private right of action and foreclosure defense for violations of the ATR/QM Rule after three years. Commenters asserted that TILA's statutory requirements allow borrowers to raise a violation of the ATR/QM rule as a defense at any time in response to a foreclosure, and that Congress intended that these claims not be cut off. In addition, they maintained that, by extending the general one-year statute of limitations under TILA to three years for ability-to-repay claims, Congress recognized that it could take consumers a minimum of three years to recognize the right to bring an action against a creditor. Finally, commenters asserted that the performance requirements in the final rule are beyond the Bureau's authority to define QMs because Congress intended to limit the definition of QM to only those conditions that could be determined at or prior to the consummation of a loan. These commenters suggested that the Bureau's proposal is contrary to Congressional intent and exceeds the Bureau's authority.

Many of these commenters also asserted that the Bureau did not provide enough evidentiary support and data analysis demonstrating that Seasoned QMs are the types of high-quality, low-cost loans for which Congress intended the Bureau to exercise its exemption authority. Commenters stated that the proposal could afford a QM safe harbor and a release from risk retention requirements to loans that are higher cost, have high DTIs, and have limited income documentation. These commenters asserted that the analysis in part VII of the proposal demonstrated that a meaningful percentage of loans suffer a disqualifying event after three years and that the proposal's three-year seasoning period is arbitrary. They also maintained that the Bureau's objective to increase access to credit and innovation in the mortgage market is not a sufficient justification absent a clearer explanation of how the proposal advances the statutory objective of affordable and responsible mortgage lending.

One consumer advocate commenter argued that the proposal could have unanticipated disparate impacts on borrowers of color and would likely burden these borrowers with higher mortgage costs without affording them the underwriting and assessment protections that the Dodd-Frank Act sought to provide. The commenter pointed to historical evidence that minority borrowers have been steered into predatory, higher-priced mortgage products, and that the foreclosure crisis preceding the Dodd-Frank Act resulted in a significant loss in housing wealth among minority homeowners. The commenter stated that the proposal would target vulnerable consumers and remove their statutorily provided life-of-loan defense to foreclosure.

Several consumer advocates also stated that the proposal could restrict remedies for high cost loans under the Home Ownership and Equity Protection Act of 1994 (HOEPA).[108] They asserted that the Bureau has not made the necessary case to restrict remedies under HOEPA for violations of HOEPA's ability-to-repay requirements.

Commenters also argued that loan performance should not be equated with ability to repay. They pointed to survey data and anecdotal evidence that many consumers take extraordinary measures to pay an unaffordable mortgage, such as drawing down retirement accounts, foregoing food, medicine, and utilities, or borrowing from relatives and friends. One consumer advocate commenter

[108] Public Law 103–325, tit. I, subtit. B, 108 Stat. 2190 (1994).

cited its survey of housing counselors and attorneys, which showed that 70 percent of respondents reported that their clients had forgone or decreased essential expenses in order to make payments for the first three years. Several commenters also asserted that the proposal is inconsistent with the statutory mandate that ability to repay is determined at origination, and that a change in circumstance (*e.g.,* winning the lottery) whereby a borrower is able to pay a loan that was unaffordable at origination should not relieve creditors of their obligation to conduct a prudent ability-to-repay evaluation at origination. Several consumer advocates also expressed concern that the Seasoned QM definition may restrict the ability of the Bureau and other agencies to conduct supervisory examinations beyond the three-year seasoning period when the loan obtains QM safe harbor status.

Several commenters also questioned the Bureau's use of the GSE representation and warranty framework as a model for the proposal's three-year seasoning period. They stated that the FHFA and GSE analysis is based on an investor's view of the aggregate financial impact on the GSEs' portfolios, as opposed to Congress's objective in enacting the ATR mandate to protect individual consumers from harm. They also noted that the GSE representation and warranty framework includes life-of-loan exclusions for more material defects such as misstatements, misrepresentations, and omissions. Lastly, the commenters pointed out that the GSEs perform post-purchase quality control checks and audits shortly after acquiring the loans and before loans have defaulted, to ensure they are able to require creditors to repurchase defective loans within the three-year sunset. These commenters asserted that the proposal lacked similar quality control checks and exceptions for misconduct and fraud.

Several commenters maintained that the proposal's assessment of the litigation risks associated with originating non-QM loans and the impact on cost of credit are unproven and inconsistent with the Bureau's findings in the January 2013 Final Rule. They noted that Congress has balanced the interest of consumers and creditors over the years, as evidenced by the limitations that TILA's general rules of liability place on possible litigation exposure. They also pointed out that there are practical limitations on litigation exposure for non-compliance with ability-to-repay violations, such as access to a limited supply of legal services and public interest attorneys.

E. The Final Rule

The Bureau is creating a Seasoned QM definition in this final rule because it concludes that providing a pathway to a QM safe harbor for performing non-QM and rebuttable presumption QM loans at consummation will maintain or expand access to responsible and affordable mortgage credit for loans that were originated in compliance with the ATR/QM Rule. The Bureau observed in the January 2013 Final Rule that increased legal certainty may benefit consumers if, as a result, creditors are encouraged to make loans that satisfy the statutory QM criteria, and further, that increased legal certainty may result in loans with a lower cost than would be charged in a context of legal uncertainty.[109] Consistent with that earlier finding, the Bureau finds here that the increased compliance certainty and reduction in litigation risk associated with providing a conclusive presumption of compliance for Seasoned QMs will encourage creditors to lend to consumers whose loans may fall outside of the QM safe harbor at consummation but who nonetheless have the ability to repay. In particular, the Bureau concludes that there are a significant number of creditworthy consumers who are unable to readily obtain mortgage financing because they fall outside of the GSE and government lending guidelines, particularly those with non-traditional credit or income sources and self-employed borrowers. The Bureau also concludes that if combined with certain other factors, successful loan performance over a number of years indicates sufficient certainty to presume that loans were originated in compliance with the ATR/QM Rule.

This final rule provides a conclusive presumption of compliance for loans that are originated as non-QM or rebuttable presumption QM loans, that meet certain performance criteria and portfolio requirements over the seasoning period of at least 36 months, and that satisfy certain product restrictions, points-and-fees limits, and underwriting requirements. Specifically, the Seasoned QM definition is limited to fixed-rate, first-lien mortgages that also satisfy the product-feature requirements and limits on points and fees under the General QM loan definition. Under the final rule, creditors are required to consider the consumer's DTI ratio or residual income, income or assets other than the value of the dwelling, and debts and verify the consumer's income or assets other than the value of the dwelling and the consumer's debts, using the same consider and verify requirements established for General QMs in the General QM Final Rule. The final rule generally requires the original creditor or purchasing institution to hold the loan in portfolio until the end of the seasoning period, except that it permits a single whole-loan transfer, as further described in the section-by-section analysis of § 1026.43(e)(7)(iii) below.

The Bureau adopts a Seasoned QM definition because it concludes that the definition strikes the best balance between the competing consumer protection and access-to-credit considerations described herein. Specifically, the Bureau concludes that, if coupled with other consumer protections, a seasoning period of at least 36 months provides a sufficient length of time to conclusively presume that a creditor reasonably determined a consumer's ability to repay at the time of consummation, while promoting continued access to credit and incentivizing creditors to make certain loans that may not have otherwise been made in the absence of potentially greater ability-to-repay compliance certainty.[110] As discussed in further detail in the section-by-section analysis of § 1026.43(e)(7)(ii), the Bureau concludes that, for loans that meet the eligibility requirements to season into a QM safe harbor, it is reasonable to attribute any subsequent default after the 36-month seasoning period to a change in economic conditions or consumer circumstances that a creditor could not reasonably have anticipated from the consumer's application or the records used to determine repayment ability rather than to a failure by the creditor to make a reasonable

[109] 78 FR 6408, 6507 (Jan. 30, 2013).

[110] This final rule, like the Assessment Report and the General QM Final Rule, reflects a shared underlying rationale that early payment difficulties indicate higher likelihood that the consumer may have lacked ability to repay at origination, and that delinquencies occurring soon after consummation are more likely indicative of a consumer's lack of ability to repay than later-in-time delinquencies. The Assessment Report and the General QM Final Rule measure early distress as whether a consumer was ever 60 days or more past due within the first two years after origination. The performance requirements for Seasoned QMs reflect the Bureau's consideration of this measure of early distress, but also its view of what requirements strike the best balance between facilitating responsible access to the credit in question while assuring protection of the consumer interests covered by ATR requirements. Similarly, the Bureau recognizes that the definition of delinquency and performance requirements in § 1026.43(e)(7) differ in some respects from the measure of early distress used in the Assessment Report, but concludes that this final rule's definition and performance requirements further the specific purposes of this final rule for the reasons explained in the section-by-section analyses of § 1026.43(e)(7)(ii) and (iv)(A) below.

determination of ability to repay at consummation.

The Bureau concludes that the Seasoned QM definition will maintain or expand access to credit for non-QM and rebuttable presumption QM loans that otherwise may not have been made due to perceived litigation or compliance risks, even if the creditor has confidence that it could originate the loan in compliance with the ATR requirements. Indeed, many industry commenters specifically indicated in their comments that they anticipated that the proposal would do so. The Bureau concludes that the Seasoned QM definition will also facilitate innovation in underwriting in the non-QM market to better serve consumers with non-traditional credit profiles, allow for more flexibility to adapt to future changes in the work force and technology, and better support emerging research and technologies into alternative mechanisms to assess a consumer's ability to repay, such as cash flow underwriting. Several commenters noted that the impacts on access to credit are uncertain or unproven given these loans would be consummated without a conclusive presumption of compliance, and that therefore uncertainty and legal risk will persist with respect to these loans. The Bureau acknowledges that not every creditor may seek to expand their product offerings as a result of this final rule, but the Bureau nonetheless concludes the final rule will further its policy objectives, as many industry commenters indicated in their comments.

Furthermore, the Bureau concludes that the objective of increasing access to responsible non-QM lending is of particular importance in light of recent contractions in that segment of the market. As described in the proposal, the non-QM market has been further reduced by the recent economic disruptions associated with the COVID–19 pandemic, with most mortgage credit now available in the form of loans that obtain QM status at consummation. During periods of economic stress, investors seek safer assets such as cash and government-backed securities. Because non-QM loans are generally perceived as riskier by investors in part for the reasons discussed in the proposal, the decreases in originations related to the pandemic were particularly acute in the non-QM sector of the mortgage market. While the non-QM market has begun to recover, recent events have illustrated how investors' perception of risk—including uncertainty over compliance and litigation risk—can exacerbate the impacts on access to credit, particularly during periods of economic distress. The Bureau concludes that the Seasoned QM definition in this final rule should help counteract these impacts.

The Bureau acknowledges the concerns expressed by some commenters that the Seasoned QM definition will limit a consumer's foreclosure-related defense by recoupment or set off for alleged violations of the ATR requirements after three years under TILA section 130(k).[111] These commenters suggested that availability of this defense indicates that Congress contemplated that consumers would default later than the ability-to-repay three-year statute of limitations period, and intended for consumers who defaulted at any point to be able to raise the creditor's failure to reasonably determine ability to repay as a defense against foreclosure.

The Bureau disagrees with this understanding of TILA section 130(k) and its implications regarding the scope of the Bureau's authority to define a QM. TILA section 130(k) authorizes a consumer to assert a violation of the ATR requirements in section 129C(a) as a defense in the event of judicial or nonjudicial foreclosure, without regard for the time limit on a private action for damages for such a violation. With TILA section 130(k), Congress provided consumers with a degree of relief from the finality generally associated with a statute of limitations period so that they may assert a violation of TILA section 129C(a) as a matter of defense by recoupment or set off in connection with judicial or nonjudicial foreclosure. TILA section 130(k) thus conditions a consumer's actual right to obtain recoupment or set off on a finding that a creditor in fact violated TILA section 129C(a). But, on this matter of substantive law, TILA section 129C(b)(1) expressly provides that a creditor may presume its compliance with TILA section 129C(a) with respect to any mortgage that falls within the definition of a QM. TILA section 129C(b)(2) and (3) grant the Bureau broad authority to revise, add to, or subtract from the criteria defining a QM for purposes of presuming compliance with TILA section 129C(a). Consistent with that authority, the final rule concludes that—if coupled with certain product restrictions and other factors—successful loan performance over a number of years indicates with sufficient certainty creditor compliance with TILA section 129C(a).

Consequently, creditors of loans satisfying the final rule's requirements may lawfully invoke the loan's status to show that there is no ''violation'' for the purposes of TILA section 130(k), just as creditors properly originating loans under other QM categories have been able to do since the effective date of the January 2013 Final Rule. Consumers in turn may respond with evidence and argument establishing that a loan in fact does not satisfy the final rule's requirements to qualify as a Seasoned QM. But the Bureau does not read TILA section 130(k) to preserve for consumers a right to assert a violation of TILA section 129C(a) when the Bureau has determined as a matter of substantive law to conclusively presume the loan's compliance with TILA section 129C(a).[112] This regulatory regime, under which QM status may affect a consumer's ability to raise a defense to foreclosure under TILA section130(k), is precisely what Congress intended and the introduction of a Seasoned QM category in no way alters that regime.

The Bureau also disagrees with the concerns expressed by some commenters that the performance requirements in the final rule are beyond the Bureau's authority to define QMs because Congress intended to limit the definition of QM to only those conditions that could be determined before a loan is consummated. These commenters specifically point to the statutory QM provisions, which they argue are conditions directly related to underwriting that can be met prior to

[111] One academic commenter indicated that under the proposal, loans could season during pending litigation, cutting off affirmative claims filed within the statute of limitations period. Acknowledging this possibility, the Bureau nonetheless concludes that the final rule should not be revised to prevent that possibility in all cases. The reasoning underlying this final rule—that satisfaction of the seasoning requirements for the duration of the seasoning period demonstrates that the creditor made a reasonable determination of the consumer's ability to repay at consummation—is not any less applicable when litigation is initiated during the seasoning period, but the consumer continues making on-time payments for the remainder of the seasoning period. The mere filing of the lawsuit itself does not indicate the creditor failed to make a reasonable determination of ability to repay at consummation. Accordingly, the Bureau does not believe there is a good reason to create and administer potentially complex rules managing the effects that various court or litigant actions should have on the seasoning period.

[112] Likewise, the Bureau disagrees with commenters who suggest that the final rule is a statute of limitations or statute of repose. In contrast to statutes of limitations or repose—which limit liability based solely on the passage of time measured *after* a certain event occurs—the performance requirements in the final rule are based on a series of events, periodic payments, that must occur before a loan can season. Moreover, whereas a statute of limitations or repose cuts off a consumer's right to raise a claim for reasons unrelated to the merits of a claim, the performance requirements in the final rule are probative of the merits of a section 129C(a) violation.

consummation, unlike the performance requirements in the final rule.

The Bureau concludes that nothing in the text of TILA section 129C(b) prevents the Bureau from creating categories of QMs that are based on conditions that can be observed after a loan is consummated. The Bureau instead believes that QM conditions that are indicative of creditor compliance with the ATR requirements at consummation, regardless of when they are satisfied, are consistent with the text and structure of TILA section 129C(b). Congress only required that additional QM conditions be necessary or proper to ensure responsible, affordable mortgage credit remains available to consumers in a manner consistent with the purposes of TILA section 129C or necessary and appropriate to effectuate the purposes of TILA sections 129B and 129C. And although some of the statutory QM conditions focus on underwriting,[113] most of these statutory conditions instead focus on prohibiting risky product features that may be probative of a creditor's non-compliance with the ATR requirements, such as interest-only loans, or loan terms that exceed 30 years.[114] The final rule goes beyond these statutory QM conditions with performance requirements and restrictions on creditors that, like the statutory product restrictions, are probative of whether a consumer was offered and received a loan on terms that the creditor reasonably determined reflected the consumer's ability to repay the loan. The Bureau does not believe that Congress intended to allow certain QM conditions that provide prospective evidence of creditor compliance with the ATR requirements but prohibit conditions that instead provide retrospective evidence of the same.[115] Thus, while a creditor undoubtedly must determine a consumer's ability to repay at consummation, there is no indication that Congress intended to preclude or limit the Bureau's authority to defer its decision on the merits of presuming such compliance until the occurrence of later-in-time events.

Commenters' insistence that QM status be determined at consummation is an approach the Bureau could have taken in the final rule. But the Bureau concludes that it has as much authority under TILA to grant QM status at consummation and to later withdraw it based on later-in-time events, on the one hand, as it does to condition the same presumption on the occurrence of post-consummation events, so long as the later-in-time event is probative of or related to creditor compliance with the ATR requirements at consummation.[116] The Bureau further concludes that the wait-and-see approach adopted in this final rule is the most reasonable approach in this context. As already noted above, consumer distress during the first three years of a loan supports an inference that consumers lacked the ability to repay at consummation. By withholding the presumption during the first three years of a loan, the final rule ensures that consumers are afforded greater consumer protections by being able to assert their rights without being forced to first default on their loan. The final rule also ensures that creditors benefit from the presumption only once there is enough evidence that the creditor made a reasonable ATR determination at consummation. The Bureau thus concludes that creating a new category of QMs for seasoned loans that meet the statutory QM requirements and other appropriate criteria is consistent with the Bureau's authority under and the purposes of TILA sections 129B and 129C.

The Bureau recognizes the concerns expressed by many consumer advocate commenters that loan performance does not always equate to ability to repay and that consumers may take extraordinary measures to make payments on their mortgage. The Bureau acknowledged in the proposal that it is possible that a consumer could continue making on-time payments for some period of time despite lacking the ability to repay by foregoing payments on other obligations, and that a meaningful percentage of non-QM loans may end up delinquent in later years. However, as discussed in part VIII below, in general, the later a delinquency occurs, the less likely it is due to a lack of ability to repay at consummation rather than a change in circumstance after consummation that the creditor could not have reasonably anticipated from the consumer's application or the records at consummation.[117]

Furthermore, the Bureau finds that the final rule's inclusion of additional consumer protections mitigates the risks cited by commenters that a consumer lacks ability to repay but is nonetheless able to make timely payments for at least 36 months. As discussed further in the section-by-section analysis of § 1026.43(e)(7)(i)(A) and (B), this final rule's product restrictions prohibit loan features such as adjustable rates, interest-only payments, and negative amortization that can lead to sharp payment increases shortly after consummation, and limits Seasoned QM status to first-lien loans. The final rule also generally requires the creditor or first purchaser to hold the loan in portfolio until the end of the seasoning period. As discussed in the section-by-section analysis of § 1026.43(e)(7)(iii), this requirement gives creditors a greater incentive to make responsible and affordable loans at consummation by ensuring that the creditor or first purchaser of the loan bears the risk if the loan defaults during the seasoning period.

Lastly, the final rule maintains the requirement that a creditor consider the consumer's DTI ratio or residual income, income or assets other than the value of the dwelling, and debts and verify the consumer's income or assets other than the value of the dwelling and the consumer's debts. As discussed in the section-by-section analysis of § 1026.43(e)(7)(i)(B), this final rule aligns the Seasoned QM consider and verify requirements with that of the General QM Final Rule, which will help to ensure that loans for which the creditor has not made a good faith determination of the consumer's ability to repay do not season into a QM safe harbor.

A number of commenters expressed concern that the Bureau lacks the evidentiary support and data analysis to demonstrate that Seasoned QMs are safe and high-quality loan products. These concerns are addressed in greater detail in part VIII below. The Bureau concludes that the delinquency and foreclosure analysis presented in part VIII, combined with the consumer protections discussed above, provides sufficient support to presume compliance with the ATR requirements when a loan performs over a seasoning period of at least 36 months and meets the other requirements in this final rule.

Some consumer advocate commenters expressed concern about the potential effects of this final rule given that minority homeowners historically have had higher-priced mortgage products relative to White consumers with similar credit characteristics. These commenters stated that this final rule could result in unanticipated disparate

[113] 15 U.S.C. 1639c(b)(2)(A)(iii) through (v).

[114] 15 U.S.C. 1639c(b)(2)(A)(i) through (ii), (vii) through (viii); *see* 78 FR 6408, 6503–04 (Jan. 30, 2013).

[115] *See* 78 FR 6408, 6462 (Jan. 30, 2013).

[116] For example, if justified by the merits, the final rule could have mimicked the QM category adopted by Congress in EGRRCPA and granted QM status to all covered loans at consummation with the caveat that the loan could lose QM status if a borrower fails the performance requirements. 15 U.S.C. 1639c(b)(2)(F)(ii)(I)(aa), (iii).

[117] As illustrated in Figure 3 in part VIII below, the Bureau estimates that nearly two-thirds of loans that experience delinquencies that would prevent a loan from becoming a Seasoned QM under the final rule do so within 36 months, and the rate at which loans disqualify diminishes beyond 36 months.

impacts on borrowers of color if they lose their set off or recoupment rights after three years. The Bureau recognizes that some creditors may violate Federal fair lending laws by charging certain borrowers higher prices on the basis of race or national origin compared to non-Hispanic White borrowers with similar credit characteristics, and the Bureau affirms its commitment to consistent, efficient, and effective enforcement of Federal fair lending laws.[118] The Bureau further emphasizes that the QM criteria, including the Seasoned QM definition added by this final rule, do not create an inference or presumption that a loan satisfying the QM criteria is compliant with any Federal, State, or local anti-discrimination laws that pertain to lending. A creditor has an independent obligation to comply with the Equal Credit Opportunity Act[119] and Regulation B,[120] and an effective way for a creditor to minimize and evaluate fair lending risks under these laws is by monitoring its policies and practices and implementing effective compliance management systems.

This final rule's performance criteria, product restrictions, underwriting criteria, and portfolio requirements are designed to ensure that Seasoned QMs do not contain risky product features identified in TILA section 129C(b)(2) and that they are underwritten with appropriate attention to consumers' resources and obligations. Moreover, as discussed in the section-by-section analysis of § 1026.43(e)(7)(i)(E), this final rule also clarifies that the Seasoned QM definition does not extend to high-cost mortgages covered by HOEPA, thus excluding the highest cost loans on the market from eligibility for Seasoned QM status.

As discussed above, commenters expressed differing views on the utilization of the GSE representation and warranty framework as an analog or model for the Seasoned QM definition. Many industry commenters supported the Seasoned QM definition, citing consistency with the industry standards set by the GSE representation and warranty framework and the mortgage insurers' rescission relief policies. One consumer advocate commenter, on the other hand, pointed out several differences relative to the Seasoned QM definition and questioned the utility of the GSE model as a precedent, as described above. The Bureau acknowledges that the GSE framework may have been developed based on an aggregate analysis of the GSE portfolio to provide certainty for lenders by clarifying when a loan may be subject to repurchase. However, the GSE framework nonetheless illustrates a recognition based on experience by both GSEs and lenders that after 36 months of strong loan performance, a default should fairly be attributed to a change in consumer's circumstances that the creditor could not have reasonably anticipated from the consumer's application or the records at consummation or other cause besides that of the lender's underwriting. The FHFA's stated purpose for the framework is to ''provide more certainty for lenders, facilitate greater liquidity to the primary market, and help increase access to credit without compromising safety and soundness.''[121] Furthermore, although commenters are correct that the GSE representation and warranty framework includes life-of-loan exclusions for more material defects, this final rule includes many important and consumer-protective loan-level requirements, some of which are not required under the GSE framework, such as the portfolio requirement and exclusion for adjustable-rate mortgages.

The Bureau also acknowledges that the GSEs have developed a robust post-purchase quality control and audit framework to identify loan defects typically within a few months of consummation and well within the 36-month representation and warranty relief sunset. However, the Bureau concludes that this final rule's portfolio requirement provides similar incentives for creditors to originate loans with ability to repay. That is, if a financial institution purchases a loan from a creditor that it is required to hold in portfolio for 36 months, that purchaser has similar incentives to perform loan-level due diligence as the GSEs given the purchaser, like the GSEs, bears the credit risk of default. The prospect of being able to sell the loan only if it passes that due diligence creates a strong incentive for the creditor to employ rigorous underwriting at consummation akin to post-purchase quality control and audit under the GSE representation and warranty framework. In fact, given the size and scale of the GSEs' credit risk transfer programs whereby much of the risk of default for a large portion of the GSEs' guaranteed portfolio is syndicated to private market participants,[122] purchasers that are required to hold the loan in portfolio for 36 months may have an even greater incentive to ensure the loans they purchase will perform well than the GSEs do. Moreover, like the GSEs, financial institutions have similar remedies to require the originating creditor to repurchase loans that were consummated with defects, including a lack of ability to repay. For these reasons, the Bureau has decided to base its adoption of a 36-month seasoning period in part on the 36-month representation and warranty sunset for GSE loans.

Some consumer groups suggested that the Bureau's concern regarding potential and perceived litigation risks associated with originating non-QM loans and their impact on access to credit is inconsistent with the Bureau's findings in the January 2013 Final Rule and unproven. However, as discussed in the proposal, the analysis that the Bureau subsequently published in the Assessment Report found that some of the observed effect of the January 2013 Final Rule on access to credit was likely driven by creditors' interest in avoiding litigation or other risks associated with non-QM status, rather than by creditors' determinations that consumers were unlikely to repay the loan based on traditional indicators of creditworthiness.[123] Many industry commenters also reaffirmed the impact of compliance uncertainty and litigation risk on creditors' willingness to originate non-QM and rebuttable presumption QM loans as well as the secondary market's willingness to purchase them. They asserted that the conclusive presumption of compliance for a Seasoned QM after 36 months would result in higher secondary market liquidity for these loans as investors are extended the liability protections that QM status provides. Based on its Assessment Report, external feedback to the Bureau, and the comments, the Bureau has concluded that many secondary market investors are unable or unwilling to accept the litigation risk associated with assignee liability particularly with respect to non-QM loans, which has in turn contributed to the relative scarcity of non-QM loans.

[118] *See, e.g.,* Consent Order, *U.S.* v. *Bancorpsouth Bank,* No. 1:16–cv–00118, ECF No. 8 (N.D. Miss. July 25, 2016), *https://files.consumerfinance.gov/f/documents/201606_cfpb_bancorpSouth-consent-order.pdf* (joint action for discriminatory mortgage lending practices including charging African-American customers more for certain mortgage loans than non-Hispanic White borrowers with similar loan qualifications).

[119] 15 U.S.C. 1691 *et seq.*

[120] 12 CFR part 1002.

[121] Fed. Hous. Fin. Agency, *Representation and Warranty Framework, https://www.fhfa.gov/PolicyProgramsResearch/Policy/Pages/Representation-and-Warranty-Framework.aspx* (last visited Nov. 30, 2020).

[122] Fed. Hous. Fin. Agency, *Credit Risk Transfer, https://www.fhfa.gov/PolicyProgramsResearch/Policy/Pages/Credit-Risk-Transfer.aspx* (last visited Nov. 30, 2020).

[123] *See* Assessment Report, *supra* note 47, at 118, 147, 150.

VI. Section-by-Section Analysis

1026.43 Minimum Standards for Transactions Secured by a Dwelling

43(e) Qualified Mortgages

43(e)(1) Safe Harbor and Presumption of Compliance

Section 1026.43(e)(1) currently provides that a creditor that makes a QM loan receives either a conclusive or rebuttable presumption of compliance with the repayment ability requirements of § 1026.43(c), depending on whether the loan is a higher-priced covered transaction. Section 1026.43(e)(1)(i) currently provides that a creditor that makes a QM loan that is not a higher-priced covered transaction is entitled to a safe harbor from liability under the ATR provisions. The Bureau proposed to add § 1026.43(e)(1)(i)(B), identifying Seasoned QMs as a separate category of QMs for which a creditor receives a conclusive presumption of compliance with ATR requirements, regardless of whether the loan is a higher-priced covered transaction. The proposal would have redesignated current § 1026.43(e)(1)(i) as § 1026.43(e)(1)(i)(A). To conform with these changes, the Bureau proposed to revise comment 43(e)(1)–1 to add a reference to proposed § 1026.43(e)(7). The Bureau also proposed to make a technical correction to comment 43(e)(1)–1 to add references to § 1026.43(e)(5) and (6). The Bureau further proposed to remove the first sentence of comment 43(e)(1)(i)–1, which would have been duplicative of regulatory text, and to redesignate that comment as comment 43(e)(1)(i)(A)–1. For the reasons discussed below, the Bureau is finalizing the amendments to § 1026.43(e)(1) and related commentary as proposed, with minor technical changes to the proposed commentary.

The Bureau's Proposal

TILA section 129C(b) provides that loans that meet certain requirements are ''qualified mortgages'' and that creditors making QMs ''may presume'' that such loans have met the ATR requirements. As discussed above, TILA does not specify whether the presumption of compliance means that the creditor receives a conclusive presumption or a rebuttable presumption of compliance with the ATR provisions. The Bureau concluded in the January 2013 Final Rule that the statutory language is ambiguous and does not mandate either interpretation and that the presumptions should be tailored to promote the policy goals of the statute.[124] In the January 2013 Final Rule, the Bureau interpreted TILA to provide for a rebuttable presumption of compliance with the ATR provisions but used its adjustment and exception authority under TILA to establish a conclusive presumption of compliance for loans that are not ''higher-priced covered transactions.'' [125]

In the January 2013 Final Rule, the Bureau identified several reasons why the performance of QMs that are not higher-priced loans could suggest consumers have the ability to repay and should receive a safe harbor.[126] The Bureau noted that the QM requirements would ensure that the loans do not contain certain risky product features and are underwritten with careful attention to consumers' DTI ratios.[127] The Bureau also noted that a safe harbor would provide greater legal certainty for creditors and secondary market participants and might promote enhanced competition and expand access to credit.[128] The Bureau noted that it was not possible to define by a bright-line rule a class of mortgages for which each consumer would have the ability to repay.[129]

In the Seasoned QM Proposal, the Bureau preliminarily concluded that, in conjunction with the QM statutory and other requirements in proposed § 1026.43(e)(7), a loan's satisfaction of portfolio and seasoning requirements provides sufficient grounds for supporting a conclusive presumption that the creditor made a reasonable determination that the consumer had the ability to repay, in compliance with the ATR requirements. The Bureau also preliminarily concluded that satisfaction of the seasoning requirements—in particular, the fact that the consumer made timely payments for the duration of the seasoning period—supports the inference that the consumer was offered and received a loan on terms that the creditor reasonably determined reflected the consumer's ability to repay the loan. The Bureau noted that proposed § 1026.43(e)(7) would require creditors to comply with TILA requirements applicable to QMs and minimum underwriting requirements. The Bureau also noted that the proposed requirements would ensure that the loans do not contain risky product features identified in TILA section 129C(b)(2), the loans are underwritten with attention to consumers' resources and obligations, and the conclusive presumption would be available to creditors only after the loans have performed for a substantial period of time.

In the proposal, the Bureau stated that providing creditors with an alternative pathway to greater ATR compliance certainty for loans that satisfy the criteria set forth in proposed § 1026.43(e)(7) may result in greater access to responsible, affordable mortgage credit. For example, creditors may be more willing to maintain or expand access to credit to consumers with non-traditional income or a limited credit history, or to employ innovative methods of assessing financial information, as these loans could season into safe harbor QMs with satisfactory performance. In addition, the Bureau noted in the proposal that, similar to the Small Creditor QM definition and the pathway to QM status provided in EGRRCPA section 101, the Seasoned QM definition would include a requirement for the creditor to hold the loan in portfolio. Finally, in the proposal the Bureau preliminarily concluded that, in combination with the other Seasoned QM requirements in proposed § 1026.43(e)(7), the proposed portfolio requirement would provide an added layer of assurance that the Seasoned QM definition would encourage responsible non-QM lending and creditors would not make unaffordable loans.

The Bureau sought comment on all aspects of the proposal that would be applicable to determining whether, by meeting the requirements of § 1026.43(e)(7) for a particular loan, a creditor has demonstrated that the consumer had a reasonable ability to repay the loan according to its terms and the loan should be accorded safe harbor QM status. In addition, the Bureau sought comment on whether there are other approaches to providing QM status to seasoned loans that would better accomplish the Bureau's objectives.

Comments Received

The Bureau received a number of comments relating to the proposed amendments to § 1026.43(e)(1). As discussed in greater detail in part V above, industry commenters generally supported the proposed amendments to § 1026.43(e)(1), and consumer advocate commenters generally opposed the proposed amendments to § 1026.43(e)(1).

Industry commenters generally expressed support for the Bureau's preliminary conclusion that a loan's satisfaction of the proposed seasoning requirements provides sufficient

[124] 78 FR 6408, 6511 (Jan. 30, 2013).

[125] *Id.* at 6514.

[126] *Id.* at 6511.

[127] *Id.*

[128] *Id.*

[129] *Id.*

grounds for supporting a conclusive presumption that the creditor made a reasonable determination that the consumer had the ability to repay, in compliance with the ATR requirements. These commenters stated that the proposed amendments to § 1026.43(e)(1), and the proposal in general, retain consumer safety considerations and legal protections consistent with the existing ATR/QM Rule. Industry commenters agreed that providing safe harbor QM status to loans that season would incentivize responsible non-QM lending, while maintaining market stability. Several of these commenters noted that safe harbor QM status would provide legal certainty to loans that previously did not receive safe harbor QM status at consummation, and thereby remove risk associated with originating non-QM loans.

Consumer advocate commenters opposed the Bureau's proposal, cautioning that a seasoning period is not an adequate basis for determining compliance with the ATR requirements. They also suggested that ATR determinations should remain a case-by-case determination, because there may be situations in which borrowers remain current on their loan for 36 months but did not have an ability to repay the loan at consummation.

A joint comment from a number of consumer advocates and other non-profit organizations suggested that the Bureau adopt a two-tiered approach to seasoning instead of providing all loans that season with safe harbor QM status. A two-tiered approach would allow non-QM loans to season into rebuttable presumption QM loans, and loans that are originated as QMs under other QM categories to season into safe harbor QM loans, after meeting the requirements for seasoning.

Some commenters made suggestions to modify proposed § 1026.43(e)(7), which are discussed and addressed in the section-by-section analysis of § 1026.43(e)(7) below.

The Final Rule

For the reasons discussed above and, pursuant to its authority under TILA section 105(a) as discussed below, the Bureau is finalizing § 1026.43(e)(1) as proposed. As finalized, § 1026.43(e)(1) provides that loans meeting the Seasoned QM requirements in § 1026.43(e)(7) obtain a conclusive presumption of compliance with the repayment ability requirements of § 1026.43(c).

Since the January 2013 Final Rule, the Bureau has noted that a safe harbor provides greater legal certainty for creditors and secondary market participants and may promote enhanced competition and expand access to credit. As discussed in part V above, the Bureau concludes that a Seasoned QM definition will encourage creditors to originate more responsible, affordable loans that are not QMs at consummation, and to ensure that responsible, affordable credit is not lost because of legal uncertainty in non-QM status.

The Bureau declines to adopt the two-tiered approach that some commenters suggested that would provide only rebuttable presumption status to Seasoned QMs originated as non-QM loans. Adopting such a two-tiered approach would lessen the prospect of legal certainty for loans originated as non-QMs and could thereby undermine the final rule's primary objective, which is to promote continued and potentially increased access to responsible and affordable credit by incentivizing the origination of non-QM loans that otherwise may not be made. The Bureau recognizes that it has decided in the General QM Final Rule not to provide a similar safe harbor at consummation to General QMs priced 1.5 percentage points or more above APOR. That decision reflects a balancing of the relevant consumer protection and access-to-credit considerations in view of the Bureau's findings that (i) such loans have higher delinquency rates than lower-priced loans and (ii) it lacks sufficient evidence to suggest that having provided those loans with only a rebuttable presumption of ATR compliance since the January 2013 Final Rule took effect has resulted in a significant disruption of access to responsible, affordable mortgage credit. A balance of the same statutory considerations leads the Bureau to a different conclusion with respect to Seasoned QMs. The final rule's performance requirements will ensure that only loans with strong early performance receive the Seasoned QM safe harbor. When coupled with the final rule's other requirements, the Bureau concludes that loans meeting the Seasoned QM definition will have demonstrated that the creditor made a reasonable determination of the ability to repay, regardless of the loan's QM or non-QM status at origination. The Bureau also recognizes that the prospect of a safe harbor three years after origination will provide a stronger incentive to originate loans that will be non-QM for at least the first three years than the prospect of a rebuttable presumption three years after origination. In light of these considerations, the Bureau concludes that extending Seasoned QMs a safe harbor strikes the best balance between consumer protection and ensuring continued access to responsible, affordable credit. The Bureau is therefore finalizing the amendments to § 1026.43(e)(1) and related commentary as proposed, with minor technical changes to the proposed commentary.

Legal Authority

The Bureau is revising § 1026.43(e)(1) pursuant to its adjustment authority under TILA section 105(a) to establish a conclusive presumption of compliance for loans that meet the criteria in proposed § 1026.43(e)(7). The Bureau concludes that providing a safe harbor for seasoned loans is necessary and proper to facilitate compliance with and to effectuate the purposes of section 129C and TILA, including to assure that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loans. The Bureau also concludes that providing such a safe harbor is consistent with the Bureau's authority under TILA section 129C(b)(3)(B)(i) to prescribe regulations that revise, add to, or subtract from the criteria that define a QM upon a finding that such regulations are necessary or proper to ensure that responsible, affordable mortgage credit remains available to consumers in a manner consistent with the purposes of this section, necessary and appropriate to effectuate the purposes of TILA sections 129B and 129C, to prevent circumvention or evasion thereof, or to facilitate compliance with such sections.

43(e)(2) Qualified Mortgage Defined—General

Section 1026.43(e)(2) sets out the general criteria for meeting the definition of a QM and provides exceptions for QMs covered by requirements set out in other specific paragraphs in § 1026.43(e). The Bureau proposed a conforming amendment to § 1026.43(e)(2) to include a reference to § 1026.43(e)(7), which sets out the requirements applicable to Seasoned QMs and is described in the section-by-section analysis below. The Bureau did not receive comments specifically relating to proposed § 1026.43(e)(2). To conform with the other amendments in this final rule, the Bureau is adopting the amendment to § 1026.43(e)(2) as proposed.

43(e)(7) Qualified Mortgage Defined—Seasoned Loans

The Bureau is adding § 1026.43(e)(7) to define a new category of QMs, Seasoned QMs, for covered transactions

that meet certain criteria. The Bureau concludes that providing creditors an alternative path to a QM safe harbor for these types of loans is likely to increase creditors' willingness to make these loans despite their ineligibility for a QM safe harbor at consummation. The Bureau recognizes that there is some risk that a consumer can lack an ability to repay at loan consummation yet manage to make timely payments for the seasoning period defined in § 1026.43(e)(7)(iv)(C) of this final rule. The Bureau concludes that such risk, as well as the potential benefits that a Seasoned QM might offer in terms of fostering access to responsible, affordable mortgage credit, would vary depending on the loan characteristics. To mitigate this risk, the Bureau is limiting Seasoned QMs to first-lien covered transactions that satisfy the other requirements in § 1026.43(e)(7), as explained below.

The Bureau concludes that adding a definition of Seasoned QM for covered transactions, as well as establishing the requirements for Seasoned QMs in § 1026.43(e)(7) discussed below, is consistent with the Bureau's authority under TILA section 129C(b)(3)(B)(i) to prescribe regulations that revise, add to, or subtract from the criteria that define a qualified mortgage upon a finding that such regulations are necessary or proper to ensure that responsible, affordable mortgage credit remains available to consumers in a manner consistent with the purposes of TILA section 129C, necessary and appropriate to effectuate the purposes of TILA sections 129B and 129C, to prevent circumvention or evasion thereof, or to facilitate compliance with such sections. The Bureau finds that the provisions in § 1026.43(e)(7) establishing criteria to define a Seasoned QM are necessary or proper to ensure that responsible, affordable mortgage credit remains available to consumers in a manner consistent with and appropriate to the purposes of TILA sections 129B and 129C, which include assuring that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loan and that responsible, affordable mortgage credit remains available to consumers. In particular, the Bureau has concluded that establishing a QM safe harbor pathway for seasoned loans is likely to increase creditors' willingness to make additional loans that do not qualify for a QM safe harbor at origination, or to make such loans with better pricing. The Bureau finds that limiting Seasoned QMs to covered transactions that meet the requirements in § 1026.43(e)(7) provides assurance that those loans that may qualify for Seasoned QM status after the seasoning period are made to creditworthy consumers.

In addition, TILA section 129C(b)(3)(A) provides the Bureau with authority to prescribe regulations to carry out the purposes of the qualified mortgage provisions—to ensure that responsible, affordable mortgage credit remains available to consumers in a manner consistent with the purposes of TILA section 129C. TILA section 105(a) also provides authority to the Bureau to prescribe regulations to carry out the purposes of TILA, including the purposes of the qualified mortgage provisions, and states that such regulations may contain such additional requirements, classifications, differentiations, or other provisions and may further provide for such adjustments and exceptions for all or any class of transactions that the Bureau judges are necessary or proper to effectuate the purposes of TILA, to prevent circumvention or evasion thereof, or to facilitate compliance therewith. TILA section 129C(b)(2)(A)(vi) provides authority to the Bureau specifically to establish guidelines or regulations relating to ratios of total monthly debt to monthly income or alternative measures of ability to pay regular expenses after payment of total monthly debt, taking into account the income levels of the borrower and such other factors as the Bureau may determine are relevant and consistent with the purposes described in TILA section 129C(b)(3)(B)(i). Accordingly, the Bureau exercises its authority under TILA sections 105(a), 129C(b)(2)(A)(vi), (3)(A), and (3)(B)(i) to adopt § 1026.43(e)(7) for the reasons discussed above and below.

43(e)(7)(i) General

The Bureau proposed adding § 1026.43(e)(7) to define a new category of QMs for covered transactions that meet certain criteria. The Bureau proposed as initial criteria under § 1026.43(e)(7)(i) that Seasoned QM status would be available for first-lien covered transactions that meet certain additional requirements. Additional proposed requirements were set out generally in § 1026.43(e)(7)(i)(A) through (D) and included restrictions on product features and points and fees, as well as certain underwriting and performance requirements. The proposed criteria and related public comments are discussed below.

In its proposal the Bureau tentatively concluded that limiting Seasoned QMs to first-lien covered transactions that satisfy the other requirements in proposed § 1026.43(e)(7) recognizes both the risk of consumers lacking an ability to repay at consummation and the potential benefits of fostering access to responsible, affordable mortgage credit through a Seasoned QM category. This final rule adopts in the introductory text for § 1026.43(e)(7)(i) the requirement that a Seasoned QM be a first-lien covered transaction as proposed.

Comments Received

A significant number of industry commenters and industry trade associations requested that the Bureau extend Seasoned QM eligibility to subordinate liens that otherwise meet the criteria. Several of these commenters noted that closed-end subordinate liens are included within the broader scope of requirements in § 1026.43. One industry commenter stated that its subordinate liens have better repayment and lower delinquencies than the overall first-lien industry and noted that the demand for cash-out subordinate-lien loans may grow as consumers looking to equity as a source of funds in a future, higher-interest-rate environment also want to retain the advantage of current, historically low rates on the remaining balance of their first-lien mortgages. Although two industry commenters suggested generally that the Bureau could make extension of Seasoned QM eligibility to subordinate liens more acceptable by tailoring the performance requirements for subordinate liens, the commenters did not provide specific suggestions. Commenters supporting extension of Seasoned QM eligibility to subordinate liens stated that doing so would encourage innovation, reduce litigation risk, and expand access to credit. An industry commenter, without elaboration, expressly supported limiting Seasoned QMs to first-lien loans, while a consumer advocate commenter stated that, if a Seasoned QM definition is finalized, the loan characteristics included in the proposal to limit the scope of the definition should be retained, even though those characteristics would not adequately protect consumers.

The Final Rule

For the reasons stated below, the Bureau adopts in § 1026.43(e)(7)(i) the requirement that a Seasoned QM be a first-lien covered transaction, as proposed. The Bureau continues to recognize, as it did in the proposal, that the potential risks and benefits of a Seasoned QM category will tend to vary depending on loan characteristics. The Bureau is exercising its discretionary

authority to establish an additional way in which covered transactions can achieve qualified mortgage status under the ATR requirements of TILA and Regulation Z. However, it is not apparent that extending Seasoned QM eligibility to subordinate lien loans can be done in a manner that improves access to credit without introducing unnecessary complexity in application.[130] Subordinate-lien loans may be an example of loans with an elevated risk of showing timely payments even when a consumer lacks ability to repay. A consumer may make on-time payments on the second-lien loan but fail to make payments on the first-lien loan because the consumer is unable to afford the combination of the two periodic payments and the second-lien payment is often smaller than the first-lien payment.[131] In light of the significant changes being made in the General QM Final Rule, the Bureau concludes that limiting Seasoned QM status to first-lien transactions will provide an opportunity for the market to gain experience with how access to credit and consumer ability-to-repay protections will be affected by both the portfolio and performance criteria in the new Seasoned QM definition and the revised underwriting requirements and other criteria in the General QM Final Rule. This experience could help inform any future changes to the Seasoned QM criteria that may be in accordance with the purposes of TILA.

The Bureau notes, as it did in the proposal, that loans that satisfy another QM definition at consummation also could be Seasoned QMs, as long as the requirements of § 1026.43(e)(7) are met.[132] A loan that becomes a Seasoned QM after seasoning might have been eligible as a QM at consummation under the General QM, Small Creditor QM, or EGRRCPA QM definitions. Although the various QM categories may overlap, each QM category is based on a particular set of factors that support a presumption that the creditor at consummation complied with the ATR requirements, and each QM category imposes requirements of varying degrees of restrictiveness relative to others. For example, EGRRCPA section 101 provides a presumption of compliance starting at consummation and is available only to insured depository institutions and insured credit unions with assets below $10 billion who hold those loans in portfolio, except that transfer of the loans is permitted in certain limited circumstances. QM status under EGRRCPA section 101 is available to both fixed and variable rate mortgages, as well as subordinate-lien loans, and section 101 also does not impose any requirements on post-consummation loan performance. The Seasoned QM category established in this final rule, by contrast, is not limited by creditor size, and is available only for fixed-rate, first-lien loans that meet a portfolio requirement, and only after a seasoning period during which the loans must meet performance requirements. The Bureau concludes that the Seasoned QM category and the EGRRCPA QM category, therefore, identify unique and discrete factors that, for different reasons, support a presumption of creditor compliance with the ATR requirements. The Bureau similarly concludes that because each QM category is based on a distinct set of factors that support a presumption of compliance with ATR requirements, it is possible for some transactions to fall within the scope of multiple QM categories. Accordingly, the Bureau determines that it is appropriate to exercise its authority under TILA sections 105(a), 129C(b)(2)(A)(vi), (3)(A), and (3)(B)(i) to make the Seasoned QM definition available to any first-lien covered transaction that meets the requirements in § 1026.43(e)(7), including transactions that might be eligible at consummation for the General QM loan definition, the Small Creditor QM definition, or the EGRRCPA QM definition.

43(e)(7)(i)(A)

The Bureau proposed to add § 1026.43(e)(7)(i)(A) which would limit the Seasoned QM definition to fixed-rate mortgages with fully amortizing payments. Proposed § 1026.43(e)(7)(i)(A) would have applied the definition of fixed-rate mortgage set out in § 1026.18(s)(7)(iii). Section 1026.18(s)(7)(iii) defines fixed-rate mortgage as a transaction secured by real property or a dwelling that is not an adjustable-rate mortgage or a step-rate mortgage.[133] In addition, proposed § 1026.43(e)(7)(i)(A) would have applied the definition of fully amortizing payments set out in § 1026.43(b)(2). Section 1026.43(b)(2) defines fully amortizing payments as a periodic payment of principal and interest that will fully repay the loan amount over the loan term.

Proposed comment 43(e)(7)(i)(A)–1 would have clarified that a covered transaction that is an adjustable-rate mortgage or a step-rate mortgage would not be eligible to become a Seasoned QM. Proposed comment 43(e)(7)(i)(A)–2 would have clarified that loans could become Seasoned QMs only if the scheduled periodic payments on them do not require a balloon payment to fully amortize the loan within the loan term. Proposed comment 43(e)(7)(i)(A)–2 also would have clarified that the requirement that a Seasoned QM have fully amortizing payments does not prohibit a qualifying change, as defined in the proposal, that is entered into during or after a temporary payment accommodation in connection with a disaster or pandemic-related national emergency.[134]

The Bureau adopts § 1026.43(e)(7)(i)(A) and comments 43(e)(7)(i)(A)–1 and –2 as proposed, except that comment 43(e)(7)(i)(A)–2 is revised to clarify that § 1026.43(e)(7)(i)(A) does not prohibit a qualifying change that is entered into during or after a temporary payment

[130] The Bureau currently has limited data to use in analyzing the interaction of first- and subordinate-lien loans and how that interaction affects the consumers' ability to repay those mortgages over time. As discussed in part VIII below, the primary data source relating to loan performance that the Bureau has relied upon in the Seasoned QM Proposal and this final rule is the National Mortgage Database (NMDB), which does not include subordinate-lien mortgages. The NMDB data include de-identified performance information for a nationally representative 5 percent sample of active first-lien mortgages. *See* Bureau of Consumer Fin. Prot., *Sources and Uses of Data at the Bureau of Consumer Financial Protection* at 55–56 (Sept. 2018), *https://files.consumerfinance.gov/f/documents/bcfp_sources-uses-of-data.pdf;* Robert B. Avery *et al., National Mortgage Database Technical Report 1.2,* at 1 (Nat'l Mortg. Database, Bureau of Consumer Fin. Prot., and Fed. Housing Fin. Agency, Technical Report Series, 2017), *https://www.fhfa.gov/PolicyProgramsResearch/Programs/Documents/NMDB-Technical-Report_1.2_10302017.pdf.*

[131] For example, a 2012 New York Federal Reserve Bank study noted that among consumers who are seriously delinquent on their first-lien loans for more than a year and have a second-lien loan, about 20 to 30 percent of consumers are current on their second-lien loans. The authors suggested possible explanations for why some consumers remain current on their subordinate-lien loans even a year beyond a continuing delinquency on their first-lien loan, including that (1) consumers may choose to pay as many bills as possible each month so will prioritize smaller bills over first-lien mortgages with likely larger payments; and (2) consumers may strategically default on first-lien loans in order to qualify for targeted modification programs. Donghoon Lee *et al.,* Fed. Reserve Bank of New York, *A New Look at Second Liens* (Staff Report No. 569) (Aug. 2012), *https://www.newyorkfed.org/medialibrary/media/research/staff_reports/sr569.pdf.*

[132] 85 FR 53568, 53581–82 (Aug. 28, 2020).

[133] As applicable to the definition of fixed-rate mortgage, § 1026.18(s)(7)(i) defines adjustable-rate mortgage as a transaction for which the APR may increase after consummation, and § 1026.18(s)(7)(ii) defines step-rate mortgage as a transaction for which the interest rate will change after consummation, and the rates that will apply and the periods for which they will apply are known at consummation.

[134] Qualifying changes are discussed more fully below in the section-by-section analysis of § 1026.43(e)(7)(iv).

accommodation in connection with a disaster or pandemic-related national emergency, even if the qualifying change involves a balloon payment or lengthened loan term.

Comments Received

Some industry commenters recommended amending the proposed criteria to permit ARMs to become Seasoned QMs, with a couple of these commenters suggesting that the seasoning period begin from the date of the new payment when the interest rate first adjusts. One industry commenter suggested that the Bureau could draft the final rule in a way that would extend eligibility to ARMs at least for purposes of relieving securitizers of separate risk retention requirements on those loans, so as to allow resultant cost savings to be passed on to consumers at origination.[135] Other industry commenters and a number of consumer advocate commenters supported the proposal's limitation to fixed-rate loans. Consumer advocate commenters that were not supportive of adding a Seasoned QM definition generally nonetheless supported excluding from any final rule adjustable-rate and balloon features, which they described as exacerbating the risks of unaffordable and irresponsible lending. One industry commenter supportive of the limitation to fixed-rate loans stated that the General QM loan definition should be applied to ARMs because payments can increase over time beyond the proposed seasoning period.

Commenters generally supported the Bureau's proposal to allow only loans with fully amortizing payments to become Seasoned QMs. Several industry and industry trade association commenters, however, requested that the Bureau clarify that the restriction on balloon payments does not affect a loan's eligibility for Seasoned QM status if the loan is restructured to include a balloon payment as part of a qualifying change that is entered into during or after a temporary payment accommodation in connection with a disaster or pandemic-related national emergency.

The Final Rule

For the reasons stated below, the Bureau adopts § 1026.43(e)(7)(i)(A) as proposed. The final rule limits Seasoned QMs to fixed-rate mortgages, excluding ARMs. ARMs typically have an introductory interest rate that is applicable for several years. The introductory interest rate for a typical ARM could be in place for some or all of the seasoning period and could extend beyond the seasoning period. After the introductory interest rate expires, the interest rate adjusts periodically and could increase through the life of the loan.

The Bureau concludes that a consumer's payment history immediately after consummation of an ARM would not be a reliable indicator of whether at consummation the creditor reasonably determined the consumer's continuing ability to repay the loan after any interest rate adjustment, which could increase the consumer's periodic payment amount. In addition, because an ARM may continue to reset periodically after the first interest rate reset date, even a seasoning period that begins on the first reset date would not necessarily be sufficient to assure a consumer's ability to repay after the seasoning period. Given this possibility for increases in payment amounts in later years, therefore, timely payments during the seasoning period are not as strong of an indicator on an ARM as they are on a fixed-rate mortgage of the consumer's ability to repay at the time of consummation. Although a few commenters provided suggestions concerning how the Bureau might provide some Seasoned QM eligibility to ARMs, the suggestions were only general in nature and did not include analyses that would support modification of the proposal. The Bureau therefore is not extending eligibility for the new Seasoned QM category to ARMs.

Similarly, the Bureau remains concerned that, as a general matter, the ability of a consumer to stay current on mortgage payments during the seasoning period would not be reliable as an indicator that at consummation a consumer had the ability to meet balloon payment obligations beyond the seasoning period. In this final rule, the Bureau is not extending eligibility for the new Seasoned QM category to loans that do not provide for fully amortizing payments. As highlighted by several commenters, however, the Bureau understands that, in instances of financial hardship, including during the current COVID–19 pandemic, creditors and consumers often agree to restructure loans to defer delinquent amounts and create a balance due at maturity or payoff of the loan. As suggested by these commenters, the Bureau is revising proposed comment 43(e)(7)(i)(A)–2 to clarify that the general Seasoned QM criteria set out in § 1026.43(e)(7)(i)(A) do not prohibit a qualifying change that is entered into during or after a temporary payment accommodation in connection with a disaster or pandemic-related national emergency, even if the qualifying change involves a balloon payment or lengthened loan term. Qualifying changes are discussed in more detail in the section-by-section analysis of § 1026.43(e)(7)(iv)(B), below.

43(e)(7)(i)(B)

TILA section 129C(b)(1) provides a presumption of compliance with ATR requirements if a loan is a qualified mortgage. TILA section 129C(b)(2)(A) defines a qualified mortgage as a loan that includes general restrictions on product features and points and fees and meets certain underwriting requirements. Regulation Z § 1026.43(e)(2) codifies these criteria in the Bureau's definition of a General QM. In the Seasoned QM Proposal, the Bureau proposed adding § 1026.43(e)(7)(i)(B) to extend to Seasoned QMs the same general restrictions on product features and points and fees that exist under the General QM and Small Creditor QM definitions, and to impose the same or similar requirements to consider and verify certain consumer information as part of the underwriting process.[136] Proposed comment 43(e)(7)(i)(B)–1 stated that a loan that complies with the consider and verify requirements of any other qualified mortgage definition would be deemed to comply with the consider and verify requirements applicable to a Seasoned QM.

For the reasons described below, the Bureau adopts § 1026.43(e)(7)(i)(B) as proposed, except that the criteria relating to prohibited product features, points-and-fees cap, and requirements to consider and verify certain consumer

[135] The commenter noted that the definition of qualified residential mortgage (QRM) used by other Federal regulatory agencies to exempt securities from Dodd-Frank Act section 941 risk retention requirements is limited by the Bureau's definition of QM. An industry trade association also addressed the separate QRM requirements but suggested only that the Bureau should work with other regulators to reform assignee liability and develop a mechanism that enables investors to put back loans with defects at origination.

[136] Proposed § 1026.43(e)(7)(i)(B) would have incorporated by cross-reference the QM requirements set out for Small Creditor QMs in § 1026.43(e)(5)(i)(A) and (B). Those Small Creditor QM requirements generally cross-referenced the existing General QM requirements in § 1026.43(e)(2), except for the requirements in paragraph (e)(2)(vi) of that section, which established a DTI limit. In the Seasoned QM Proposal, the Bureau noted that it had recently proposed certain conforming changes to § 1026.43(e)(5)(i)(A) and (B) in the General QM proposal. 85 FR 53568, 53583 n.120 (Aug. 28, 2020). As discussed above, the Bureau is issuing this final rule simultaneously with the General QM Final Rule.

information are established by direct cross-reference to the relevant General QM requirements in § 1026.43(e)(2), as amended by the General QM Final Rule. The Bureau has decided not to adopt proposed comment 43(e)(7)(i)(B)–1 because, with the revisions made to § 1026.43(e) in the General QM Final Rule and this final rule, the comment is unnecessary and could be confusing.

Comments Received

Additional Criteria, Generally. Commenters generally agreed that only loans with QM product protections should be allowed to season. Some of those commenters objected to the addition of a Seasoned QM definition—with one consumer advocate commenter stating that the additional loan features are not a bulwark against improvident lending—but stated that if the rule is adopted, the additional required characteristics in § 1026.43(e)(7)(i)(A) through (D) should be retained. An industry trade association stated that the product restrictions and continuance of underwriting requirements, along with performance requirements, provide sufficient assurance of ATR compliance. Another industry trade association noted that aligning the product features and underwriting requirements of different kinds of QMs is appropriate and avoids inappropriately incentivizing any particular category of QMs.

Product and Points-and-Fees Restrictions. A few commenters addressed particular aspects of the Seasoned QM criteria that the Bureau proposed to adopt by cross-reference to other QM requirements. Several industry commenters requested that the Bureau clarify that limiting the Seasoned QM definition to loans with terms not exceeding 30 years does not affect a loan's eligibility for Seasoned QM status when the loan is restructured to include a longer repayment period as part of a qualifying change that is entered into during or after a temporary payment accommodation in connection with a disaster or pandemic-related national emergency. One industry commenter recommended that the limit on points and fees be eliminated, while another supported including the limit in the proposal. One industry trade association advocated generally to include only points and fees paid directly by the consumer in the calculation of the 3 percent cap, and another stated that the calculation should exclude fees paid to affiliated service providers. An academic commenter expressed concern that the proposal did not address separate Dodd-Frank Act prepayment penalty restrictions and requested that the Bureau affirm the applicability of those restrictions.

Underwriting Requirements. Several commenters referenced and incorporated the comments they had submitted on the consider and verify requirements in the General QM Proposal and indicated that the requirements in the General QM and Seasoned QM rules should be aligned. Comments on the underwriting requirements generally were consistent between the General QM Proposal and the Seasoned QM Proposal. Commenters widely recognized the importance of the consider and verify requirements in underwriting a QM loan. An industry trade association supported the proposal's avoidance of using the appendix Q methodology for calculating consumer income and debts and commented that underwriting requirements should provide flexibility to allow for innovation. An industry trade association noted a concern that the final language should not inadvertently introduce a reasonableness standard for the DTI ratio through application of the § 1026.43(c)(7) calculation requirement. Some consumer advocate commenters cautioned that lax underwriting requirements, especially if in combination with relaxed product features, would not comply with TILA and would not be consistent with congressional intent. On the other hand, commenters noted that alignment of underwriting requirements and product features among different QM categories would help ensure these requirements do not create an incentive to make one type of QM loan rather than another.

The Final Rule

For the reasons stated below, the Bureau adopts in § 1026.43(e)(7)(i)(B) the proposed prohibited product features and points and fees and underwriting requirements as part of the Seasoned QM definition. In this final rule, however, the Bureau is adopting those additional criteria by direct cross-reference to the provisions in § 1026.43(e)(2)(i) through (v) of the General QM loan definition, rather than by indirectly cross-referencing the same requirements as adopted in § 1026.43(e)(5)(i)(A) and (B) for Small Creditor QMs, as the Bureau had proposed.[137] The General QM Final Rule issued simultaneously with this final rule revises the General QM loan definition. As a result of these changes, the Bureau concludes that referencing the General QM criteria directly in § 1026.43(e)(7)(i)(B) is preferable. The General QM criteria will be widely used by creditors in connection with General QMs, and creditors will be able to apply those criteria consistently in connection with Seasoned QMs.

In addition to applying the previously established criteria, discussed above, that a Seasoned QM be a first-lien covered transaction with a mortgage that has a fixed rate and fully amortizing payments, applying the relevant criteria in § 1026.43(e)(2)(i) through (v) will mean that a covered transaction can qualify as a Seasoned QM only if:

1. The covered transaction provides for regular periodic payments that are substantially equal;
2. There is no negative amortization and no interest-only or balloon payment;
3. The loan term does not exceed 30years;
4. The total points and fees generally do not exceed 3 percent of the loan amount; and
5. The creditor considers the consumer's DTI ratio or residual income, income or assets other than the value of the dwelling, and debts and verifies the consumer's income or assets other than the value of the dwelling and the consumer's debts.[138]

The Bureau concludes that these additional criteria deriving from the statutory definition of QM best assure that consumers have a reasonable ability to repay their Seasoned QMs. With few exceptions, commenters did not raise issues about whether these criteria should be applied to Seasoned QMs and were supportive of their inclusion. As discussed above, in response to commenter requests the Bureau is revising and adopting comment 43(e)(7)(i)(A)–2 to clarify that § 1026.43(e)(7)(i)(A) does not prohibit a qualifying change that is entered into during or after a temporary payment accommodation in connection with a disaster or pandemic-related national emergency, even if the qualifying change involves a balloon payment or lengthened loan term.

The Bureau declines to remove or adjust the requirement for Seasoned QMs to meet the points-and-fees cap as set out in § 1026.43(e)(2)(iii) of the General QM loan definition. Only one

[137] The Bureau did not propose to adopt in this final rule any DTI limit, pricing threshold, or similar requirement applicable under § 1026.43(e)(2)(vi) to covered transactions in the General QM loan definition. The Small Creditor QM definition also does not include any such criteria.

[138] In addition, because § 1026.43(e)(7)(i)(B) incorporates the requirements of § 1026.43(e)(2)(iv), the underwriting for the loan must use a payment schedule that fully amortizes the loan over the loan term and takes into account the monthly payment for mortgage-related obligations.

commenter recommended that the points-and-fees cap be eliminated for Seasoned QMs, and the commenter did not provide supporting rationale or data. Changes recommended by a few commenters relate to a calculation methodology for points and fees that is beyond the scope of this rule. The Bureau also declines to revise the proposal to address the statutory prepayment penalty restrictions added separately by the Dodd-Frank Act and codified in § 1026.43(g).[139] Those restrictions continue to apply in accordance with that section and are not affected by the addition of a Seasoned QM definition that includes a requirement for a seasoning period of at least 36 months.[140]

By incorporating the requirements of § 1026.43(e)(2)(iv) and (v), this final rule implements the QM definition requirements in TILA section 129C(b)(2)(A)(iii) and (iv). TILA section 129C(b)(2)(A)(iii) includes a requirement for verifying and documenting the income and financial resources relied upon to qualify the obligors on the loan. For a fixed-rate QM, TILA section 129C(b)(2)(A)(iv) requires in part that the underwriting process take into account all applicable taxes, insurance, and assessments. The Bureau also finds that incorporation of the requirements in § 1026.43(e)(2)(v) is authorized by TILA section 129C(b)(2)(A)(vi), which permits, but does not require, the Bureau to adopt guidelines or regulations relating to DTIs or alternative measures of ability to pay regular expenses after payment of total monthly debt.

In the General QM Final Rule issued separately today, the Bureau modifies the requirements for General QMs relating to consideration of the consumer's DTI ratio or residual income, income or assets other than the value of the dwelling, and debts and verification of the consumer's income or assets other than the value of the dwelling and the consumer's debts. The Bureau is adopting those same requirements for Seasoned QMs in this final rule. As such, it should be clear that, in defining Seasoned QMs as a new category of QMs, the Bureau is not substituting performance requirements applicable during a seasoning period for the underwriting requirements applicable at or before consummation. Rather, the Bureau concludes that a sustained period of successful payments, combined with underwriting requirements and product restrictions, supports presuming that the creditor complied with ATR requirements at consummation and made loans that warrant QM status. Unlike other QM definitions that confer QM status upon consummation, though, the Seasoned QM definition confers QM status only after the consumer makes on-time payments, with limited exceptions, for at least 36 months.

The Bureau continues to believe that sufficient consideration of a consumer's DTI ratio or residual income, income or assets other than the value of the dwelling, and debts is fundamental to any determination of ability to repay. Neither the General QM Final Rule nor this final rule requires that creditors apply specific DTI ratios or pricing thresholds in their underwriting criteria in order for their loans to be eligible for QM status. Stakeholders are encouraged to review the section-by-section analyses of § 1026.43(e)(2)(v) and (v)(A) and (B) in the General QM Final Rule, as well as the regulatory text and accompanying commentary for those sections, for a more complete discussion of the consider and verify requirements as they are being incorporated in this final rule.

The General QM Final Rule requires a creditor to consider the consumer's DTI ratio or residual income and to consider and verify the debt and income used to calculate DTI or residual income as part of the General QM loan definition. When this final rule and the General QM revisions take effect, creditors will no longer be required to consider and verify this information in accordance with complex rules set out as appendix Q to Regulation Z.[141] Instead, to comply with the revised General QM consider requirements, a creditor is required to take into account income, assets, debt obligations, alimony, child support, and monthly DTI ratio or residual income in its ATR determination.

The revised General QM requirements do not prescribe how a creditor must take these factors into account, but a creditor must maintain written policies and procedures for how it takes into account the factors and retain documentation showing how it took into account the factors for a given loan. The General QM Final Rule also does not impose a particular standard or threshold applicable to the requirement that a creditor calculate and consider DTI or residual income, and it includes commentary to make clear that creditors have flexibility in how they consider income or assets, debt obligations, alimony, child support, and monthly DTI ratio or residual income.[142] With the revisions made by the General QM Final Rule to the General QM loan definition, as adopted in the Seasoned QM definition, for purposes of determining the consumer's monthly DTI or residual income, the consumer's monthly payment on the covered transaction is calculated in accordance with § 1026.43(e)(2)(iv).

Creditors are also required to verify income and debt consistent with the general ATR standard.[143] Creditors will receive a safe harbor for compliance with the verification requirements if they comply with verification standards in manuals specified in the General QM Final Rule, as well as with revised versions of those manuals that are substantially similar.[144] The General QM Final Rule also provides a safe harbor for compliance with the verification standards to creditors that ''mix and match'' the verification standards in the specified manuals. The General QM Final Rule discusses that permitting creditors to mix and match standards for verifying income, assets, debt obligations, alimony, and child support from each of the manuals would provide creditors with greater flexibility without undermining consumer protection. Further, in the General QM Final Rule, the Bureau encourages stakeholders, including groups of stakeholders, to develop additional verification standards that it could review for inclusion in the verification safe harbor.

The Bureau's primary objective in providing the new Seasoned QM definition is to increase access to responsible and affordable credit by incentivizing the origination of non-QM loans for which creditworthy consumers have an ability to repay, but that may not otherwise be eligible for QM status for various reasons. The Bureau notes that the proposal included proposed

[139] Dodd-Frank Act section 1414, adding TILA section 129C(c), 15 U.S.C. 1639c(c).

[140] Pursuant to § 1026.43(g)(1), a covered transaction must not include a prepayment penalty unless: (1) The prepayment penalty is otherwise permitted by law; and (2) the transaction: (A) has an annual percentage rate that cannot increase after consummation; (B) is a qualified mortgage under § 1026.43(e)(2), (4), (5), (6), or (f); and (C) is not a higher-priced mortgage loan, as defined in § 1026.35(a).

[141] *See* 12 CFR part 1026, appendix Q. The effective date of the General QM Final Rule is 60 days after publication in the **Federal Register**, although creditors will not have to comply with the revised requirements until July 1, 2021. The effective date of this final rule is discussed in part VII below.

[142] *See* comment 43(e)(2)(v)(A)–2 in the General QM Final Rule.

[143] *I.e.,* consistent with § 1026.43(c)(3) (debt, alimony, and child support) and (4) (income and assets).

[144] The General QM Final Rule provides the verification safe harbor in connection with specified provisions of the GSE, FHA, VA, and USDA underwriting manuals.

comment 43(e)(7)(i)(B)–1 as a possible clarification that a loan that complies with the consider and verify requirements of any other QM definition also would have complied with the consider and verify requirements in the Seasoned QM definition. In the proposal the Bureau also requested comment on whether the final rule should cross-reference the consider and verify requirements for General QMs on which the General QM Proposal had requested comment. For the reasons discussed above, this final rule adopts the revised General QM consider and verify requirements, which the Bureau expects will facilitate consistent use in connection with Seasoned QMs, so the Bureau is not finalizing proposed comment 43(e)(7)(i)(B)–1.

43(e)(7)(i)(C) and (D)

The Bureau proposed § 1026.43(e)(7)(i)(C) to include in the Seasoned QM criteria that covered transactions would have to meet certain performance requirements set out in detail in § 1026.43(e)(7)(ii). The Bureau proposed § 1026.43(e)(7)(i)(D) to include in the Seasoned QM criteria that covered transactions would also have to meet certain portfolio requirements set out in detail in § 1026.43(e)(7)(iii).

The Bureau adopts § 1026.43(e)(7)(i)(C) and (D) as proposed. The Bureau discusses the final performance requirements and related public comments more fully in the section-by-section analysis of § 1026.43(e)(7)(ii) below. The Bureau discusses the final portfolio requirements and related public comments more fully in the section-by-section analysis of § 1026.43(e)(7)(iii) below.

43(e)(7)(i)(E)

Prior to the enactment of the Dodd-Frank Act, HOEPA amended TILA to add a prohibition against originating a high-cost mortgage without regard to a consumer's repayment ability, as more specifically set out in TILA section 129(h).[145] The Dodd-Frank Act created a new ATR requirement for mortgage loans within TILA, as discussed above, but did not amend the HOEPA ability-to-repay provision relating specifically to high-cost mortgages. Regulation Z currently defines high-cost mortgage [146] and implements the HOEPA ability-to-repay requirement for closed-end high-cost mortgages by providing that a creditor must comply with the ATR/QM Rule's repayment ability requirements set forth in § 1026.43.[147] The proposal did not explicitly address whether Seasoned QM status would extend to high-cost mortgages subject to HOEPA, but the Bureau is adding § 1026.43(e)(7)(i)(E) to clarify that it does not.

Three consumer advocate commenters noted that the proposal did not explicitly address whether Seasoned QM status would extend to high-cost mortgages subject to HOEPA. These commenters also asserted that the Bureau had not made the necessary case to restrict remedies under HOEPA for violations of HOEPA's ability-to-repay requirement.

The Bureau's purpose in this rulemaking is not to change the ability-to-repay requirement under HOEPA, which governs high-cost mortgages that constitute a very small percentage of the overall mortgage market.[148] Although HOEPA gives the Bureau the authority to make certain exemptions from HOEPA's requirements,[149] the Bureau has not sought to use that authority in this rulemaking. To clarify the scope of the final rule, the Bureau is adding § 1026.43(e)(7)(i)(E), which excludes high-cost mortgages as defined in § 1026.32(a) from the Seasoned QM definition.

43(e)(7)(ii) Performance Requirements

Proposed § 1026.43(e)(7)(ii) set forth the following proposed performance criteria that a covered transaction must meet to be a Seasoned QM under proposed § 1026.43(e)(7): the covered transaction must have no more than two delinquencies of 30 or more days and no delinquencies of 60 or more days at the end of the seasoning period. In the proposal, the Bureau tentatively concluded that the proposed standard for the number and duration of delinquencies would strike the appropriate balance of allowing flexibility for issues unrelated to a consumer's repayment ability while treating payment histories that more clearly signal potential issues with ability to repay as disqualifying. It also noted that the proposed performance standards would be consistent with the GSEs' representation and warranty framework and the master policies of mortgage insurers, which reflect market experience. For the reasons set forth below, the Bureau adopts in the final rule these performance criteria as proposed.

Comments Received

The Bureau received a number of comments on the proposed performance criteria, expressing a variety of views. Among the commenters that supported the proposed performance criteria, several industry commenters and consumer advocate commenters expressed support for how the proposed criteria would be consistent with the GSEs' representation and warranty framework. Another industry commenter agreed with the Bureau's tentative conclusion that the proposed limits on the number of delinquencies during the seasoning period appropriately balanced the need to limit the Seasoned QM safe harbor to loans with strong evidence of a consumers' ability to repay and the practical reality that some brief delinquencies do not indicate the consumer lacks the ability to repay. Additionally, some industry commenters joined several consumer advocate groups to urge the Bureau not to loosen the criteria in a final rule. Further, an industry commenter expressed general support for limiting the seasoning pathway to QM status to loans with three years of performance with minor delinquencies.[150]

With respect to commenters that did not support the criteria as proposed, several industry commenters asked the Bureau to increase the number of permissible 30-day delinquencies. An industry commenter suggested that the Bureau could increase the number of 30-day delinquencies to three or four because the Bureau's own analysis in

[145] 15 U.S.C. 1639(h).

[146] Under 12 CFR 1026.32(a), there are several ways that a loan secured by the consumer's principal dwelling can be a high-cost mortgage subject to HOEPA. One is if the APR exceeds the relevant APOR by a specific amount, which is 6.5 percentage points for most first-lien mortgages. The other ways relate to points and fees and prepayment penalties. 12 CFR 1026.32(a)(1).

[147] 12 CFR 1026.34(a)(4) (exempting temporary or ''bridge'' loans with terms of twelve months or less from this requirement).

[148] According to HMDA data, there were only 6,507 HOEPA loans total originated in 2019, and many of those loans would be ineligible for seasoning even if they were not subject to HOEPA due to other features (for example, because they have an adjustable rate or are secured by a subordinate lien). Bureau of Consumer Fin. Prot., *Data Point: 2019 Mortgage Market Activity and Trends* at 55 (June 2020), *https://files.consumerfinance.gov/f/documents/cfpb_2019-mortgage-market-activity-trends_report.pdf.*

[149] 15 U.S.C. 1639(p)(1) (authorizing the Bureau to make certain exemptions from HOEPA's requirements, if the Bureau finds that the exemption ''is in the interest of the borrowing public'' and ''will apply only to products that maintain and strengthen home ownership and equity protection'').

[150] This commenter asked the Bureau to clarify that certain delinquencies during the seasoning period are not counted for purposes of the performance criteria if they occur during or immediately preceding periods of forbearance. Several other industry commenters also suggested adjustments to the proposed definitions of delinquency, qualifying change, and temporary payment accommodation extended in connection with a disaster or pandemic-related national emergency. These comments are addressed in the section-by-section analysis of § 1026.43(e)(7)(iv)(A), (B), and (D) below.

the proposal showed that such an increase would have modest effects on the number of loans that would season while providing for additional flexibility during the seasoning period. Another industry commenter asserted that increasing the number of permissible 30-day delinquencies to three would benefit consumers whose jobs involve travel and who may miss payments because they have limited access to technology on job-rated travel. Several industry commenters urged the Bureau to increase the number of permissible 30-day delinquencies to three or four, asserting that such increase would accommodate consumers who need additional flexibility due to the COVID–19 pandemic's negative economic impacts. One industry commenter argued that there should be no restriction on the number of delinquencies as long as a consumer cures them before the end of the seasoning period.

On the other hand, two consumer advocate commenters expressed the concern that the proposed performance criteria would not be restrictive enough. They stated that the Bureau should clarify that rolling delinquencies (*i.e.,* certain delinquencies that continue month after month) would not be permitted. They also suggested that the Bureau revise the proposed performance standards to limit permissible late payments to no more than two payments outside of a loan's grace period.

Lastly, an industry commenter suggested that the Bureau undertake additional research to examine the risks of aligning the proposed performance standards with the existing GSE representation and warranty framework. It stated that it believes a careful market analysis must be done to consider empirical evidence of minor and severe delinquencies which later cure and that the Bureau and industry must understand the unintended consequences of potentially altered borrower behavior with a seasoning approach to QMs.

The Final Rule

The Bureau is adopting the performance standards as proposed. Final § 1026.43(e)(7)(ii) is adopted based on the legal authorities discussed in the section-by-section analysis of § 1026.43(e)(7)(i) above.

As explained in the proposal, the Bureau considered the existing practices of the GSEs and mortgage insurers in developing the 36-month period for successful payment history. As described in part V, each GSE generally provides creditors relief from its enforcement with respect to certain representations and warranties a creditor must make to the GSE regarding its underwriting of a loan. The GSEs generally provide creditors that relief after the first 36 monthly payments if the borrower had no more than two 30-day delinquencies and no delinquencies of 60 days or more. Similarly, the master policies of mortgage insurers generally provide that the mortgage insurer will not issue a rescission with respect to certain representations and warranties made by the originating lender if the borrower had no more than two 30-day delinquencies in the 36 months following the borrower's first payment, among other requirements.[151]

The Bureau recognizes that the payment history conditions laid out in the GSEs' representation and warranty framework and the mortgage insurers' master policies reflect market experience. Consistent with the GSEs' representation and warranty framework and the master policies of mortgage insurers, the final rule provides that more than two delinquencies of 30 days or more during the seasoning period or any delinquency of 60 days or more disqualifies a covered transaction from being a Seasoned QM under § 1026.43(e)(7).[152]

The Bureau concludes that the number and duration of delinquencies set forth in the performance criteria requirement strike the best balance between allowing flexibility for issues unrelated to a consumer's repayment ability (*e.g.,* a missed payment due to vacation or to a mix-up over automatic withdrawals) and treating payment histories that more clearly signal potential issues with ability to repay as disqualifying. The Bureau disagrees with the industry commenter who suggested that there should be no restrictions on the number of delinquencies as long as a consumer cures them before the end of the seasoning period. The Bureau concludes that the ability of consumers to consistently make timely payments in accordance with a mortgage loan's terms is an important indication of the consumer's ability to repay. The Bureau also declines to increase the number of permissible 30-day delinquencies, because it concludes that market experience, as reflected through the GSEs' representation and warranty framework and the master policies of mortgage insurers, strongly suggests that if a loan has more than two 30-day delinquencies in a 36-month period, it may indicate issues related to the underwriting of the loan. For the same reason, the Bureau also declines to adopt delinquency and performance standards that are based on a loan's grace period, as suggested by some consumer advocate commenters. The Bureau has decided to base the definition of delinquency for purposes of § 1026.43(e)(7) on the date that payment becomes due, even if the consumer is afforded a period after the due date to pay before the servicer assesses a late fee.

The Bureau's adoption of the performance criteria as proposed is also informed by its analysis of potential impacts if the number of permissible 30-day delinquencies were increased from two to three or four 30-day delinquencies. As discussed in more detail in part VIII below, the Bureau concluded that in light of the General QM Final Rule, there would be little benefit in terms of access to credit from increasing the number of permissible 30-day delinquencies, while there would be some negative impact in the form of increased foreclosure risk. The Bureau noted that increasing the number of allowable 30-day delinquencies by one increases the relative foreclosure start rate[153] between Seasoned QMs and loans that were safe harbor QM loans at consummation by approximately 4 percent.

Further, with respect to commenters who suggested that the Bureau increase the number of permissible 30-day delinquencies to accommodate consumers who need additional flexibility due to the COVID–19 pandemic's economic impacts, the Bureau concludes that the final rule's exclusion of periods of temporary payment accommodation due to a disaster or pandemic-related national emergency from the seasoning period pursuant to § 1026.43(e)(7)(iv)(C)(*2*) will

[151] Fannie Mae, *Amended and Restated GSE Rescission Relief Principles for Implementation of Master Policy Requirement #28 (Rescission Relief/ Incontestability)* (Sept. 10, 2018), *https://singlefamily.fanniemae.com/media/16331/display.*

[152] As discussed in the proposal and in part VIII below, the Bureau considered alternative seasoning periods and alternative performance requirements of allowable 30-day delinquencies. Each of the alternatives permits no 60-day delinquencies. The analysis of alternatives found that varying the number of allowable 30-day delinquencies could have some impact on foreclosure risk, even though the Bureau also found that varying the length of the seasoning period may have a greater impact.

[153] The term ''foreclosure start rate'' used in this final rule refers to the rate at which mortgage loans first entered into any one of the following: Foreclosure proceeding, deed in lieu of foreclosure, foreclosure, voluntary surrender, or repossession, as tracked by the NMDB.

be sufficient in providing such requested flexibility.[154]

Lastly, the Bureau notes that the proposal would have not permitted, and the final rule does not permit, rolling delinquencies of 30 days or more. As further discussed in the section-by-section analysis of § 1026.43(e)(7)(iv)(A) below, a periodic payment is 60 days delinquent under this final rule if the consumer is more than 30 days delinquent on the first of two sequential scheduled periodic payments and does not make both sequential scheduled periodic payments before the due date of the next scheduled periodic payment after the two sequential scheduled periodic payments. Under the delinquency definition in § 1026.43(e)(7)(iv)(A) and the performance requirements in § 1026.43(e)(7)(ii), a loan could not season if, for example, a consumer was 30 days or more delinquent on a monthly periodic payment due on January 1 and subsequently failed to make both the periodic payment due on January 1 and the periodic payment due on February 1 before March 1. In this example, if the consumer made the January 1 periodic payment on February 5, but did not make the payment due on February 1 by March 1, the loan would be considered 60 days delinquent as of March 1 and therefore would not be eligible to become a Seasoned QM. Rolling delinquencies of 30 days or more are therefore not permitted under this final rule due to a combination of the definition of delinquency for purposes of the rule and the prohibition on any delinquencies of 60 days or more.

43(e)(7)(iii) Portfolio Requirements

Proposed § 1026.43(e)(7)(iii) set forth certain proposed portfolio requirements for a covered transaction to be a Seasoned QM. It provided that to be a Seasoned QM, the loan must satisfy the following requirements. First, at consummation, the loan must not have been subject to a commitment to be acquired by another person. Second, legal title to the loan could not be sold, assigned, or otherwise transferred to another person before the end of the seasoning period, except in circumstances specified in proposed § 1026.43(e)(7)(iii)(B)(*1*) and (*2*). Proposed § 1026.43(e)(7)(iii)(B)(*1*) provided that the loan may be sold, assigned, or otherwise transferred to another person pursuant to a capital restoration plan or other action under 12 U.S.C. 1831o; actions or instructions of any person acting as conservator, receiver, or bankruptcy trustee; an order of a State or Federal government agency with jurisdiction to examine the creditor pursuant to State or Federal law; or an agreement between the creditor and such an agency. Proposed § 1026.43(e)(7)(iii)(B)(*2*) provided that the loan may be sold, assigned, or otherwise transferred pursuant to a merger of the creditor with another person or acquisition of the creditor by another person or of another person by the creditor.

The Bureau also proposed to add comments 43(e)(7)(iii)–1 through –3 to clarify the proposed portfolio requirement. Proposed comment 43(e)(7)(iii)–1 would have explained that a loan is not eligible to season into a QM under proposed § 1026.43(e)(7) if legal title to the debt obligation is sold, assigned, or otherwise transferred to another person before the end of the seasoning period, unless one of the exceptions in proposed § 1026.43(e)(7)(iii)(B) applies. Proposed comment 43(e)(7)(iii)–2 would have clarified the application of proposed § 1026.43(e)(7)(iii) to subsequent transferees. Proposed comment 43(e)(7)(iii)–3 would have explained the impact of supervisory sales. For the reasons discussed below, the Bureau adopts proposed § 1026.43(e)(7)(iii) and comments 43(e)(7)(iii)–1 through –3 with changes that allow a single transfer during the seasoning period provided that certain requirements are met, as discussed below.

Comments Received

Consumer advocate commenters and some industry commenters supported the proposed portfolio requirement and agreed with the Bureau's rationale that the proposed requirement would provide an important incentive for creditors to make diligent ATR determinations at origination. Some consumer advocate commenters supported adopting the proposed portfolio requirement as proposed to mitigate some of the risks they anticipated in a Seasoned QM final rule.

However, various industry commenters and a United States senator opposed the proposed portfolio requirement. They asserted that it would reduce the number of loans eligible to season and, as such, diminish the potential of the final rule to lower mortgage prices and increase market liquidity. They also asserted that the requirement would create an unfair playing field, disadvantaging non-bank lenders that rely on warehouse lending and secondary market sales for liquidity. Several commenters asserted that loan performance is sufficiently probative of a consumer's ability to repay even without a portfolio requirement, and some suggested that the Bureau has not shown why the fact that a loan is held in portfolio is evidence that the consumer had the ability to repay the loan at consummation. Commenters also asserted that other factors would sufficiently ensure responsible lending by creditors, including the following: the proposed product restrictions and underwriting requirements for Seasoned QMs; the interagency credit risk retention rule; due diligence performed by loan aggregators; and originators' concerns about indemnification and reputational risks that result if the loans they sell to third parties fail. One industry commenter asserted that if the final rule is limited to portfolio lenders, non-QM mortgage lending is likely to become dominated by portfolio lenders, which would lead to a system that is less diversified and in which risk is concentrated in certain market segments.

An industry trade association and another industry commenter proposed broadening the portfolio requirement to include a one-time sale by the creditor to a third-party purchaser that then holds the loan for the requisite 36-month seasoning period. They asserted that a whole loan sale model as they described is considerably less risky than a securitization model for several reasons. Specifically, they noted that, as compared to investors in mortgage-backed securities, whole loan purchasers have a more direct relationship with the originator, are better positioned to understand and evaluate a loan's underlying fundamentals, and have strong incentives to be prudent as they own all of the credit risk. One industry commenter also sought to broaden the list of proposed exceptions to the portfolio requirement to permit transfers pursuant to a creditor's default or breach of loan covenants in situations where the loan serves as collateral securing the financing the creditor uses to fund the loan.

Meanwhile, an academic commenter asserted that the proposed portfolio requirement would be substantially weaker than the EGRRCPA's portfolio requirement because the proposal lacked the same resale restrictions that Congress established in the EGRRCPA. Moreover, the commenter asserted that the proposal did not contain evidence to

[154] The exclusion of any period during which the consumer is in a temporary payment accommodation extended in connection with a disaster or pandemic-related national emergency from the seasoning period is discussed more fully in the section-by-section analysis of § 1026.43(e)(7)(iv)(C)(*2*).

support the Bureau's assertion that the proposed requirement would make creditors underwrite mortgages more carefully. An industry commenter referenced a study by the Board in which researchers found that large lenders were more apt to reduce quality and receive government bailouts in the 2008 financial crisis. This commenter expressed concern that the proposed portfolio requirement may not be sufficient to incentivize large banks to engage in responsible lending because banks that are deemed too-big-to-fail do not face sufficient negative consequences if loans they hold in portfolio fail.

Lastly, several industry commenters expressed concern that mortgage loans that bank creditors pledge as collateral to the Federal Home Loan Banks or the Board may not meet the proposed portfolio requirement and sought clarification or confirmation that such pledged loans are deemed to be held in the bank creditors' portfolios.

The Final Rule

Under the proposal, for a covered transaction to become eligible for Seasoned QM status, the creditor that originates the transaction would have to hold the transaction in its portfolio, unless one of two exceptions, set forth in proposed § 1026.43(e)(7)(iii)(B)(*1*) (transfers of ownership pursuant to certain supervisory sales) or § 1026.43(e)(7)(iii)(B)(*2*) (transfers of ownership pursuant to certain mergers or acquisitions), applied. Proposed § 1026.43(e)(7)(iii)(B)(*1*) and (*2*) are adopted as proposed.

However, the Bureau is adopting in § 1026.43(e)(7)(iii)(B)(*3*) an additional exception, which provides that the covered transaction may be sold, assigned, or otherwise transferred once before the end of the seasoning period, so long as the covered transaction is not securitized as part of the sale, assignment, or transfer or at any other time before the end of the seasoning period. In light of this change, this final rule makes a related change to proposed § 1026.43(e)(7)(iii)(A) to provide that § 1026.43(e)(7)(iii)(B)(*3*) is an exception to the general prohibition against subjecting the covered transaction, at consummation, to a commitment to be acquired by another person to become a Seasoned QM under § 1026.43(e)(7). Conforming changes are also made to proposed comments 43(e)(7)(iii)-1 through –3 in light of the adoption of § 1026.43(e)(7)(iii)(B)(*3*).

The exception in § 1026.43(e)(7)(iii)(B)(*3*) may only be used one time for a covered transaction during the seasoning period. This means that until the end of the seasoning period, a purchaser that acquires the covered transaction pursuant to § 1026.43(e)(7)(iii)(B)(*3*) may not subsequently transfer the covered transaction to any other entity and maintain the covered transaction's eligibility to become a Seasoned QM, except that the purchaser may transfer the covered transaction pursuant to § 1026.43(e)(7)(iii)(B)(*1*) or (*2*). Section 1026.43(e)(7)(iii)(B)(*3*) also provides that the covered transaction may not be securitized as part of a transfer permitted under § 1026.43(e)(7)(iii)(B)(*3*) or at any other time before the end of the seasoning period. For an illustrative example, a covered transaction is considered to be securitized under this final rule if it is transferred to an entity such as a securitization trust, and interests in the trust are held by investors, even if legal title to the covered transaction is retained by the securitization trust.

As noted in the discussion of comments received on the proposed portfolio requirement, two industry commenters suggested the Bureau permit a one-time sale of the covered transaction to another purchaser as long as the owner or purchaser holds the covered transaction in its portfolio for the requisite 36-month seasoning period and does not securitize the covered transaction. The Bureau has concluded that a one-time transfer of a whole loan should not preclude the loan from becoming a Seasoned QM for the following reasons. First, a fundamental goal of creating the Seasoned QM category is to encourage creditors to increase the origination of non-QM loans in a responsible manner. Many creditors, particularly non-banks, rely on borrowed funds to make loans and then sell these loans in order to originate additional new loans. Further, non-banks are particularly active in the non-QM market, with only one depository institution included among the 10 largest non-QM originators.[155] Allowing a one-time transfer as permitted in this final rule broadens the category of responsible, non-QM originations that could benefit from this final rule to include loans made by such creditors and thus furthers the Bureau's goal of increasing such originations. Additionally, the Bureau notes that non-banks play a key role in expanding access to credit as evidenced by the lower average FICO scores and higher DTIs associated with their loans as compared to depositories.[156]

Second, while allowing a single transfer may mean that the originating creditor has a somewhat weaker incentive to originate affordable loans, relative to the proposal, the Bureau concludes that requiring the purchaser of the covered transaction to hold the transaction in its portfolio until the end of the seasoning period will ensure that the originating creditor and the purchaser together have sufficient incentive to ensure that the originating creditor makes a diligent ATR determination. The whole-loan transfer puts the purchaser in a similar position to the original creditor in the legal and credit exposure the purchaser faces if a consumer defaults on the covered transaction. As such, to the extent that all or part of the seasoning period remains after the transfer, the purchaser will have an incentive to ensure the loan is high quality, which in turn will incentivize the creditor to make a diligent ATR determination at consummation.

One of the industry commenters that suggested the single transfer exception indicated that, as part of the exception, the Bureau could specifically require the purchaser to hold the loan for 36 months after the date of transfer. The type of transfers that § 1026.43(e)(7)(iii)(B)(*3*) permits commonly occur before or around the due date for the first periodic payment. For such transactions, § 1026.43(e)(7)(iii) as finalized requires the purchaser to hold the loan in portfolio for approximately 36 months after the date of transfer, because § 1026.43(e)(7)(iv)(C) provides that the seasoning period does not end until at least 36 months after the due date for the first periodic payment. Additionally, as the proposal explained, given the increasing likelihood that intervening events contribute to delinquencies, the Bureau generally does not view delinquency after 36 months in the lifecycle of a loan product as undermining the presumption of creditor compliance with the ATR requirements at consummation. In light of these considerations, and the incentives discussed above that the initial 36-month seasoning period creates for the originating creditor and the purchaser, the Bureau has determined it is unnecessary to extend

[155] Inside Mortg. Fin., *Top Originators of Securitized Expanded-Credit Mortgages: 2019–3Q20, https://www.insidemortgagefinance.com/products/300059-top-originators-of-securitized-expanded-credit-mortgages-2019-3q20-pdf* (last visited Nov. 19, 2020). The only depository institution included amongst the 10 largest non-QM originators is JPMorgan Chase.

[156] Urban Inst., *Housing Finance at a Glance,* at 17–18, (Oct. 2020), *https://www.urban.org/sites/default/files/publication/103123/october-chartbook-2020_2.pdf.*

or reset the seasoning period for loans transferred after the first payment date pursuant to § 1026.43(e)(7)(iii)(B)(*3*) to include a period of 36 months beginning on the date of the transfer.

The Bureau concludes that it is appropriate to exclude loans that are securitized because it recognizes whole loan purchasers will likely have a more direct relationship with the originator than investors in mortgage-backed securities and may therefore have more visibility into the seller's underwriting process and be better positioned to use remedies to make the originating creditor buy back the loan if the loan performs poorly or is otherwise defective. The Bureau believes that a whole loan purchaser's incentive remains regardless of whether there is a mandatory commitment between the seller and purchaser to deliver a mortgage loan at a predetermined price by a specified date. Even in the case of mandatory commitments, the seller has an obligation to deliver the loan in accordance with the investor requirements and in compliance with applicable State and Federal requirements. The Bureau acknowledges that purchasers are often incentivized to preserve their business relationship by attempting to cure loan defects without requiring the seller to repurchase the loan. However, in the event of a material and uncurable defect, purchasers can and do exercise remedies requiring the seller to repurchase the loan, rather than assume the liability of a non-compliant loan or retain a defective loan in portfolio that they anticipate will perform worse than expected.

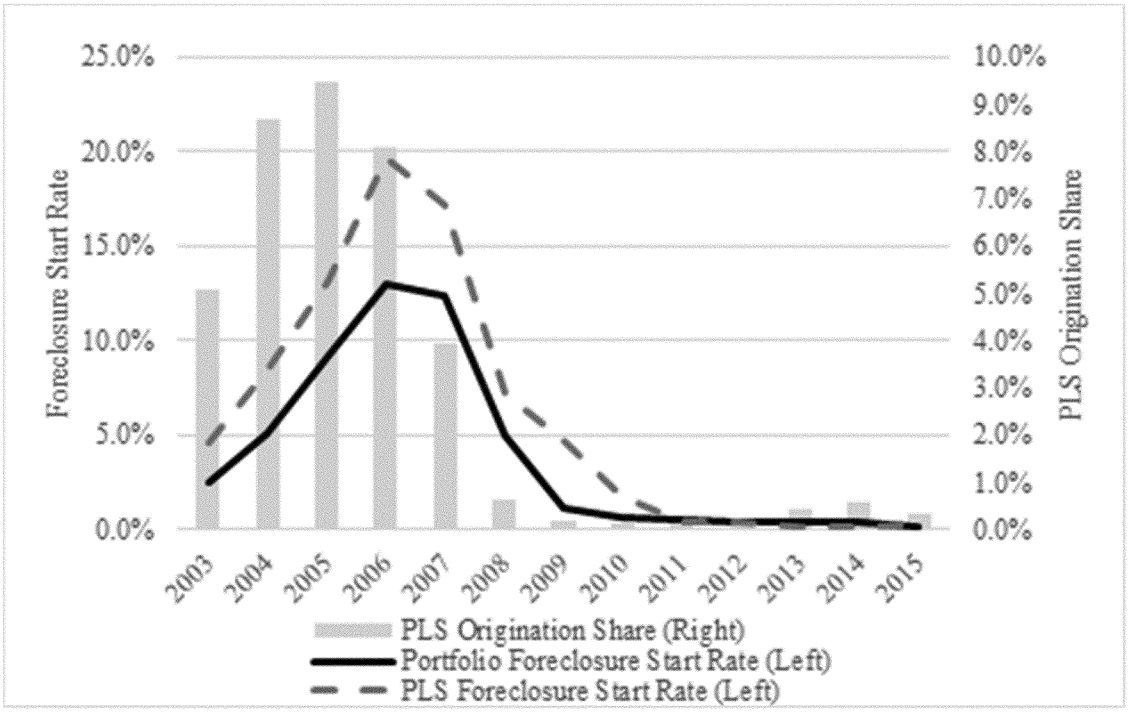
The Bureau declines to adopt a final rule without any portfolio requirement, as a number of industry commenters urged the Bureau to do. As discussed in greater detail in the section-by-section analysis of § 1026.43(e)(7)(i) above, the final rule does not impose a DTI limit or a pricing limit on loans that are eligible to become Seasoned QMs. In this respect, the Seasoned QM definition is similar to some other QM definitions such as the Small Creditor QM definition. While covered transactions are subject to certain product restrictions, limitations on points and fees, and underwriting requirements, in the absence of a specific DTI or pricing limit applicable at consummation, the Bureau has decided to impose a portfolio requirement to help ensure the creditor makes a reasonable determination that the loan is within the consumer's ability to repay. As discussed above, it is conceivable that under certain circumstances, the record of a consumer's payments could make it appear that the consumer had the ability to repay at consummation even when that is not in fact the case. Other provisions of this final rule attempt to reduce that possibility (such as by providing that payments made by a servicer or from a consumer's escrowed funds are not considered as on-time payments), but the Bureau has decided to provide further assurance that the creditor's ATR determination at consummation was a diligent and reasonable one by including a portfolio requirement.

Further, although the Bureau recognizes that the interagency credit risk retention rule [157] provides an indirect incentive to originate responsible and affordable loans for sale and securitization in the secondary markets, the Bureau concludes that limiting the Seasoned QM definition to loans that are held in portfolio by the originating creditor or first purchaser will provide stronger incentives to originate responsible and affordable loans.

Moreover, while not necessary for the Bureau's conclusion to retain a portfolio requirement, that conclusion is consistent with the Bureau's analysis of the foreclosure start rates of mortgage loans originated between 2003 and 2015 that were designated to be held in portfolio at origination and mortgage loans originated during the same time period that were designated for private-label securitization. The loans the Bureau evaluated had fixed interest rates, were first-lien transactions, were not high-cost mortgages subject to HOEPA, and did not have any features that disqualified them from being QMs. The results are shown in Figure 1 below.

[157] The QM definition is related to the definition of qualified residential mortgage (QRM). Section 15G of the Securities Exchange Act of 1934, added by section 941(b) of the Dodd-Frank Act, generally requires the securitizer of asset-backed securities (ABS) to retain not less than 5 percent of the credit risk of the assets collateralizing the ABS. 15 U.S.C. 78o-11. Six Federal agencies (not including the Bureau) are tasked with implementing this requirement. Those agencies are the Board, the OCC, the FDIC, the Securities and Exchange Commission, the FHFA, and HUD (collectively, the QRM agencies). Section 15G of the Securities Exchange Act of 1934 provides that the credit risk retention requirements shall not apply to an issuance of ABS if all of the assets that collateralize the ABS are QRMs. *See* 15 U.S.C. 78o–11(c)(1)(C)(iii), (4)(A) and (B). Section 15G requires the QRM agencies to jointly define what constitutes a QRM, taking into consideration underwriting and product features that historical loan performance data indicate result in a lower risk of default. *See* 15 U.S.C. 78o–11(e)(4). Section 15G also provides that the definition of a QRM shall be ''no broader than'' the definition of a qualified mortgage, as the term is defined under TILA section 129C(b)(2), as amended by the Dodd-Frank Act, and regulations adopted thereunder. 15 U.S.C. 78o–11(e)(4)(C). In 2014, the QRM agencies issued a final rule adopting the risk retention requirements. 79 FR 77601 (Dec. 24, 2014). The final rule aligns the QRM definition with the QM definition defined by the Bureau in the ATR/QM Rule, effectively exempting securities comprised of loans that meet the QM definition from the risk retention requirement. The final rule also requires the agencies to review the definition of QRM no later than four years after the effective date of the final risk retention rules. In 2019, the QRM agencies initiated a review of certain provisions of the risk retention rule, including the QRM definition, and have extended the review period until June 20, 2021. 84 FR 70073 (Dec. 20, 2019). Among other things, the review allows the QRM agencies to consider the QRM definition in light of any changes to the QM definition adopted by the Bureau.

Figure 1: Foreclosure Start Rates of Portfolio and PLS Loans by Vintage



Source: NMDB 10.0. Loans with restricted features or high-cost mortgages subject to HOEPA are excluded from computation of foreclosure rates and market share. PLS loans are classified as such if they are ever placed in a private label security, which usually occurs soon after consummation. Portfolio loans are privately held loans that were not sold to a PLS.

Figure 1 shows that loans designated to be held in portfolio at origination consistently foreclosed at lower rates for eight of the 13 years that made up the period of time that the Bureau evaluated, from 2003 through 2010. Although the foreclosure start rates in the years 2011 through 2015 of loans designated to be held in portfolio and loans designated for private-label securitization appear to be similar, the number of such securitized loans during those years is too small to be informative.[158] These data further support the Bureau's determination that creditors are more likely to do diligent ATR determinations when loans are held in portfolio rather than securitized.

The Bureau also declines to create an additional exception in § 1026.43(e)(7)(iii) to permit transfers pursuant to a creditor's default or breach of loan covenants in situations in which the loan serves as collateral securing the financing the creditor uses to fund the loan, as one industry commenter requested. Such transfers may fall within the single-transfer exception in § 1026.43(e)(7)(iii)(B)(*3*) if the requirements for that exception are met, and the Bureau concludes an additional exception for circumstances involving default or breach of loan covenants is not warranted.

Lastly, the Bureau has decided that no change to the proposal is required to address whether loans pledged as collateral to the Federal Home Loan Banks or the Board are deemed to be held in the bank creditors' portfolios for purposes of the Seasoned QM portfolio requirement. Whether a given covered transaction meets the portfolio requirement depends generally on (1) whether the transaction is subject, at consummation, to a commitment to be acquired by another person and (2) whether legal title is sold, assigned, or otherwise transferred to another person before the end of the seasoning period, outside of the specified exceptions. This general test is modeled on the test set forth in the Small Creditor QM and Balloon Payment QM definitions, and, as explained above, the Bureau has also added a single-transfer exception to the Seasoned QM portfolio requirement if the standards articulated above are met. If loans pledged to the Federal Home Loan Banks or the Board comply with the general test or comply with any of the three specified exceptions set forth in § 1026.43(e)(7)(iii)(B), then they are considered to be held in portfolio until the end of the seasoning period pursuant to § 1026.43(e)(7)(iii).

43(e)(7)(iv) Definitions

The Bureau proposed to adopt several definitions for purposes of proposed § 1026.43(e)(7). The Bureau solicited comments on all of its proposed definitions. The Bureau addresses each of the proposed definitions in turn below.

Paragraph 43(e)(7)(iv)(A)

As explained above, § 1026.43(e)(7)(i)(C) and (ii) as finalized provides that only covered transactions that have no more than two delinquencies of 30 or more days and no delinquencies of 60 or more days at the end of the seasoning period can become Seasoned QMs. Proposed § 1026.43(e)(7)(iv)(A) would have defined delinquency as the failure to

[158] The numbers of loans designated for private-label securitization from 2011 through 2015 that met the criteria described above (*i.e.,* non-HOEPA, first-lien, fixed-rate loans that did not have features that would make them ineligible to be QMs) were as follows: 9,700, 17,500, 25,720, 22,900, and 16,800. In contrast, the numbers of loans designated to be held in portfolio during those years and that met the same criteria were between 1.4 and 2.2 million.

make a periodic payment (in one full payment or in two or more partial payments) sufficient to cover principal, interest, and, if applicable, escrow by the date the periodic payment is due under the terms of the legal obligation. The proposed definition in § 1026.43(e)(7)(iv)(A) would have excluded other amounts, such as late fees, from the definition. Proposed § 1026.43(e)(7)(iv)(A)(*1*) through (*5*) would have addressed additional, specific aspects of the definition of delinquency, which are discussed in the section-by-section analyses that follow. Proposed comment 43(e)(7)(iv)(A)–1 would have clarified that, in determining whether a scheduled periodic payment is delinquent for purposes of proposed § 1026.43(e)(7), the due date is the date the payment is due under the terms of the legal obligation, without regard to whether the consumer is afforded a period after the due date to pay before the servicer assesses a late fee.

Industry commenters generally supported proposed § 1026.43(e)(7)(iv)(A), while consumer advocate commenters opposed the Seasoned QM Proposal as a whole. Both industry and consumer advocate commenters raised concerns about specific aspects of the definition that are discussed in the section-in-section analyses of § 1026.43(e)(7)(iv)(A)(*1*), (*2*), and (*4*) below. The Bureau did not receive comments on proposed comment 43(e)(7)(iv)(A)–1.

The Bureau concludes that the definition of delinquency in § 1026.43(e)(7)(iv)(A) provides a clear method of assessing delinquency for purposes of § 1026.43(e)(7). Accordingly, the Bureau is finalizing § 1026.43(e)(7)(iv)(A) and comment 43(e)(7)(iv)(A)–1 as proposed, with minor technical changes and one modification to § 1026.43(e)(7)(iv)(A)(*4*) as discussed below.

Paragraphs 43(e)(7)(iv)(A)(1) and (2)

Proposed § 1026.43(e)(7)(iv)(A)(*1*) and (*2*) specified when periodic payments are 30 days delinquent and 60 days delinquent, respectively, for purposes of proposed § 1026.43(e)(7)(iv). Proposed § 1026.43(e)(7)(iv)(A)(*1*) provided that a periodic payment would be 30 days delinquent if it is not paid before the due date of the following scheduled periodic payment. Proposed § 1026.43(e)(7)(iv)(A)(*2*) provided that a periodic payment would be 60 days delinquent if the consumer is more than 30 days delinquent on the first of two sequential scheduled periodic payments and does not make both sequential scheduled periodic payments before the due date of the next scheduled periodic payment after the two sequential scheduled periodic payments. Proposed comment 43(e)(7)(iv)(A)(*2*)–1 provided an illustrative example of the meaning of 60 days delinquent for purposes of proposed § 1026.43(e)(7).

The Bureau received a few comments that related to proposed § 1026.43(e)(7)(iv)(A)(*1*) and (*2*). An industry commenter noted that the proposed definition of delinquency refers to 30 and 60-day delinquency periods and asked the Bureau to modify proposed § 1026.43(e)(7)(iv)(A) to account for non-monthly payments schedules (*e.g.,* bi-weekly or quarterly payment schedules). Two consumer advocate commenters stated that the Bureau should provide clarifying commentary to address rolling delinquencies. They explained that it is very common for struggling homeowners to have rolling delinquencies, paying somewhat late month after month, but never bringing the loan current. These commenters indicated that borrowers who pay 29 or 30 days late every month maintain a persistent delinquency, showing clear signs of financial distress, and not demonstrating an ability to repay.

The Bureau concludes that the approach set forth in proposed § 1026.43(e)(7)(iv)(A)(*1*) and (*2*) and proposed comment 43(e)(7)(iv)(A)(*2*)–1 provide appropriate standards for determining whether a periodic payment is 30 or 60 days delinquent that would be relatively easy to apply. The Bureau also finds that proposed § 1026.43(e)(7)(iv)(A) is flexible enough to account for non-monthly payment schedules and therefore declines to provide additional flexibilities to account for non-monthly payment schedules. Proposed § 1026.43(e)(7)(iv)(A)(*1*) and (*2*) define 30 days delinquent and 60 days delinquent based on whether payments are made before the next periodic payment due date. Thus, under the proposed § 1026.43(e)(7)(iv)(A)(*1*), a bi-weekly or quarterly periodic payment would be 30 days delinquent when the periodic payment is not paid before the due date of the following bi-weekly or quarterly payment. Similarly, under proposed § 1026.43(e)(7)(iv)(A)(*2*), a bi-weekly or quarterly periodic payment would be 60 days delinquent if the consumer is more than 30 days delinquent, as defined under proposed § 1026.43(e)(7)(iv)(A)(*1*), on the first of two sequential scheduled periodic payments and does not make both sequential scheduled periodic payments before the due date of the next scheduled periodic payment after the two sequential scheduled periodic payments. The Bureau also does not believe any change is necessary to address rolling delinquencies because the performance standards in § 1026.43(e)(7)(ii) and the definition of 60 days delinquent in § 1026.43(e)(7)(iv)(A)(*2*) already capture rolling delinquencies, as discussed in the section-by-section analysis of § 1026.43(e)(7)(ii) above. Comment 43(e)(7)(iv)(A)(*2*)-1 illustrates the meaning of 60 days delinquent for purposes of § 1026.43(e)(7) by providing an example. The Bureau is adopting § 1026.43(e)(7)(iv)(A)(*1*) and (*2*) and comment 43(e)(7)(iv)(A)(*2*)-1 as proposed, with minor technical changes in the comment.

Paragraph 43(e)(7)(iv)(A)(3)

As the Bureau noted in the proposal, some servicers elect or may be required to treat consumers as having made a timely payment even if the payment is a small amount less than the full periodic payment. For purposes of proposed § 1026.43(e)(7), proposed § 1026.43(e)(7)(iv)(A)(*3*) provided that for any given billing cycle for which a consumer's payment is less than the periodic payment due, a consumer is not delinquent if: (1) The servicer chooses not to treat the payment as delinquent for purposes of any section of subpart C of Regulation X, 12 CFR part 1024, if applicable, (2) the payment is deficient by $50 or less, and (3) there are no more than three such deficient payments treated as not delinquent during the seasoning period. The Bureau did not receive any comments on proposed § 1026.43(e)(iv)(A)(*3*) and, for the reasons explained below, is now finalizing § 1026.43(e)(iv)(A)(*3*) as proposed.

The Bureau concludes that the approach to small periodic payment deficiencies in § 1026.43(e)(iv)(A)(*3*) will result in less burden for financial institutions seeking to avail themselves of the Seasoned QM definition, in the event that their servicing systems and practices already make allowances for treating a payment as not delinquent when the payment is deficient by a small amount. For example, a servicer may have systems in place to accept minimally deficient payments and not count them as delinquent for purposes of calculating delinquency under subpart C of Regulation X, 12 CFR part 1024. Further, the Bureau is concerned that, absent § 1026.43(e)(7)(iv)(A)(*3*), creditors might find it very unlikely that many of their loans would fully meet the requirements to be a Seasoned QM, undermining the rule's objectives.

Required periodic payments for covered transactions can vary over time as tax and insurance amounts change. For example, a consumer could overlook an annual escrow statement reflecting an escrow payment increase and pay the previously required amount instead of the new amount. The Bureau believes that small deficiencies in a limited amount of periodic payments often do not mean that the consumer was unable to repay the loan at the time of consummation.

The Bureau has decided, however, that unless limits are imposed, servicers and creditors could use payment tolerances to mask unaffordability in a way that might undermine the purposes of this final rule. The Bureau understands that Fannie Mae and Freddie Mac servicing guidance allows servicers to apply periodic payments that are short by $50 or less.[159] Fannie Mae limits the usage of the payment tolerance to three monthly payments during a 12-month period,[160] while the National Mortgage Settlement generally required acceptance of at least two periodic payments that were short by $50 or less.[161] In light of these practices and the considerations discussed above, the Bureau is adopting a cap of no more than three periodic payment deficiencies of $50 or less during the seasoning period to ensure that use of payment tolerances does not mask unaffordability. The Bureau concludes that allowing up to three payments deficient by $50 or less over the course of the seasoning period provides appropriate flexibility for small deficiencies such as those related to variations in tax and insurance amounts.[162]

Paragraph 43(e)(7)(iv)(A)(4)

Proposed § 1026.43(e)(7)(iv)(A)(*4*) provided that unless a qualifying change is made to the loan obligation, the principal and interest used in determining the date a periodic payment sufficient to cover principal, interest, and, if applicable, escrow becomes due and unpaid are the principal and interest payment amounts established by the terms and payment schedule of the loan obligation at consummation. Proposed § 1026.43(e)(7)(iv)(A)(*4*) focused on the principal and interest payment amounts established by the terms and payment schedule of the loan obligation at consummation because the performance requirements in proposed § 1026.43(e)(7)(ii) were designed to assess whether the creditor made a reasonable and good faith determination of the consumer's ability to repay at the time of consummation.[163]

The Bureau concludes that using a principal and interest amount that has been modified or adjusted after consummation would not provide a basis for presuming that the creditor made such a determination. For example, if a consumer has a modified payment that is much lower than the original contractual payment amount, the consumer might be able to make the modified payments even though the contractual terms at consummation were not affordable.

The Bureau recognizes, however, that certain unusual circumstances involving disasters or pandemic-related national emergencies warrant using a principal and interest amount that has been modified or adjusted after consummation. Accordingly, the Bureau proposed that if a qualifying change as defined in proposed § 1026.43(e)(7)(iv)(B) is made to the loan obligation, the principal and interest used in determining the date a periodic payment sufficient to cover principal, interest, and, if applicable, escrow becomes due and unpaid would be the principal and interest payment amounts established by the terms and payment schedule of the loan obligation at consummation as modified by the qualifying change. The Bureau is finalizing § 1026.43(e)(7)(iv)(A)(*4*) with one modification as explained below and minor technical changes.

Although the Bureau did not receive many comments relating to proposed § 1026.43(e)(7)(iv)(A)(*4*), one industry commenter cautioned that proposed § 1026.43(e)(7)(iv)(A)(*4*) was not flexible enough to apply to a small subset of loans the Bureau intended to cover within the scope of the proposal. Specifically, an industry trade association pointed out that proposed § 1026.43(e)(7)(iv)(A)(*4*), which relies on the first payment due date in the legal obligation at consummation to determine when a loan could be first delinquent, would not account for changes in the first payment due date typically associated with the delivery of new manufactured housing. This commenter also noted that proposed § 1026.43(e)(7)(iv)(A) would not account for courtesy due date changes extended by creditors, such as from the 1st to the 5th of the month for a borrower who receives Social Security benefits on the 3rd of the month.

After considering the comments received, the Bureau is finalizing § 1026.43(e)(7)(iv)(A)(*4*) with minor technical changes and one modification as described below to address the commenter's concern that creditors making loans for the purchase of new manufactured homes often estimate the first payment due date in the legal obligation signed at consummation. These dates may be uncertain at consummation due to potential delays involved with the delivery, set up, and availability for occupancy of the dwelling that secures the loan. The Bureau understands that, in these circumstances, creditors may modify the first payment date after consummation when those dates become clear so that the first payment date is not due until after the consumer occupies the home. Proposed § 1026.43(e)(7)(iv)(A)(*4*) required delinquency to be calculated based on the first payment due date established by the terms and payment schedule of the loan obligation at consummation. Thus, a loan to purchase a new manufactured home might be considered delinquent under proposed § 1026.43(e)(7)(iv)(A)(*4*), even though the consumer has not missed a payment under the terms of a modified agreement.

A primary objective of the proposal was to ensure the availability of responsible and affordable credit by incentivizing the origination of non-QM loans that otherwise might not be made. In the proposal, the Bureau noted that half of manufactured housing originations are rebuttable presumption QM loans, and that large banks tend to originate only safe harbor QM loans that are held in portfolio. The Bureau concludes that modifying proposed § 1026.43(e)(7)(iv)(A)(*4*) to allow creditors to modify the first payment due date in certain limited circumstances furthers the objective of the proposal. Accordingly, if, due to reasons related to the timing of delivery, set up, or availability for occupancy of the dwelling securing the obligation, the creditor modifies the first payment due date before the first payment due date under the legal obligation at consummation, the modified first

[159] Fannie Mae, *Servicing Guide* 218–19 (July 15, 2020), *https://singlefamily.fanniemae.com/media/23346/display* (July 2020 Servicing Guide); Freddie Mac, *Seller/Servicer Guide* at 8103–3 (Aug. 5, 2020), *https://guide.freddiemac.com/ci/okcsFattach/get/1002095_2.*

[160] July 2020 Servicing Guide, *supra* note 159, at 218–19.

[161] *See, e.g., United States* v. *Bank of Am. Corp.,* No. 1:12-cv-00361–RMC, 2012 U.S. Dist. LEXIS 188892, at *32 (D.D.C. Apr. 4, 2012).

[162] The Bureau also notes that a deficient periodic payment does not trigger a delinquency of 30 days or more under § 1026.43(e)(7)(iv)(A)(*1*) if the consumer pays the deficient amount before the next periodic payment comes due.

[163] The Bureau is not requiring that the escrow amount (if applicable) be considered in determining whether a delinquency exists for purposes of § 1026.43(e)(7) be the amount disclosed to the consumer at consummation, because escrow payments are subject to changes over time.

payment due date, rather than the first payment due date under the legal obligation at consummation, is used in determining whether a periodic payment is delinquent.

The Bureau declines to make any changes to proposed § 1026.43(e)(7)(iv)(A)(*4*) to accommodate courtesy due date changes extended by creditors. As stated in the section-by-section analysis of § 1026.43(e)(7)(ii), a loan that seasons into QM status may not have more than two delinquencies of 30 or more days or any delinquencies of 60 or more days at the end of the seasoning period. The Bureau concludes that this performance standard already provides sufficient flexibility to accommodate courtesy shifts to a different date within a month (such as from the 1st to the 5th of the month), because delinquencies of less than 30 days do not affect whether a loan can season under § 1026.43(e)(7)(ii).

Paragraph 43(e)(7)(iv)(A)(5)

Proposed § 1026.43(e)(7)(iv)(A)(*5*) addressed how to handle payments made from certain third-party sources in assessing delinquency for purposes of proposed § 1026.43(e)(7). Specifically, proposed § 1026.43(e)(7)(iv)(A)(*5*) provided that, except for making up the deficiency amount set forth in proposed § 1026.43(e)(7)(iv)(A)(*3*)(*ii*), payments from the following sources would not be considered in assessing delinquency under proposed § 1026.43(e)(7)(iv)(A): (1) Funds in escrow in connection with the covered transaction, or (2) funds paid on behalf of the consumer by the creditor, servicer, or assignee of the covered transaction, or any other person acting on behalf of such creditor, servicer, or assignee.

In the proposal, the Bureau tentatively concluded that proposed § 1026.43(e)(7)(iv)(A)(*5*) would help to ensure that payments made by consumers during the seasoning period actually reflect the consumer's ability to repay. The Bureau further noted similarities between the proposed provision and the GSEs' representation and warranty framework. As discussed below, the Bureau is adopting § 1026.43(e)(7)(iv)(A)(*5*) as proposed in this final rule.

Comments Received

The Bureau received two comments on this aspect of the proposal from industry commenters. One commenter agreed with the Bureau's rationale for the proposed requirement. The other commenter stated that the proposed provision adequately addressed its suggestion in response to the ANPR that the Bureau impose a requirement that mortgage payments come from consumers' own funds.

The Final Rule

The Bureau is finalizing § 1026.43(e)(7)(iv)(A)(*5*) as proposed because it concludes that § 1026.43(e)(7)(iv)(A)(*5*) helps to ensure that the performance history considered in assessing delinquency for purposes of § 1026.43(e)(7) reflects the consumer's ability to repay rather than payments made by the creditor, servicer, or assignee or persons acting on their behalf that could mask a consumer's inability to repay. As the Bureau explained in the proposal, the GSEs' representation and warranty framework generally prohibits lenders and third parties with a financial interest in the performance of a loan escrowing or advancing funds on a borrower's behalf to be used to make principal and interest payments to satisfy the framework's payment history requirement.[164] Similar to the GSEs' representation and warranty framework, the Bureau concludes that payments made from escrow accounts established in connection with the loan should not be considered in assessing performance for seasoning purposes because a creditor could escrow funds from the loan proceeds to cover payments during the seasoning period even if the loan payments were not actually affordable for the consumer on an ongoing basis. If a creditor needs to take funds from an escrow account to cover a periodic payment that is due on the account, the Bureau does not believe that the payment from escrow indicates the consumer is able to make the periodic payment.

Accordingly, pursuant to § 1026.43(e)(7)(iv)(A)(*5*), any payment received from one of the identified sources is not considered in assessing delinquency, except for making up the deficiency amount set forth in proposed § 1026.43(e)(7)(iv)(A)(*3*)(*ii*). Thus, for example, if a creditor or servicer advances $800 to cover a specific periodic payment on the consumer's behalf, it is treated as if the advanced $800 were not paid for purposes of assessing whether that periodic payment is delinquent under proposed § 1026.43(e)(7). However, § 1026.43(e)(7)(iv)(A)(*5*) does not prohibit creditors from making up a deficiency amount as part of a payment tolerance of $50 or less under the circumstances set forth in § 1026.43(e)(7)(iv)(A)(*3*)(*ii*).

Paragraph 43(e)(7)(iv)(B)

Proposed § 1026.43(e)(7)(iv)(C)(*2*) provided that the seasoning period does not include certain periods during which the consumer is in a temporary payment accommodation extended in connection with a disaster or pandemic-related national emergency, provided that during or at the end of the temporary payment accommodation there is a qualifying change or the consumer cures the loan's delinquency under its original terms. Proposed § 1026.43(e)(7)(iv)(C)(*2*) provided that, under those circumstances, the seasoning period consists of the period before the accommodation begins and an additional period immediately after the accommodation ends, which together must equal at least 36 months. Proposed § 1026.43(e)(7)(iv)(B) defined a qualifying change as an agreement that meets the following conditions: (1) The agreement is entered into during or after a temporary payment accommodation in connection with a disaster or pandemic-related national emergency as defined in § 1026.43(e)(7)(iv)(D), and must end any pre-existing delinquency on the loan obligation when the agreement takes effect; (2) the amount of interest charged over the full term of the loan does not increase as a result of the agreement; (3) the servicer does not charge any fee in connection with the agreement; and (4) the servicer waives all existing late charges, penalties, stop payment fees, or similar charges promptly upon the consumer's acceptance of the agreement. The Bureau is finalizing § 1026.43(e)(7)(iv)(B) largely as proposed, with modifications to the fees and charges that must be waived pursuant to § 1026.43(e)(7)(iv)(B)(*3*) and additional commentary to clarify that an agreement can be a qualifying change even if it is not in writing and that the inclusion of a balloon payment or lengthened loan term as part of a qualifying change does not disqualify a loan from seasoning. The Bureau is also making minor technical revisions to § 1026.43(e)(7)(iv)(B).

Many commenters supported the proposal's approach of restarting the seasoning period if the loan undergoes a qualifying change. Some industry

[164] For example, in addition to imposing conditions around the number and duration of delinquencies, Fannie Mae's lender selling representation and warranty framework provides that:

With the exception of mortgage loans with temporary buydowns, neither the lender nor a third party with a financial interest in the performance of the loan . . . can escrow or advance funds on behalf of the borrower to be used for payment of any principal or interest payable under the terms of the mortgage loan for the purpose of satisfying the payment history requirement.

Fannie Mae, *Selling Guide* at 56 (Aug. 5, 2020), *https://singlefamily.fanniemae.com/media/23641/display* (*Selling Guide*).

commenters suggested modifying proposed § 1026.43(e)(7)(iv)(B)(*4*) so that an agreement can meet the definition of a qualifying change even if the servicer does not waive charges, penalties, and fees that were incurred prior to a delinquency caused by a disaster or pandemic-related national emergency. Some industry commenters asked that the Bureau clarify whether an agreement needs to be in writing in order to constitute a qualifying change. Some industry commenters also suggested that the Bureau clarify whether the inclusion of a balloon payment or an extension of the loan term beyond 30 years as part of a qualifying change would disqualify the loan from seasoning. Lastly, one industry commenter urged the Bureau to modify § 1026.43(e)(7)(iv)(B)(*2*) to allow for the amount of interest charged over the full term of the loan to increase in certain circumstances, such as when certain amounts are capitalized into a new loan balance.

The Bureau understands that a variety of options may be available to bring current a loan that is subject to a temporary payment accommodation extended in connection with a disaster or pandemic-related national emergency. These options include, but are not limited to, curing the delinquency according to the terms of the original obligation, entering into a repayment plan, or entering into a permanent modification. In determining how to define a qualifying change, the Bureau seeks to establish standards that will reasonably ensure that any changes in the terms of a loan re-entering the seasoning period after a temporary payment accommodation extended in connection with a disaster or pandemic-related national emergency will not significantly change the affordability of the loan as compared to the loan terms at consummation. Accordingly, the Bureau concludes that such a qualifying change must end any pre-existing delinquency, must not add to the amount of interest charged over the full term of the loan, and must not involve an additional fee charged to the consumer in connection with the change.

Section 1026.43(e)(7)(iv)(B) references an agreement that must meet specific conditions in order to meet the definition of a qualifying change. Some commenters expressed concern that the term agreement could be interpreted to mean that a qualifying change is required to be in writing. Section 1026.43(e)(7)(iv)(B) does not require that an agreement be in writing in order for it to meet the definition of a qualifying change. The Bureau is adding comment 43(e)(7)(iv)(B)–1 to clarify that an agreement that meets the conditions specified in § 1026.43(e)(7)(iv)(B) is a qualifying change even if it is not in writing.

Some commenters expressed concern that the inclusion of a balloon payment or lengthened loan term as part of a qualifying change may disqualify a loan from seasoning due to the product restrictions listed in proposed § 1026.43(e)(7)(i)(A). Proposed comment 43(e)(7)(i)(A)–2 explained that proposed § 1026.43(e)(7)(i)(A) would not prohibit a qualifying change as defined in § 1026.43(e)(7)(iv)(B). In response to commenter concerns, the Bureau is adding additional language to comment 43(e)(7)(i)(A)–2 to clarify more specifically that § 1026.43(e)(7)(i)(A) does not disqualify a loan from seasoning eligibility if the loan undergoes a qualifying change as defined in § 1026.43(e)(7)(iv)(B), even if such a qualifying change involves a balloon payment or lengthened loan term. Although one commenter suggested that the Bureau address the applicability of certain loss mitigation protections under Regulation X in this final rule, the Bureau concludes it is not necessary to do so. Section 1026.43(e)(7)(iv)(B) defines qualifying change solely for purposes of the Seasoned QM definition in the ATR/QM Rule and does not affect other requirements, such as those in Regulation X, that may affect the servicing of a loan.

One commenter suggested that the Bureau should allow an agreement to meet the definition of a qualifying change even if the agreement allows for the capitalization of delinquent amounts and thereby causes the amount of interest charged over the full loan term to increase. As stated in the proposal, in establishing standards for a qualifying change, the Bureau sought to reasonably ensure that any such change would not significantly change the affordability of the loan as compared to the loan terms at consummation. Proposed § 1026.43(e)(7)(iv)(B)(*2*) would have required that, to meet the definition of a qualifying change, the amount of interest charged over the full term of the loan could not increase as a result of the agreement. The Bureau concludes that capitalization which leads to an increase in the total amount of interest charged as compared to the loan terms at consummation would make loans less affordable, such that the loans should not be eligible for seasoning. The Bureau is therefore adopting § 1026.43(e)(7)(iv)(B)(*2*) as proposed.

Proposed § 1026.43(e)(7)(iv)(B)(*4*) would have required the waiver of all existing late charges, penalties, stop payment fees, or similar charges promptly upon the consumer's acceptance of the agreement in order for the agreement to meet the definition of a qualifying change. As with the other criteria outlined in § 1026.43(e)(7)(iv)(B), the Bureau proposed this provision in the definition of a qualifying change to ensure that loans that ultimately become Seasoned QMs remain affordable after a temporary payment accommodation extended in connection with a disaster or pandemic-related national emergency.

The Bureau has decided to modify proposed § 1026.43(e)(7)(iv)(B)(*4*) to allow an agreement to meet the definition of a qualifying change even if servicers do not waive fees, penalties, and charges incurred prior to a delinquency caused by a disaster or pandemic-related national emergency. Adopting this change suggested by commenters is unlikely to significantly impact the affordability of a loan that enters into a qualifying change for two reasons.

First, loans with large balances for fees and charges related to delinquency (such as foreclosure preparation expenses) will likely already be disqualified from seasoning eligibility based on the performance requirements in § 1026.43(e)(7)(ii). Second, even if such fees are capitalized, § 1026.43(e)(7)(iv)(B)(*2*) will ensure that the amount of interest charged over the full term of the loan cannot increase as a result of the agreement. For these reasons, the Bureau is finalizing § 1026.43(e)(7)(iv)(B)(*4*) to provide that an agreement can meet the definition of a qualifying change if, in addition to the other requirements outlined in § 1026.43(e)(7)(iv)(B), promptly upon the consumer's acceptance of the agreement, the servicer waives a more limited set of charges than those listed in proposed § 1026.43(e)(7)(iv)(B)(*4*). Specifically, § 1026.43(e)(7)(iv)(B)(*4*) as finalized lists the following charges: All late charges, penalties, stop payment fees, or similar charges incurred during a temporary payment accommodation in connection with a disaster or pandemic-related national emergency, as well as all late charges, penalties, stop payment fees, or similar charges incurred during the delinquency that led to a temporary payment accommodation in connection with a disaster or pandemic-related national emergency.

Paragraph 43(e)(7)(iv)(C)

Section 1026.43(e)(7) requires that, to become a Seasoned QM, a covered transaction must meet certain

requirements during and at the end of the seasoning period. Proposed § 1026.43(e)(7)(iv)(C) defined the seasoning period as a period of 36 months beginning on the date on which the first periodic payment is due after consummation of the covered transaction, except that: (1) If there is a delinquency of 30 days or more at the end of the 36th month of the seasoning period, the seasoning period does not end until there is no delinquency; and (2) the seasoning period does not include any period during which the consumer is in a temporary payment accommodation in connection with a disaster or pandemic-related national emergency, provided that during or at the end of the temporary payment accommodation there is a qualifying change or the consumer cures the loan's delinquency under its original terms. The Bureau is adopting § 1026.43(e)(7)(iv)(C) largely as proposed.

Many industry commenters expressed support for the proposed general seasoning period of 36 months. These commenters agreed with the Bureau's rationale relating to consistency with the GSEs' representation and warranty framework, and expressed a belief, consistent with the Bureau's proposal, that default after 36 months is not likely to be related to underwriting deficiencies. Some industry commenters joined several consumer advocate groups to express general opposition to the adoption of a Seasoned QM rule, and these commenters urged the Bureau not to adopt a shorter seasoning period if it finalized such a rule. Some consumer advocate commenters generally asserted that three years of performance history was not sufficient to establish that a creditor had made a reasonable determination of ability to repay at origination. These commenters pointed to anecdotal and survey evidence of loans that were unaffordable at origination but did not default until after three years. These commenters did not suggest a longer seasoning period, but instead expressed opposition to the adoption of any Seasoned QM rule. One industry commenter advocated for a shorter seasoning period of two years, but only for Small Creditor QMs.

As explained in the proposal, in defining the length of the seasoning period, the Bureau seeks to balance two objectives. First, it seeks to ensure that safe harbor QM status accrues to loans for which the history of sustained, timely payments is long enough to conclusively presume that the consumer had the ability to repay at consummation. Second, in accomplishing its first objective, the Bureau seeks to avoid making the seasoning period so long that the Seasoned QM definition fails to incentivize increased access to credit, especially through increased originations of non-QM loans to consumers with the ability to repay them.

As explained in part V above, in evaluating the length of a seasoning period that is long enough to demonstrate a consumer's ability to repay, the Bureau considered the practices of market participants. These market participants typically require loans to meet certain requirements, such as a timely payment history, for a period of at least three years before releasing the loans' creditors from potential penalties and other remedies for deficiencies in underwriting practices. The Bureau also focused on the timing of the first disqualifying event from the Seasoned QM definition as well as the rate at which loans terminate, either through prepayment or foreclosure, to assess the potential population of loans that would be eligible to benefit from this proposal, as discussed in part V above and illustrated in Figures 2 and 3 of part VIII below. Based on these considerations and for the reasons discussed in part V above, the Bureau has decided to define the seasoning period generally as a period of at least 36 months, beginning on the date on which the first periodic payment is due after consummation. The Bureau declines to generally shorten or lengthen the proposed seasoning period. The Bureau concludes that the practices of market participants and the available loan performance data generally support a seasoning period of 36 months.

Paragraph 43(e)(7)(iv)(C)(1)

The Bureau proposed a seasoning period generally of 36 months beginning on the date on which the first periodic payment is due after consummation, unless an exception applies. The first proposed exception extended the seasoning period if the loan is 30 days or more delinquent at the point when the seasoning period would otherwise end. Specifically, proposed § 1026.43(e)(7)(iv)(C)(*1*) provided that if there is a delinquency of 30 days or more at the end of the 36th month of the seasoning period, the seasoning period does not end until there is no delinquency. The Bureau did not receive comments specifically addressing proposed § 1026.43(e)(7)(iv)(C)(*1*). For the reasons explained below, the Bureau is adopting § 1026.43(e)(7)(iv)(C)(*1*) as proposed.

If a delinquency of 30 days or more exists in the last month of the seasoning period, it is possible that the delinquency will be resolved quickly after the seasoning period ends or that the delinquency will continue for an extended period. In situations in which the delinquency is not resolved quickly, the Bureau concludes that the loan does not become a Seasoned QM, because the extended delinquency, if considered with the consumer's prior payment history, suggests that the creditor failed to make a reasonable, good faith determination of ability to repay at consummation. The Bureau is, therefore, extending the seasoning period under these circumstances until the loan is no longer delinquent. The loan would then have to meet the performance requirements under § 1026.43(e)(7)(ii) at the conclusion of the extended seasoning period based on performance over the entire, extended seasoning period.[165] The Bureau believes that extending the seasoning period until any delinquency of 30 days or more is resolved will help to ensure that loans for which a creditor failed to make a reasonable, good faith determination of ability to repay at consummation do not season into QMs under this final rule. As finalized, § 1026.43(e)(7)(iv)(C)(*1*) provides that, notwithstanding any other provision of § 1026.43(e)(7), if there is a delinquency of 30 days or more at the end of the 36th month of the seasoning period, the seasoning period does not end until there is no delinquency.

Paragraph 43(e)(7)(iv)(C)(2)

The Bureau proposed § 1026.43(e)(7)(iv)(C)(*2*) to address how the time during which a loan is subject to a temporary payment accommodation extended in connection with a disaster or pandemic-related national emergency[166] affects the seasoning period. Proposed § 1026.43(e)(7)(iv)(C)(*2*) provided that any period during which the consumer is in a temporary payment accommodation extended in connection

[165] A loan is eligible to season under the performance requirements in § 1026.43(e)(7)(ii) only if it has no more than two delinquencies of 30 or more days and no delinquencies of 60 or more days at the end of the seasoning period.

[166] As further discussed in the section-by-section analysis of § 1026.43(e)(7)(iv)(D) below, the Bureau is defining a temporary payment accommodation extended in connection with a disaster or pandemic-related national emergency as temporary payment relief granted to a consumer due to financial hardship caused directly or indirectly by a presidentially declared emergency or major disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, Public Law 93–288, 88 Stat. 143 (1974), or a presidentially declared pandemic-related national emergency under the National Emergencies Act, Public Law 94–412, 90 Stat. 1255 (1976).

with a disaster or pandemic-related national emergency would not be counted as part of the seasoning period. Proposed § 1026.43(e)(7)(iv)(C)(*2*) also stated that, if the seasoning period is paused due to a temporary payment accommodation defined in proposed § 1026.43(e)(7)(iv)(D), a loan must undergo a qualifying change [167] or the consumer must cure the delinquency under the loan's original terms before the seasoning period can resume. Proposed § 1026.43(e)(7)(iv)(C)(*2*) further explained that, under these circumstances, the seasoning period consists of the period from the date on which the first periodic payment was due after consummation of the covered transaction to the beginning of the temporary payment accommodation and an additional period immediately after the temporary payment accommodation ends, which together must equal at least 36 months. For the reasons discussed below, the Bureau is finalizing § 1026.43(e)(7)(iv)(C)(*2*) as proposed.

Many commenters were supportive of the Bureau's proposal to pause the seasoning period during a temporary payment accommodation extended in connection with a disaster or pandemic-related national emergency. Some industry commenters suggested that the Bureau allow the seasoning period to pause as soon as a delinquency occurs that is related to the type of disaster or pandemic-related national emergency defined in proposed § 1026.43(e)(7)(iv)(D), regardless of whether the consumer enters into a temporary payment accommodation. These commenters noted that after a disaster or emergency, consumers may not immediately enter a temporary payment accommodation, or they may not be placed in a temporary payment accommodation prior to receiving a permanent modification.

The Bureau has decided to exclude the period of time during which a loan is subject to certain temporary payment accommodations from the seasoning period for the three primary reasons stated in the proposal. First, the Bureau concludes that financial hardship experienced as a result of a disaster or pandemic-related national emergency is not likely to be indicative of a consumer's inability to afford a loan at consummation. Second, the Bureau concludes that the assessment of an entire 36-month seasoning period during which the consumer is obligated to make full periodic payments (whether based on the terms of the original obligation or a qualifying change) is necessary to demonstrate that the consumer was able to afford the loan at consummation. The Bureau concludes that a loan's performance during time spent in a temporary payment accommodation due to a disaster or pandemic-related national emergency should be excluded from this period because such accommodations typically involve reduced payments or no payment and are therefore not likely to assist in determining whether the creditor made a reasonable assessment of the consumer's ability to repay at consummation. Third, absent the exclusion of periods of such temporary payment accommodations from the seasoning period definition, financial institutions might have an incentive to delay offering these types of accommodations to consumers.

The Bureau concludes that not making payments because of financial hardship experienced as a result of a disaster or pandemic-related national emergency is not likely to be indicative of the consumer's inability to afford the loan at consummation. The consumer's failure to make payments does not indicate that the creditor did not comply with the ATR requirements at the time of consummation, because the disaster or pandemic-related national emergency is a change in the consumer's circumstances after consummation that the creditor could not have reasonably anticipated at consummation. This determination is consistent with the ATR/QM Rule's distinction between failure to repay due to a consumer's inability to repay at the loan's consummation, versus a consumer's subsequent inability to repay due to unforeseeable changes in the consumer's circumstances. Comment 43(c)(1)–2 states that ''[a] change in the consumer's circumstances after consummation . . . that cannot be reasonably anticipated from the consumer's application or the records used to determine repayment ability is not relevant to determining a creditor's compliance with the rule.'' As such, the Bureau determines that periods of temporary payment accommodation attributable to financial hardship related to a disaster or pandemic-related national emergency should not jeopardize the possibility of the loan seasoning into a QM if the consumer brings the loan current or enters into a qualifying change.

In evaluating how to treat periods of temporary payment accommodation for purposes of the seasoning period, the Bureau also considered how market participants address temporary payment accommodations with respect to penalties and other remedies for deficiencies in underwriting practices. The GSEs generally treat temporary and permanent payment accommodations as disqualifying for purposes of representation and warranty enforcement relief, but they make certain exceptions for accommodations related to disasters.[168] Similarly, the master policies of mortgage insurers generally provide rescission relief after 36 months of satisfactory payment performance, but a loan that has been subject to a temporary or permanent payment accommodation is typically not eligible for 36-month rescission relief, unless the accommodation was the result of a disaster. These practices, which extend to a significant portion of covered transactions, suggest that the GSEs and mortgage insurers have concluded, based on their experience, that payment accommodations resulting from disasters are not likely to be attributed to underwriting.[169]

Temporary payment accommodations entered into for reasons other than disasters or emergencies meeting the definition in § 1026.43(e)(7)(iv)(D) may be a sign of ongoing consumer financial distress that could indicate that the creditor did not make a reasonable assessment of the consumer's ability to repay at consummation. As such, the Bureau has decided to treat periods of temporary payment accommodation for reasons other than disasters or pandemic-related national emergencies as part of the seasoning period.

In defining limits for the types of temporary payment accommodations that qualify to be excluded from the seasoning period, the Bureau is also mindful of its goal of ensuring access to responsible, affordable mortgage credit

[167] As further discussed in the section-by-section analysis of § 1026.43(e)(7)(iv)(B) above, the Bureau is establishing specific requirements for the type of qualifying change that can restart the seasoning period.

[168] Fannie Mae's Selling Guide states that loans subject to non-disaster related payment accommodations ''may be eligible [for representation and warranty enforcement relief] on the basis of a quality control review of the loan file'' if certain other requirements are met. *See Selling Guide, supra* note 164, at 56. For purposes of representation and warranty enforcement relief, the GSEs allow disaster-related forbearance plans to count as part of seasoning periods, but only if the subject loan is brought current (via reinstatement, a repayment plan, or a permanent modification) after the forbearance plan ends. *See id.* at 57; Freddie Mac, *Seller/Servicer Guide* at 1301–19 (Aug. 5, 2020), *https://guide.freddiemac.com/ci/okcsFattach/get/1002095_2.*

[169] Although both the GSEs and mortgage insurers appear to count time spent in a disaster-related forbearance plan towards the 36-month time period, the Bureau believes that excluding temporary payment accommodations related to a disaster or pandemic-related national emergency from the seasoning period will best advance its goal of ensuring that the seasoning period allows enough time to assess whether the creditor made a reasonable determination of the consumer's ability to repay at consummation.

by establishing requirements which enable a financial institution to obtain a reasonable degree of certainty as to whether a loan has met the definition of a Seasoned QM at the end of the seasoning period. The Bureau is concerned that establishing a broader exclusion from the seasoning period (such as, for example, excluding a period of temporary payment accommodation entered into as the result of financial hardship arising from circumstances not foreseeable at origination) could lead to an uncertain standard whereby financial hardships resulting in temporary payment accommodations would need to be evaluated on a case-by-case basis to determine whether a loan subject to such accommodations could season into a QM. Therefore, the Bureau has decided to exclude from the seasoning period temporary payment accommodations only for disasters and pandemic-related national emergencies meeting the definition in § 1026.43(e)(7)(iv)(D). Some commenters raised concerns related to how the Bureau proposed to define the types of temporary payment accommodations that would be excluded from the seasoning period. Those comments, as well as the Bureau's responses to them, are addressed in the section-by-section analysis of § 1026.43(e)(7)(iv)(D).

The Bureau also emphasizes that, absent the exclusion of periods of temporary payment accommodations extended in connection with a disaster or pandemic-related national emergency from the seasoning period definition, financial institutions may be disincentivized from promptly offering these types of accommodations to consumers. Specifically, financial institutions may delay the provision of such payment accommodations until and unless affected loans are disqualified from seasoning into QM status due to accumulating two delinquencies of 30 or more days or one delinquency of 60 or more days. This final rule's exclusion of temporary payment accommodations related to a disaster or pandemic-related national emergency from the seasoning period is consistent with the Bureau's prior statements and actions encouraging financial institutions to move quickly to assist consumers affected by the urgent circumstances surrounding these types of events.[170]

At the same time, the Bureau recognizes that QM status is typically reserved for loans that meet various requirements designed to ensure affordability and wants to ensure that loans that season into QMs are affordable. For that reason, the Bureau is allowing loans to re-enter the seasoning period after a temporary payment accommodation ends only when the consumer cures the loan's delinquency under its original terms or specific qualifying changes are made to the loan obligation. As discussed further in the section-by-section analysis of § 1026.43(e)(7)(iv)(C), the limitation to qualifying changes is meant to ensure that any changes made to the loan terms after a temporary payment accommodation related to a disaster or pandemic-related national emergency do not make loans unaffordable. The Bureau is also requiring a seasoning period generally of 36 months, excluding the period of temporary payment accommodation, to ensure that there is sufficient information to evaluate the consumer's performance history using the performance requirements in § 1026.43(e)(7)(ii).

As noted above, some commenters suggested that delinquencies attributable to disasters or pandemic-related national emergencies should pause the seasoning period regardless of whether the consumer enters into a temporary payment accommodation. In developing the proposal, the Bureau evaluated the practices of market participants, such as mortgage insurers and the GSEs, with respect to penalties and other remedies for deficiencies in underwriting practices. Though mortgage insurers and the GSEs make allowances for temporary payment accommodations related to certain disasters, they do not extend these allowances to disaster-related delinquencies absent a temporary payment accommodation.

Additionally, as previously noted, the Bureau wants to avoid discouraging servicers from providing timely temporary payment accommodations after disasters or emergencies. Allowing for the seasoning period to pause for delinquencies related to disasters or emergencies even if consumers are not in a temporary payment accommodation may reduce the incentive of servicers to timely provide temporary payment accommodations.

Finally, the Bureau reiterates its goal of establishing requirements that enable financial institutions to obtain a reasonable degree of certainty as to whether a loan has met the definition of a Seasoned QM at the end of the seasoning period. Allowing an exclusion from the seasoning period for delinquencies related to certain disasters or emergencies without tying the exclusion to a temporary payment accommodation may introduce uncertainty as to whether a loan qualifies to season. Temporary payment accommodations are typically documented (for example, in servicing notes). Absent a temporary payment accommodation, it may be difficult for a creditor to retroactively demonstrate when a particular delinquency that was related to a disaster or pandemic-related national emergency began. For these reasons, the Bureau declines to adopt commenters' suggestion that delinquency relating to a disaster or pandemic-related national emergency be excluded from the seasoning period even if the consumer does not enter into a temporary payment accommodation.

Proposed comment 43(e)(7)(iv)(C)(*2*)–1 provided an example illustrating when the seasoning period begins, pauses, resumes, and ends for a loan that enters a temporary payment accommodation extended in connection with a disaster or pandemic-related national emergency. The example used a three-month temporary payment accommodation and subsequent qualifying change to illustrate that, in such circumstances, the seasoning period would end at least three months later than originally anticipated at the loan's consummation. The Bureau did not receive any substantive comments addressing proposed comment 43(e)(7)(iv)(C)(*2*)–1 and is finalizing comment 43(e)(7)(iv)(C)(*2*)–1 as proposed, with minor changes to conform to § 1026.43(e)(7)(iv)(C)(*1*).

Paragraph 43(e)(7)(iv)(D)

Proposed § 1026.43(e)(7)(iv)(D) addressed how a temporary payment accommodation made in connection with a disaster or pandemic-related national emergency is defined. The definition of the seasoning period in proposed § 1026.43(e)(7)(iv)(C)(*2*) does not include the period of time during which a consumer has been granted temporary payment relief due to a temporary payment accommodation made in connection with a disaster or pandemic-related national emergency. Proposed § 1026.43(e)(7)(iv)(D) defined

[170] *See, e.g.,* Bureau of Consumer Fin. Prot., *Statement on Bureau Supervisory and Enforcement Response to COVID–19 Pandemic* (Mar. 26, 2020), *https://files.consumerfinance.gov/f/documents/cfpb_supervisory-enforcement-statement_covid-19_2020-03.pdf;* Press Release, Bureau of Consumer Fin. Prot., *Agencies Provide Additional Information to Encourage Financial Institutions to Work with Borrowers Affected by COVID–19* (Mar. 22, 2020), *https://www.consumerfinance.gov/about-us/newsroom/agencies-provide-additional-information-encourage-financial-institutions-work-borrowers-affected-covid-19; see also* 85 FR 39055 (June 30, 2020) (the Bureau's June 2020 interim final rule amending Regulation X to allow mortgage servicers to finalize loss mitigation options without collecting a complete application in certain circumstances).

a temporary payment accommodation in connection with a disaster or pandemic-related national emergency to mean temporary payment relief granted to a consumer due to financial hardship caused directly or indirectly by a presidentially declared emergency or major disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act) or a presidentially declared pandemic-related national emergency under the National Emergencies Act.

Several commenters stated that they supported the Bureau's proposed approach of excluding from the seasoning period time spent in a temporary payment accommodation made in connection with a disaster or pandemic-related national emergency. Some industry commenters recommended that the Bureau expand the definition of a temporary payment accommodation to include accommodations related to disasters and emergencies declared on the State and local level. Some industry commenters requested that the Bureau expand the definition of a temporary payment accommodation to include accommodations related to more general financial emergencies, such as sudden job loss due to the closure of a consumer's place of employment.

The Bureau is finalizing § 1026.43(e)(7)(iv)(D) as proposed to refer only to presidentially declared emergencies or major disasters under the Stafford Act or presidentially declared pandemic-related national emergencies under the National Emergencies Act. The Bureau believes that defining a temporary payment accommodation in this way is necessary to provide sufficient certainty for financial institutions to ascertain what events can lead to financial hardships that result in temporary payment accommodations qualifying to be excluded from the seasoning period. The Stafford Act, which has been used for over 30 years to facilitate Federal disaster response, including disaster response for emergencies and major disasters affecting only certain States or localities, contains detailed definitions of what are considered to be emergencies or major disasters under that statute.[171] The National Emergencies Act, which has been in place for more than 40 years, was invoked to declare a national emergency due to the COVID–19 pandemic.[172] The Bureau has decided that referring to these two statutes is necessary to provide sufficient certainty for financial institutions to ascertain what events can lead to financial hardships that result in temporary payment accommodations qualifying to be excluded from the seasoning period.

Furthermore, the Bureau's intent is that Seasoned QM eligibility standards apply clearly and consistently on the national level. The Bureau notes that the Stafford Act has frequently been invoked to declare emergencies and major disasters that affect only certain States or localities. The Bureau intends to include such federally declared emergencies and major disasters in § 1026.43(e)(7)(iv)(D)'s definition, using the nationally applicable definitions outlined in the Stafford Act. However, while the Stafford Act and National Emergencies Act provide nationally applicable standards for emergency and disaster declarations, State and local standards for emergency and disaster declarations vary widely. Expanding the definition in § 1026.43(e)(7)(iv)(D) to State and local emergency and disaster declarations would therefore make Seasoned QM eligibility inconsistently available based on the location of the consumer's property. And as discussed above, expanding the definition to encompass a more general financial emergency standard would lead to uncertainty as to whether a loan qualifies to become a Seasoned QM. The Bureau therefore declines to expand the definition in § 1026.43(e)(7)(iv)(D) to include State and local emergency and disaster declarations or a more general financial emergency standard and is adopting § 1026.43(e)(7)(iv)(D) as proposed.

Proposed comment 43(e)(7)(iv)(D)–1 provided a non-exclusive list of examples of the types of temporary payment accommodations in connection with a disaster or pandemic-related national emergency that can be excluded from the seasoning period if they meet the definition in proposed § 1026.43(e)(7)(iv)(D) and the requirements of proposed § 1026.43(e)(7)(iv)(C)(*2*). The Bureau did not receive comments addressing proposed comment 43(e)(7)(iv)(D)–1 and is finalizing comment 43(e)(7)(iv)(D)–1 as proposed.

VII. Effective Date

The Bureau proposed that a final rule relating to this proposal would take effect on the same date as a final rule amending the General QM loan definition. In the General QM Proposal, the Bureau proposed that the effective date of a final rule relating to the General QM Proposal would be six months after publication in the **Federal Register**. The Bureau proposed that both the Seasoned QM Final Rule and the General QM Final Rule would apply to covered transactions for which creditors receive an application on or after the effective date.

Several commenters supported aligning this final rule's effective date with that of the General QM Final Rule. An industry commenter requested that the Bureau make this final rule immediately effective to take advantage of the benefits as soon as possible, while another industry commenter suggested that this final rule not take effect until 18 to 24 months after issuance to allow time for implementation.

Many industry commenters requested that the Bureau apply this final rule to loans existing before the effective date. Such commenters noted, for example, that the proposal included robust consumer protections and suggested that such protections would apply equally well to existing loans as they do to future loans. On the other hand, consumer advocate commenters urged the Bureau not to apply the rule to loans in existence before the effective date, suggesting that doing so would likely violate the vested rights of non-QM borrowers.

This final rule will take effect 60 days after publication in the **Federal Register**, which aligns with the effective date provided in the General QM Final Rule. The Bureau declines to adopt a later effective date because the Bureau concludes that 60 days will provide creditors and the secondary market adequate implementation time for this final rule, which adds a new QM definition but does not require creditors or other stakeholders to take any action if they do not intend to rely upon the new QM definition. The Bureau also declines to make the rule effective earlier than 60 days after publication in the **Federal Register**, because it wants to ensure that creditors and other stakeholders have adequate time to become familiar with this final rule before it takes effect.

Consistent with many of the industry comments received, the Bureau does not believe that there is any reason to conclude that the inference to be drawn as to ability to repay is any different

[171] Stafford Act section 102(1) and (2), 88 Stat. 144.

[172] Proclamation No. 9994, 85 FR 15337 (Mar. 13, 2020). The Stafford Act was also invoked to declare an emergency due to the COVID–19 pandemic. *See* Press Release, The White House, *Letter from President Donald J. Trump on Emergency Determination Under the Stafford Act* (Mar. 13, 2020), *https://www.whitehouse.gov/briefings-statements/letter-president-donald-j-trump-emergency-determination-stafford-act/*.

depending on whether a 36-month successful payment history begins before or after the effective date. However, the Bureau continues to believe that parties to loans existing at the time of the effective date may have significant reliance interests related to the QM status of those loans.[173] In light of these potential reliance interests, the Bureau has decided not to apply the final rule to loans in existence prior to the effective date. Thus, this final rule applies to covered transactions for which creditors receive an application on or after the effective date.

An industry trade association also asked that the Bureau use the definition found in the TILA–RESPA Integrated Disclosure Rule (TRID) to provide clarification on the meaning of ''application date'' in this final rule. The General QM Final Rule adds comment 43–2 to Regulation Z, which clarifies that, for transactions subject to TRID, creditors determine the date the creditor received the consumer's application, for purposes of the General QM Final Rule's effective date and mandatory compliance date, in accordance with § 1026.2(a)(3)(ii), which is the definition of application that applies to transactions subject to TRID. Comment 43–2 also clarifies that, for transactions that are not subject to TRID, creditors can determine the date the creditor received the consumer's application, for purposes of the General QM Final Rule's effective date and mandatory compliance date, in accordance with either § 1026.2(a)(3)(i) or (ii). The Extension Final Rule added a similar comment (comment 43(e)(4)–4) for purposes of § 1026.43(e)(4)(iii)(B), as revised by the Extension Final Rule, which takes effect on December 28, 2020. For purposes of the effective date of this final rule, the Bureau is using ''application'' in a manner consistent with new comments 43–2 and 43(e)(4)–4. Thus, for transactions subject to § 1026.19(e), (f), or (g), creditors determine the date the creditor received the consumer's application for purposes of the effective date of this final rule in accordance with TRID's definition of application in § 1026.2(a)(3)(ii). For transactions that are not subject to TRID, creditors can determine the date the creditor received the consumer's application for purposes of the effective date of this final rule in accordance with either § 1026.2(a)(3)(i) or (ii).

VIII. Dodd-Frank Act Section 1022(b) Analysis

A. Overview

In developing this final rule, the Bureau has considered the potential benefits, costs, and impacts as required by section 1022(b)(2)(A) of the Dodd-Frank Act. Specifically, section 1022(b)(2)(A) of the Dodd-Frank Act requires the Bureau to consider the potential benefits and costs of a regulation to consumers and covered persons, including the potential reduction of access by consumers to consumer financial products or services, the impact on depository institutions and credit unions with $10 billion or less in total assets as described in section 1026 of the Dodd-Frank Act, and the impact on consumers in rural areas. The Bureau consulted with appropriate prudential regulators and other Federal agencies regarding the consistency of this final rule with prudential, market, or systemic objectives administered by such agencies as required by section 1022(b)(2)(B) of the Dodd-Frank Act.

This final rule defines a new category of QMs for first-lien, fixed-rate, covered transactions that have fully amortizing payments and do not have loan features proscribed by the statutory QM requirements, such as balloon payments, interest-only features, terms longer than 30 years, or points and fees above prescribed amounts. High-cost mortgages subject to HOEPA are not eligible to season. Creditors will have to satisfy consider and verify requirements and keep the loans in portfolio until the end of the seasoning period, excepting a single whole-loan transfer, transfers related to mergers and acquisitions, and certain supervisory sales during the seasoning period. The loans will also have to meet certain performance requirements. Specifically, loans can have no more than two delinquencies of 30 or more days and no delinquencies of 60 or more days at the end of the seasoning period. Covered transactions that satisfy the Seasoned QM requirements will receive a safe harbor from ATR liability at the end of the seasoning period.

As discussed above, a goal of this final rule is to enhance access to responsible, affordable mortgage credit. This final rule incentivizes the origination of non-QM and rebuttable presumption QM loans that a creditor expects to demonstrate a sustained and timely mortgage payment history by providing a separate path to safe harbor QM status for these loans if creditors' expectations are fulfilled. This final rule therefore may encourage meaningful innovation and lending to broader groups of creditworthy consumers that would otherwise not occur.

1. Data and Evidence

The impact analyses rely on data from a range of sources. These include data collected or developed by the Bureau, including the Home Mortgage Disclosure Act of 1975 (HMDA)[174] and National Mortgage Database (NMDB)[175] data as well as data obtained from industry, other regulatory agencies, and other publicly available sources. The Bureau also conducted the Assessment and issued the Assessment Report as required under section 1022(d) of the Dodd-Frank Act. The Assessment Report provides quantitative and qualitative information on questions relevant to the analysis that follows, including the share of lenders that originate non-QM loans. Consultations with other regulatory agencies, industry, and research organizations inform the Bureau's impact analyses.

The data the Bureau relied upon provide detailed information on the number, characteristics, pricing, and performance of mortgage loans originated in recent years. In response to the Seasoned QM Proposal, the Bureau did not receive additional information or data that could inform quantitative estimates such as APRs or other costs like those associated with private mortgage insurance.

[173] As indicated in the proposal, the Bureau also recognizes that there could be legal issues related to the application of rules governing mortgage origination to loans existing prior to the effective date. *See, e.g., Landgraf* v. *USI Film Prods.,* 511 U.S. 244, 269 (1994) (holding that a rule is impermissibly retroactive when it ''takes away or impairs vested rights acquired under existing laws, or creates a new obligation, imposes a new duty, or attaches a new disability, in respect to transactions or considerations already past'') (citation omitted); *Bowen* v. *Georgetown Univ. Hosp.,* 488 U.S. 204, 208 (1988) (holding that an agency cannot ''promulgate retroactive rules unless that power is conveyed by Congress in express terms'').

[174] Public Law 94–200, tit. III, 89 Stat. 1125 (1975). HMDA requires many financial institutions to maintain, report, and publicly disclose loan-level information about mortgages. These data help show whether creditors are serving the housing needs of their communities; they give public officials information that helps them make decisions and policies; and they shed light on lending patterns that could be discriminatory. HMDA was originally enacted by Congress in 1975 and is implemented by Regulation C. *See* Bureau of Consumer Fin. Prot., *https://www.consumerfinance.gov/data-research/hmda* (last visited Nov. 30, 2020).

[175] The NMDB, jointly developed by the FHFA and the Bureau, provides de-identified loan characteristics and performance information for a 5 percent sample of all mortgage originations from 1998 to the present, supplemented by de-identified loan and borrower characteristics from Federal administrative sources and credit reporting data. *See* Bureau of Consumer Fin. Prot., *Sources and Uses of Data at the Bureau of Consumer Financial Protection* at 55–56 (Sept. 2018), *https://www.consumerfinance.gov/documents/6850/bcfp_sources-uses-of-data.pdf.* Differences in total market size estimates between NMDB data and HMDA data are attributable to differences in coverage and data construction methodology.

The data provide only limited information on the costs to creditors of uncertainty related to legal liability that this final rule may mitigate. As a result, the analysis of impacts of this final rule on creditor costs from reduced uncertainty related to legal liability relies on simplifying assumptions and qualitative information as well as the limited data that are available. This analysis indicates the relative magnitude of the potential effects of this final rule on these costs.

Finally, as discussed further below, the analysis of the impacts of this final rule requires the Bureau to use current data to predict the number of originations of certain types of non-QM loans and the performance of these loans. It is possible, however, that the market for mortgage originations may shift in unanticipated ways given the changes considered below.

2. Description of the Baselines

The Bureau considers the benefits, costs, and impacts of the final rule against two baselines. The first baseline (Baseline 1) takes into account that the Bureau's final rule amending the General QM loan definition is adopted. The second baseline (Baseline 2) assumes that the Bureau does not amend the General QM loan definition and the Temporary GSE QM loan definition expires when the GSEs cease to operate under conservatorship.

Under each baseline, there are different numbers of loans that would be originated, and which would meet all of the requirements for a Seasoned QM at consummation except for the performance and portfolio requirements of this final rule. These are the loans under each baseline that are first-lien, fixed-rate covered transactions that comply, as described above, with certain general restrictions on product features, points-and-fees limits, and underwriting requirements. Further, only some of these loans would benefit if they met the performance and portfolio requirements for a Seasoned QM, meaning that as a result of meeting those requirements, they would obtain QM status or a stronger presumption of compliance, or would not need to satisfy the portfolio retention requirements that would be necessary to maintain safe harbor QM status under the EGRRCPA. The analysis below predicts the annual number of loan originations under each baseline, in years similar to 2018, that would meet all of the requirements of a Seasoned QM at consummation (except for the performance and portfolio requirements) and would benefit if they met the performance and portfolio requirements during the seasoning period. Upon satisfying all the requirements of the Seasoned QM definition, these loans would obtain QM status or a stronger presumption of compliance, or would not need to satisfy the portfolio retention requirements of the EGRRCPA.[176] Relative to the proposal, the Bureau has updated its methodology in two ways. First, the estimates for Baseline 1 have been updated to reflect updates to the pricing thresholds in the General QM Final Rule. Second, the Bureau has also adjusted its analysis to reflect an improved methodology to identify creditors eligible to originate loans as small creditors under § 1026.43(e)(5), consistent with the section 1022(b) analysis accompanying the General QM Final Rule.

As stated above, under Baseline 1, the General QM Final Rule is adopted. Consider first all of the non-QM loans under Baseline 1 that would meet all of the requirements at consummation for a Seasoned QM and would benefit if they met the performance and portfolio requirements of the seasoning period.[177] To count these loans, the Bureau used 2018 HMDA data to identify all residential first-lien, fixed-rate conventional loans for one-to-four unit housing that do not have prohibited features or other disqualifying characteristics; are not Small Creditor QMs or entitled to a presumption of compliance under the EGRRCPA QM definition;[178] and for which the APR exceeds APOR by the amounts specified in the General QM Final Rule's amendments to § 1026.43(e)(2)(vi)(A) through (F). The Bureau estimates that there are 21,269 of these loans. These loans would benefit from this final rule by obtaining safe harbor QM status if they meet the performance and portfolio requirements of the seasoning period, and not otherwise.[179]

Consider next all of the rebuttable presumption QM loans under Baseline 1 that would meet all of the requirements at consummation for a Seasoned QM and would benefit if they met the performance and portfolio requirements of the seasoning period. To count these loans, the Bureau has used 2018 HMDA data to identify two groups of loans. The first group is all fixed-rate, higher-priced covered transactions that meet the proposed General QM loan definition but are not Small Creditor QM loans or loans entitled to a presumption of compliance under the EGRRCPA QM definition. The Bureau estimates that there are 108,020 of these loans. The second group is all fixed-rate rebuttable presumption Small Creditor QMs. The Bureau estimates that there are 3,137 of these loans. Thus, the Bureau estimates that 111,157 loans would benefit from this final rule by obtaining safe harbor QM status instead of rebuttable presumption QM status if they meet the performance and portfolio requirements of the seasoning period, and not otherwise.[180]

Finally, consider all of the loans under Baseline 1 that are entitled to a presumption of compliance under the EGRRCPA QM definition and that (1) meet all of the requirements at consummation for a Seasoned QM and (2) do not otherwise satisfy the criteria to qualify for a safe harbor under the General QM Final Rule or the Small Creditor QM definition. The Bureau estimates that there are 23,200 loans in this category. This set of loans could obtain a safe harbor as Seasoned QMs without satisfying the portfolio retention requirements that would be necessary to obtain protection from liability under the EGRRCPA, provided they meet the performance and portfolio requirements of the seasoning period, and not otherwise.

Thus, under Baseline 1, approximately 155,626 loans would meet all of the requirements at consummation for Seasoned QMs and would obtain QM status or a stronger presumption of compliance, or would not need to satisfy the portfolio retention requirements of the EGRRCPA, if they subsequently meet the performance and portfolio requirements of the seasoning period. This is the

[176] Thus, the analysis estimates the maximum number of loans under each baseline that would become Seasoned QMs if the loans met the performance and portfolio requirements. The Bureau has discretion in any rulemaking to choose an appropriate scope of analysis with respect to benefits, costs, and impacts, as well as an appropriate baseline or baselines.

[177] Analysis of HMDA data for Baseline 1 excludes loans where rate spread is not observed.

[178] EGRRCPA section 101 provides that loans must be originated and retained in portfolio by a covered institution, except for limited permissible transfers. Although EGRRCPA section 101 took effect upon enactment, the Bureau has not undertaken rulemaking to address any statutory ambiguities in Regulation Z.

[179] Note that the analysis uses 2018 data, but this final rule does not apply to these loans since this final rule applies to covered transactions for which creditors receive an application on or after the effective date.

[180] The Bureau assumes solely for purposes of this section 1022(b) analysis that all loans originated under the EGRRCPA QM definition will obtain a safe harbor in the form of a conclusive presumption of compliance with the ATR requirements. To the extent some subset of such loans should qualify for a lesser presumption, however, these loans would comprise a third group for consideration here, since these loans would benefit if they met the performance and portfolio requirements of the seasoning period.

expected annual number of loan originations under Baseline 1 in years similar to 2018 that meet all of the requirements of a Seasoned QM at consummation and would benefit if they met the performance and portfolio requirements of the seasoning period. Some of these loans very likely will meet those performance and portfolio requirements, and some very likely will not.[181]

Now consider Baseline 2. As stated above, under Baseline 2, no amendments to the General QM loan definition are adopted, and the Temporary GSE QM loan definition expires when the GSEs cease to operate under conservatorship. The Bureau estimates effects under Baseline 2 subsequent to the expiration of the Temporary GSE QM loan definition. While there is not a fixed date on which the Temporary GSE QM loan definition will expire in the absence of the final rule amending the General QM requirements, the Bureau anticipates that the GSEs will eventually cease to operate under conservatorship. Consider first all of the non-QM loans under Baseline 2 that would meet all of the requirements at consummation for a Seasoned QM and would benefit if they met the performance and portfolio requirements of the seasoning period.[182] To count these loans, the Bureau has used 2018 HMDA data to identify all residential first-lien, fixed-rate conventional loans for one-to-four unit housing that do not have prohibited features or other disqualifying characteristics; are not Small Creditor QMs or originated under the EGRRCPA QM definition; and do not satisfy the DTI requirement specified in § 1026.43(e)(2)(vi) of the current General QM loan definition. The Bureau estimates that there are 718,509 of these loans. These loans would benefit from this final rule by obtaining safe harbor QM status if they meet the performance and portfolio requirements of the seasoning period, and not otherwise.

Consider next all of the rebuttable presumption QM loans under Baseline 2 that would meet all of the requirements at consummation for a Seasoned QM and would benefit if they met the performance and portfolio requirements of the seasoning period. To count these loans, the Bureau has used 2018 HMDA data to identify two groups of loans. The first group is all first-lien, fixed-rate higher-priced covered transactions that meet the current General QM loan definition, but which are not Small Creditor QMs or loans entitled to a presumption of compliance under the EGRRCPA QM definition. The Bureau estimates that there are 87,122 of these loans. The second group is all first-lien, fixed-rate rebuttable presumption Small Creditor QMs. The Bureau estimates that there are 3,137 of these loans. Thus, the Bureau estimates that 90,259 loans would obtain safe harbor QM status instead of rebuttable presumption QM status if they meet the performance and portfolio requirements of the seasoning period, and not otherwise.[183]

Finally, consider all of the loans under Baseline 2 that are entitled to a presumption of compliance under the EGRRCPA QM definition and that (1) meet all of the requirements at consummation for a Seasoned QM and (2) do not otherwise satisfy the criteria to qualify for a safe harbor under the General QM Final Rule or the Small Creditor QM definition. The Bureau estimates that there are 123,875 loans that would fall into this category. This set of loans could obtain a safe harbor as Seasoned QMs without satisfying the portfolio retention requirements that would be necessary to obtain protection from liability under the EGRRCPA, provided they meet the performance and portfolio requirements of the seasoning period, and not otherwise.

Thus, under Baseline 2, approximately 932,643 loans would meet all of the requirements at consummation for Seasoned QMs and would obtain QM status, a stronger presumption of compliance, or relief from portfolio retention requirements, if they subsequently meet the performance and portfolio requirements of the seasoning period. This is the expected annual number of loan originations under the baseline in years similar to 2018 that meet all of the requirements of a Seasoned QM and would benefit if they met the performance and portfolio requirements of the seasoning period. Some of these loans very likely will meet those performance and portfolio requirements, and some very likely will not.

B. Potential Benefits and Costs to Covered Persons and Consumers

This final rule reduces the chance a consumer will assert or succeed when asserting violations of ATR requirements in a defense to foreclosure. This section considers the potential benefits and costs of this final rule on creditors first and then consumers. The analysis begins by assessing how this final rule could potentially affect creditors' litigation risk, cost of origination, and the price of borrowing, holding originations constant. The analysis then considers the potential impacts of this final rule on originations and the benefits and costs of this effect. The Bureau cannot reliably quantify this effect, so the analysis considers qualitatively the potential benefits to both creditors and consumers of market expansion.

Several commenters noted that the proposal lacked an analysis that quantified market expansion and subsequently weighed the consumer value of those effects against the consumer value of changes to foreclosure defense. The Bureau agrees that it would be valuable to conduct such an analysis. However, the Bureau is not aware of data that would permit it to reliably do so. One would first need to estimate how this final rule will change creditors' cost savings by decreasing litigation risk. Second, one needs to estimate how much of those cost savings will be passed through to consumers, for which consumers, and via which mortgage products. Third, one needs to estimate how many new consumers would obtain mortgage loans and which loans they would obtain. Fourth, one would need to estimate how much these new consumers value their newfound access to credit. Fifth, an analysis needs two pieces of information for two classes of borrowers: Those who would borrow regardless of whether the Bureau promulgates this final rule and those who are induced to borrow as a result of it. For each class, one would need to estimate the rate at which such borrowers experience foreclosure and the value to such borrowers of an ATR defense in foreclosure. If the Bureau does not have the data that would be needed to produce these estimates, the Bureau provides a qualitative discussion below based on economic principles and the Bureau's experience within and expertise in the mortgage markets.

1. Benefits and Costs to Covered Persons

Benefits From Reduced Litigation Risk

Covered persons, specifically mortgage creditors, primarily benefit

[181] The Bureau cannot reliably measure the full expansionary effect of this final rule on loan originations. One effect might be that this final rule would cause the share of loan applications that lead to originations of non-QM loans under the baseline (88 percent) to match the overall share (95 percent for loan applications for which Bureau data include the rate spread). This would lead to an additional 1,800 non-QM originations not accounted for above.

[182] Analysis of HMDA data for Baseline 2 excludes loans where rate spread or DTI are not observed.

[183] The same caveat with respect to EGRRCPA section 101 discussed for Baseline 1 applies here as well.

from decreased litigation risk under this final rule. Generally, the statute of limitations for a private action for damages for a violation of the ATR requirement is three years after the date on which the violation occurs. In the proposal, the Bureau anticipated that the Seasoned QM definition would not curtail the ability of consumers to bring affirmative claims seeking damages for alleged violations of the ATR requirements because the proposed seasoning period would generally coincide with the statute of limitations. One academic commenter indicated that under the proposal, loans could season during pending litigation, cutting off claims filed within the three-year statute of limitations period. The Bureau acknowledges that because litigation takes time, it is possible that some loans could season under § 1026.43(e)(7) after an ATR/QM claim is timely filed, cutting off claims filed prior to the statute of limitations. Nevertheless, the aggregate effects of consumers' loans seasoning during litigation are likely to be small under current levels of originations and rates of affirmative claims. However, because the Bureau does not have either the data to quantify the new loans that will be originated as a result of the final rule nor the rate at which claims will be brought against creditors of those loans, it also cannot reliably forecast these economic impacts on consumers in the case of market expansion or changing market conditions.

TILA also authorizes a consumer to assert a violation of the ATR requirements as a defense in the event of a foreclosure without regard for the time limit on a private action for damages for such a violation. For Seasoned QMs that are non-QM loans or rebuttable presumption QM loans at consummation, this final rule will effectively limit the consumer's ability to establish non-compliance with the ATR requirements after the seasoning period has run as a general matter.

The creditors' economic value of the reduction of litigation risk is related to how each of three factors changes with this final rule relative to the baseline: (1) The fraction of consumers that enter foreclosure, (2) the likelihood that ATR defenses are successful in foreclosure lawsuits, and (3) the costs associated with the lawsuits. The Bureau analyzed NMDB data to assess the first factor and, in the Seasoned QM Proposal, sought pertinent information related to ATR defenses in foreclosure proceedings and related costs. One consumer advocate commenter argued that the value of ATR defense can be ascertained from past experiences with ATR litigation. Noting only a single case of ATR litigation since the ATR/QM Rule went into effect, the commenter offered several case studies from prior to the January 2013 Final Rule. Given the differences in legal circumstances between before and after the Dodd-Frank Act, it is not clear that ATR litigation from prior to the Dodd-Frank Act provides a sound basis for assessing changes in aggregate litigation risk from this final rule.

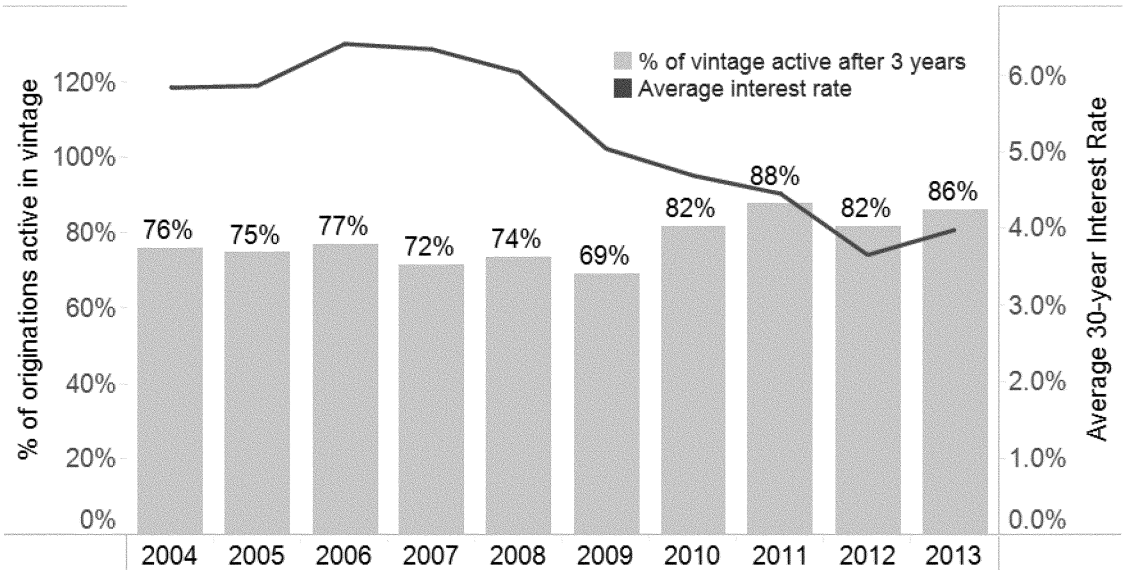
An academic commenter asserted that if the proposal were adopted, the resulting new non-QM originations could reflect riskier features and suggested that, as a result, those that would season would also enter foreclosure at a rate higher than the Bureau's foreclosure analysis suggests. The Bureau acknowledges that its foreclosure analysis reflects characteristics of loans originated in the past and not necessarily those that would be originated as a result of this final rule. However, the Bureau does not agree with the commenter's premise that if this final rule resulted in an expansion of credit, the new loans would necessarily reflect riskier features, and default and foreclosure start rates would increase. Accompanying the consider and verify requirements, product restrictions (such as the limitation to first-lien, fixed-rate loans), and points-and-fees restrictions of this final rule, the portfolio and performance requirements incentivize creditors to originate loans that will perform, since otherwise they will not season and obtain a safe harbor. Nonetheless, the Bureau is unaware of data that would allow it to forecast new originations' characteristics or the fraction that would meet the performance requirements to become Seasoned QMs. Correspondingly, the Bureau cannot assess how the foreclosure start rate of the subsequent non-QM loans, seasoned or otherwise, would differ from the foreclosure start rate of loans originated in the past. Finally, the overall foreclosure start rate reflects foreclosure starts of both loans that would be originated as a result of this final rule's expansion of credit and those that would be originated regardless. If this final rule results in an expansion of credit of only a few loans, the foreclosure analysis would be relatively unaffected regardless of the foreclosure risk of those loans. Conversely, the Bureau's foreclosure analysis may be less reliable if this final rule results in a major expansion of credit. As stated previously, the Bureau is unaware of data that would allow it to quantify the size of market expansion.

The full NMDB data are a nationally representative sample of mortgages from 1998 to 2020, covering periods with differing economic and interest rate environments. Of these mortgages, the analysis focuses on conventional, fixed-rate purchase and refinance loans with no prohibited features that were privately held at consummation. Due to data limitations in the NMDB, the analysis of loan performance makes three assumptions. First, loans would continue to be originated under each baseline with the same characteristics regardless of QM status. Second, potentially seasonable loans are ineligible for the portfolio requirements of the EGRRCPA and thus can only achieve safe harbor status via this final rule. The proposal would have required that loans be held in portfolio unless transfers are related to mergers and acquisitions and certain supervisory sales during the seasoning period. This final rule additionally allows a single whole-loan transfer. The change does not affect the analysis.[184]

The likely quantitative impact of this final rule depends in part on the rate of attrition for loans during the first three years, as well as on the performance of the loans that are active for at least three years. Figure 2 plots the fraction of higher-priced loans, those with an interest rate 150 basis points or more over the Primary Mortgage Market Survey (PMMS), that were open after three years between 2004 and 2013 in order to provide context for the quantitative foreclosure analysis that follows.

[184] NMDB data do not permit one to ascertain the number of times ownership of privately held loans that were not securitized was transferred between institutions. Whereas the analysis in the proposal assumed that unsecuritized, privately held loans were held in portfolio by a single party, this analysis assumes that the same loans were not transferred more than once.

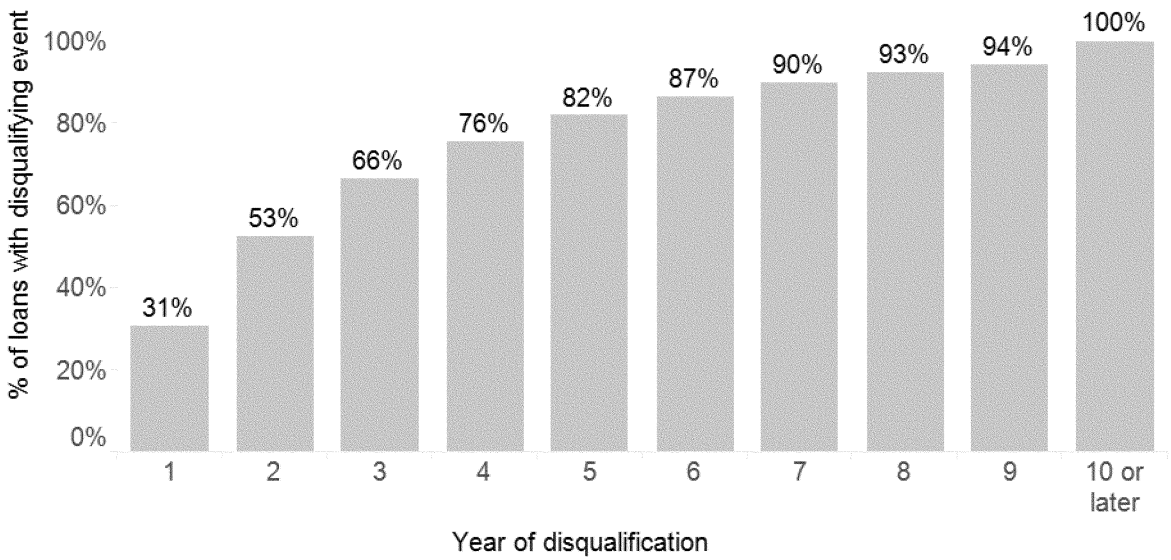
Figure 2: Percentage of Higher-Priced Active Loans by Year



Source: NMDB (percent active) and Federal Reserve Economic Data (FRED), Federal Reserve Bank of St. Louis (average interest rate); NMDB numbers show fixed-rate conventional loans held in portfolio with no restricted product features; higher-priced loans are defined as those with an interest rate 150 basis points or more over the PMMS, which is a slightly different rate spread measure from those that use APR; loans with imputed loan purpose or ARM-flag are not included.

Figure 2 serves as a reminder that, over time, the effects of this final rule will depend on trends in interest rates. Loans originated between 2004 and 2009 were typically originated at higher interest rates and therefore would receive a significant benefit from refinancing when interest rates declined during and after the 2008 financial crisis. Loans originated in these same years also experienced elevated foreclosure start rates during the 2008 financial crisis. As a result, a lower share of loans remained active beyond three years, and so the potential effects of this final rule would be smaller. This contrasts to post-crisis origination years where initial mortgage rates and foreclosure start rates remained low and a larger share of loans remained active beyond three years.

Figure 3: Percentage of higher-priced loans originated between 1998–2008 that had suffered a disqualifying event among those that ever suffer a disqualifying event



Source: NMDB; fixed-rate conventional loans held in portfolio with no restricted product features; higher priced loans are defined as those with an interest rate 150 basis points or more over the PMMS, which is a slightly different rate spread measure from those that use APR; loans with imputed loan purpose or ARM-flag are not included; disqualifying event could be either the third 30-day late payment, the first rolling 30-day delinquency, or the first 60-day delinquency.

Figure 3 provides additional context for the quantitative foreclosure analysis. The figure considers higher-priced loans originated between 1998 to 2008, all of which incur sufficient late payments or delinquencies to disqualify them from seasoning depending on the specified length of the seasoning period. Figure 3 shows, for example, that 66 percent of loans with these performance problems would have been disqualified from seasoning under this final rule's seasoning period of 36 months. This compares to 53 percent of such loans if the seasoning period were 24 months and 76 percent if the seasoning period were 48 months.

Foreclosure Risk of Loans That Meet Seasoned QM's Performance Requirements in Baseline 1

To assess this final rule's potential effect on foreclosure risk, the Bureau analyzed data from the NMDB on the 1,275,480 conventional fixed-rate, first-lien loans that were originated between 2012 and 2013 without prohibited features. The loans potentially would have met this final rule's Seasoned QM performance criteria in 2015 and 2016.

The analyses first classify loans by whether they would have satisfied the General QM Final Rule's requirements for safe harbor and rebuttable presumption in Baseline 1 at consummation.[185] Ten percent of loans would have been either rebuttable presumption or non-QM loans and would have potentially benefited from the Seasoned QM definition's pathway to safe harbor if they had met the final rule's performance requirements.

TABLE 1—SHARE OF LOANS UNDER BASELINE 1 THAT WERE OPEN AND HAD NOT ENTERED FORECLOSURE AFTER THREE YEARS AND WOULD HAVE MET PERFORMANCE CRITERIA

Type of loan	Open and had not entered foreclosure after three years (percent)	Met performance criteria (cond. on open) (percent)
Safe Harbor	78	99
Seasonable Loans	78	92
Rebuttable Presumption	81	94
Non-QM	73	86
Missing Rate Spread	61	87

[185] The NMDB data do not enable the Bureau to ascertain whether loans were originated by creditors that meet the size criteria for originating QM loans under the Small Creditor QM or EGRRCPA QM definitions.

TABLE 1—SHARE OF LOANS UNDER BASELINE 1 THAT WERE OPEN AND HAD NOT ENTERED FORECLOSURE AFTER THREE YEARS AND WOULD HAVE MET PERFORMANCE CRITERIA—Continued

Type of loan	Open and had not entered foreclosure after three years (percent)	Met performance criteria (cond. on open) (percent)
All Loans	77	97

Classifying loans according to their status under Baseline 1, Table 1 reports the fraction of loans that were open and had not entered foreclosure after three years and of those open loans, the fraction that would have met the performance criteria of this final rule. Seventy-eight percent of loans that would have been originated as either rebuttable presumption QM loans or non-QM loans were still open after three years, and of those, 92 percent satisfied the performance criteria to qualify for Seasoned QM status under this final rule. By way of comparison, the corresponding fractions for loans originated as safe harbor were 78 percent and 99 percent, respectively. Altogether, 71 percent of the loans that would have been rebuttable presumption QM loans and non-QM loans under Baseline 1 would have performed well enough to gain safe harbor status via Seasoned QM under this final rule.

The relief from litigation risk depends in part on the fraction of these loans that would eventually enter foreclosure proceedings. Table 2 reports the share of loans under Baseline 1 that entered foreclosure between origination and the first quarter of 2020 among all loans consummated between 2012 and 2013, those that were still open and had not entered foreclosure three years after origination, and those that met the performance criteria of this final rule. 0.2 percent of loans open for at least three years enter foreclosure proceedings before March 2020. Among the loans that would have satisfied this final rule's Seasoned QM performance requirements, foreclosure proceedings began for 1.6 percent of loans that would be non-QM loans in Baseline 1 and for 0.5 percent of loans that would be rebuttable presumption QM loans under Baseline 1. Combined, 0.8 percent of loans that met the performance requirements and were potentially seasonable at consummation would have started foreclosure proceedings. By comparison, for loans that were still open, had not entered foreclosure after three years, and would have been originated as safe harbor under Baseline 1, only 0.1 percent of loans entered foreclosure after year three. Thus, the average foreclosure start rate among open loans with safe harbor status after three years—either from General QM status at consummation or from Seasoned QM status—would be higher than under Baseline 1, reflecting the inclusion of Seasoned QMs.

TABLE 2—SHARE OF LOANS THAT ENTERED FORECLOSURE UNDER BASELINE 1

Type of loan	All loans (percent)	. . . open and had not entered foreclosure after 3 years (percent)	. . . and met performance criteria (percent)
Safe Harbor	0.3	0.2	0.1
Seasonable Loans	2.3	2.3	0.8
Rebuttable Presumption	1.1	1.1	0.5
Non-QM	4.5	4.7	1.6
Missing Rate Spread	3.8	1.8	0.4
All Loans	0.7	0.5	0.2

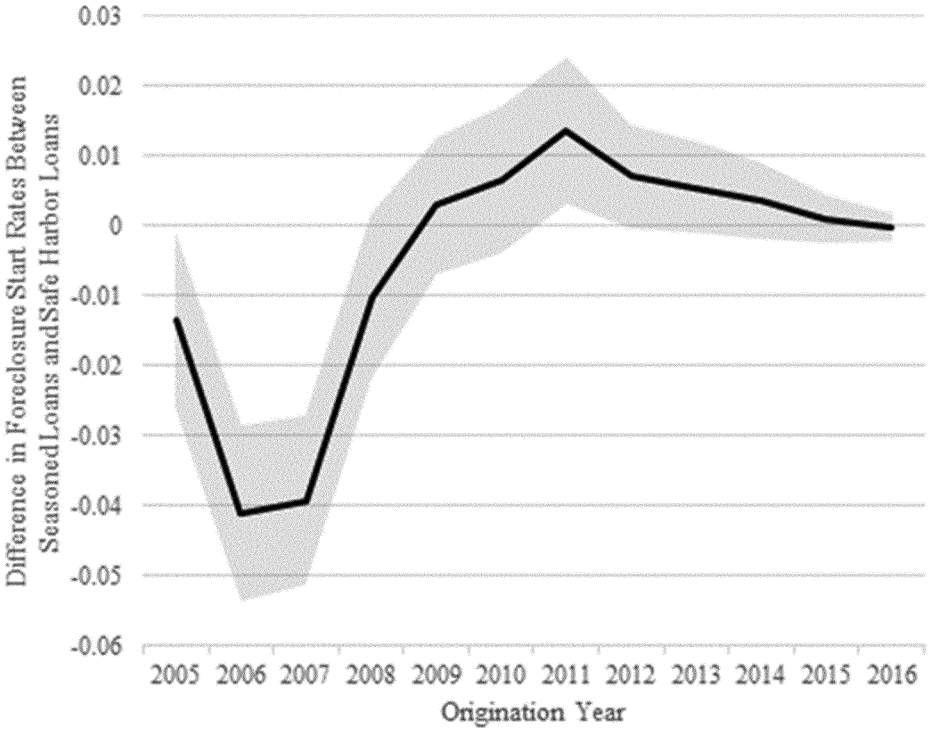
The Bureau analyzed loans originated in 2012 and 2013 instead of other periods for several reasons. This period likely predicts the benefits and costs of this final rule during a period of normal economic expansion. The Bureau excluded later vintages because the analysis requires both a minimum three-year look-forward period to assess Seasoned QM's performance requirements as well as additional time to see whether foreclosures eventually emerge. As the Bureau explained in the proposal,[186] the Bureau excluded earlier vintages whose loan performance may have been affected by the 2008 financial crisis. The crisis years were somewhat unusual in the high number of homes with negative equity and the slow pace of the subsequent economic recovery. Thus, the number of loans that would have disqualifying events would be overstated compared to those in a typical business cycle. Using data from an even earlier cycle of expansion and contraction might be more informative about average benefits and costs over the long term, but older data would also reflect the features of the housing and mortgage markets of an earlier time that may no longer be relevant to current market conditions. The analysis below should be understood with this background in mind.

Notwithstanding these considerations, one commenter asserted that the narrow selection of vintages would lead one to overstate the effectiveness of the proposed Seasoned QM performance criteria in limiting foreclosure. Instead, the Bureau's analysis of loan vintages from periods of economic distress such as the 2008 financial crisis suggests that their exclusion had the opposite effect. Continuing to limit the analysis to conventional, fixed-rate purchase and refinance loans with no prohibited features that were privately held at consummation, open, and had not

[186] 85 FR 53568, 53596 n.154 (Aug. 28, 2020).

entered foreclosure after three years, Figure 4 plots the difference in foreclosure start rates between loans that would have had a safe harbor at origination under Baseline 1 with loans that would have met the performance criteria of this final rule and obtained a safe harbor from Seasoned QM status. Among loans that were originated between 2005 and 2009, those that would have obtained a safe harbor from seasoning entered foreclosure at a lower rate than loans that would have obtained a safe harbor from satisfying the General QM requirements at origination. Loan vintages from the 2008 financial crisis overstate rather than understate this final rule's effectiveness for two reasons. First, a greater share of potentially seasonable loans became delinquent within 36 months, and thus a smaller share of potentially seasonable loans met the performance criteria of this final rule. Second, while the remainder did enter foreclosure at a higher rate than in other periods, lower priced loans that would have had a safe harbor from origination became delinquent and entered foreclosure at an even higher rate.

Figure 4: Foreclosure start rate of loans that meet Seasoned QM eligibility and performance criteria minus foreclosure start rate of loans that obtain a QM safe harbor at origination under Baseline 1



Source: NMDB; the loans analyzed are those held in portfolio with no restricted product features that were open and had not entered foreclosure after 3 years; loans that enter foreclosure are those that enter into any one of the following after the third year: foreclosure proceeding, a deed in lieu of foreclosure, foreclosure, voluntary surrender, or repossession, as tracked by the NMDB. Ninety-five percent confidence intervals of the differences are plotted in grey.

Foreclosure Risk of Loans That Meet Seasoned QM's Performance Requirements in Baseline 2

Paralleling the analyses of this final rule relative to Baseline 1, the analyses here classify loans by whether they would have satisfied the General QM requirements for safe harbor and rebuttable presumption QM loans in Baseline 2 and whether they would have satisfied the performance requirements of this final rule. Eight percent of analyzed loans would have been non-QM loans or rebuttable presumption QM loans at consummation under Baseline 2 and would have potentially gained safe harbor status if they had met this final rule's Seasoned QM performance criteria. Most of these loans (92 percent) would be non-QM at consummation. These estimates likely overestimate the fraction of non-QM loans that would be originated under Baseline 2.

TABLE 3—SHARE OF LOANS UNDER BASELINE 2 THAT WERE OPEN AND HAD NOT ENTERED FORECLOSURE AFTER THREE YEARS AND MEET PERFORMANCE CRITERIA

Type of loan	Open and had not entered foreclosure after three years (percent)	Met performance criteria (cond. on open) (percent)
Safe harbor	85	99
Seasonable loans	86	98
Rebuttable presumption	58	92
Non-QM	89	99
Missing rate spread	76	97
All loans	77	97

Classifying loans according to their status under Baseline 2, Table 3 reports the fraction of loans that were open and had not entered foreclosure after three years and of those open loans, the fraction that would have met the performance criteria of this final rule. Eighty-six percent of the loans that would have been potentially seasonable at consummation under Baseline 2 were still open after three years, of which 98 percent would have satisfied this final rule's Seasoned QM performance requirements.

Table 4 reports the share of loans under Baseline 2 that entered foreclosure between origination and the first quarter of 2020 among all loans consummated between 2012 and 2013, those that were still open and had not entered foreclosure three years after origination, and those that met the performance criteria of this final rule. Among the loans that satisfied this final rule's performance requirements, foreclosure proceedings began for 0.2 percent of loans that would have been potentially seasonable at consummation under Baseline 2. By comparison, 0.1 percent of loans that would have already met General QM's safe harbor requirements entered foreclosure after year three.

TABLE 4—SHARE OF LOANS THAT ENTER FORECLOSURE UNDER BASELINE 2

Type of loan	All loans	. . . open and had not entered foreclosure after 3 years (percent)	. . . and met performance criteria (percent)
Safe Harbor	0.2	0.2	0.1
Seasonable Loans	0.4	0.5	0.2
Rebuttable Presumption	2.3	4.0	0.0
Non-QM	0.2	0.2	0.2
Missing Rate Spread	0.7	0.5	0.2
All Loans	0.7	0.5	0.2

The analysis suggests that the foreclosure start rate for open loans with safe harbor status after three years—either from General QM at consummation or from Seasoned QM—would not be appreciably different than under Baseline 2.

As explained above, the Bureau cannot translate the reduction in foreclosure start rates into dollar savings on litigation costs because the Bureau lacks data on the likelihood each consumer would successfully challenge foreclosure and on the cost of each subsequent case of litigation. In the January 2013 Final Rule, the Bureau estimated litigation costs under the ability-to-repay standards for non-QM loans. The Bureau concluded that to reflect the expected value of these litigation costs, the costs of non-QM loans would increase by 10 basis points or $212 for a $210,000 loan.[187] However, the estimates set forth in the January 2013 Final Rule do not predict changes in costs from Baseline 1 on non-QM loans that obtain QM status by seasoning or on the remaining non-QM loans. In response to the Seasoned QM Proposal, the Bureau did not receive comments on methods or data that would allow the Bureau to quantify potential changes in costs.

[187] One commenter contrasted the proposal's analysis with that from the January 2013 Final Rule, 78 FR 6408, 6569 (Jan. 30, 2013). The 2013 analysis's conclusion of a 10 basis point and $212 cost associated with non-QM litigation risk came from three assumptions: 1.5 percent of loans would foreclose, 20 percent of consumers who entered foreclosure would claim violations of ATR as a defense, and consumers would succeed 20 percent of the time. As noted previously, to the Bureau's knowledge there has been a single ATR claim made in litigation, a rate of litigation far smaller than that implied by the assumptions. The Bureau cannot reliably forecast the rate of ATR defenses in foreclosure litigation under expanded non-QM lending that would arise if litigation risk were curtailed.

Benefits to Covered Persons From Market Expansion

The Bureau's analysis of the NMDB holds constant the quantity and composition of loans. However, creditors could potentially gain from originating loans that would not be profitable without this final rule. Such loans may be directly more profitable because they are less costly due to the decreased litigation risk discussed in the previous section. Among these loans, loans that achieve a stronger presumption of compliance via seasoning may also be indirectly more profitable because they can more easily be sold on the secondary market, creating liquidity for creditors. Increased liquidity may come from both

loans that were non-QM from origination and loans that achieved a safe harbor by fulfilling the portfolio requirements of the EGRRCPA. The Assessment Report found that while non-depository institutions sold non-QM loans on the secondary market, almost all surveyed depository institutions kept non-QM loans in their portfolio.

Altogether, the Bureau cannot reliably predict how many additional loans would be originated under this final rule's additional incentives and subsequently how much potential profit creditors would accrue relative to either baseline.[188] In the Seasoned QM Proposal, the Bureau sought comment as to whether these effects could be ascertained but received no additional data to quantify the effects. One academic commenter expressed skepticism that the proposal would provide enough incentive to generate more non-QM lending because lenders would still be potentially liable for ATR violations in the first three years. However, several industry commenters indicated that they would increase non-QM lending as a result of this final rule.

Other Costs to Covered Persons

The Bureau concludes that this final rule will not directly impose additional costs to creditors relative to the baseline. This final rule offers a pathway for performing mortgages to gain a safe harbor presumption. Loans meeting this final rule's Seasoned QM definition will have at least as much of a presumption of compliance as under either baseline. However, if this final rule succeeds in expanding non-QM loans originations by causing new creditors to enter the market for non-QM loans, existing creditors' profits may be eroded by competitive pressures.

2. Benefits and Costs to Consumers

Consumers will primarily benefit from this final rule indirectly via the potential expansion of rebuttable presumption and non-QM loans originated due to decreased litigation risk to creditors. As noted in the January 2013 Final Rule, increased legal certainty may benefit consumers if it encourages creditors to make loans that satisfy the QM criteria, as such loans cannot have certain risky features and have a cap on upfront costs. Furthermore, increased certainty may result in loans with a lower cost than would be charged in a context of legal uncertainty. Thus, a safe harbor may also allow creditors to provide consumers additional or more affordable access to credit by reducing their expected total litigation costs. Applied here, for consumers that choose to pursue high APR loans without safe harbor QM status at origination, borrowing may be cheaper or more widely available relative to either baseline. However, the Bureau cannot ascertain the additional number of consumers who would choose loans without safe harbor QM status under this final rule relative to the baselines as stated in the previous section.

Consumers who would select loans without safe harbor QM status under either baseline and this final rule may or may not benefit from this final rule. On the one hand, decreased litigation risk may translate into lower costs in competitive mortgage markets.[189] However, decreased litigation risk for creditors would come from limiting the ability of consumers who make payments throughout the seasoning period to raise violations of ATR requirements as defenses, should they enter foreclosure after the third year. The Bureau neither has the data to estimate consumers' value of using such violations in foreclosure defense, nor to estimate this final rule's potential to decrease loan prices.

Several industry commenters suggested that workers who earn income via sources not reportable on W–2 forms (*e.g.,* self-employed or gig economy workers) would potentially benefit from expanded access to credit. Others argued that ATR arguments in foreclosure defense can be pivotal to the outcome of individual cases, and thus very valuable to individual consumers, but that in aggregate, there is not enough foreclosure litigation to substantially lower costs that would be passed on to consumers *en masse.* Even in markets where mortgage lending is competitive and cost savings are passed to consumers, evaluating the benefits to consumers in the form of increased access to credit against the costs to consumers in terms of eliminating potentially winning arguments in foreclosure defense requires information on how consumers and creditors value litigation risk. The Bureau is not aware of data that would allow it to quantify how consumers and creditors value litigation risk, and the commenters did not offer supplementary evidence to quantify those effects.

3. Consideration of Alternatives

The Bureau considered alternative seasoning periods of various numbers of years and alternative performance requirements of various numbers of allowable 30-day delinquencies. None of the alternatives permits 60-day delinquencies. The Bureau assesses each alternative along two different measures: (1) The estimated fraction of loans that would be originated as non-QM or rebuttable presumption QM loans in each baseline that would satisfy the performance requirements; and (2) the differences in foreclosure start rates between those loans that would gain safe harbor status and those that were safe harbor at consummation.

Mirroring the approach of the foreclosure analysis in part VIII.B.1 above, the Bureau analyzes the same data on conventional, fixed-rate, first-lien purchase and refinance mortgage loans without prohibited features that were originated in 2012 and 2013 and held privately in portfolio at consummation. The analyses of alternatives also make the same assumptions on how loans with certain characteristics can obtain safe harbor status and hold constant the quantity and composition of the loans. Specifically, the consideration of alternatives is similar to the analysis of this final rule in that the Bureau cannot reliably predict how many additional loans would have been originated under its alternatives.

[188] Assessment Report, *supra* note 47, at 117. In the Assessment Report, the Bureau estimated that the ATR/QM Rule eliminated between 63 and 70 percent of non-GSE eligible, high DTI loans for home purchase over the period of 2014 to 2016, accounting for 9,000 to 12,000 loans. The Bureau does not believe it can reliably estimate whether the number of additional loans would be less than, the same as, or more than those that the Assessment Report found were lost as a result of the ATR/QM Rule. The pool of loans analyzed in the Assessment Report is somewhat different from the 150,628 loans in Baseline 1 that would meet all of the requirements at consummation for Seasoned QMs derived above, and the benefit of seasoning would vary across these loans.

[189] One academic study examined how lower secondary market costs passed through to consumers in markets with different amounts of competition. David S. Scharfstein & Adi Sunderam, *Market Power in Mortgage Lending and the Transmission of Monetary Policy,* Mimeo (Aug. 2016), *https://www.hbs.edu/faculty/Publication%20Files/Market%20Power%20in%20Mortgage%20Lending%20and%20the%20Transmission%20of%20Monetary%20Policy_8d6596e6-e073-4d11-83da-3ae1c6db6c28.pdf.*

TABLE 5—PERCENTAGE OF POTENTIALLY SEASONABLE LOANS UNDER BASELINE 1 THAT WOULD HAVE SATISFIED THIS FINAL RULE'S SEASONED QM PERFORMANCE CRITERIA UNDER ALTERNATIVE SEASONING PERIODS AND ALLOWABLE 30-DAY DELINQUENCIES

Seasoning period (months)	Allowable 30-day delinquencies					
	0 (percent)	1 (percent)	2 (percent)	3 (percent)	4 (percent)	5 (percent)
12	91.7	93.1	93.9	94.3	94.4	94.5
24	79.5	81.3	82.4	82.8	83.0	83.4
36	68.1	70.4	71.3	71.7	72.2	72.5
48	57.3	59.7	60.7	61.3	61.7	61.9
60	47.7	49.7	50.7	51.4	51.8	52.1

Table 5 reports the fraction of loans originated as either non-QM or rebuttable presumption QM loans under the General QM standards of Baseline 1 that would have met the seasoning requirements under various alternatives. Allowing for different 30-day delinquencies has modest effects on the fraction of loans that would have seasoned. In contrast, varying the seasoning period from 12 months to 60 months captures vastly different numbers of loans that would have seasoned.

Some industry commenters noted that similar analyses of alternatives in the Seasoned QM Proposal showed only minor differences in the estimated fraction of seasonable loans that meet the performance criteria under two, three, or four 30-day delinquencies. Accordingly, the commenters suggested increasing the number of allowable 30-day delinquencies. The Bureau interprets the same data to suggest that there also would be little benefit in terms of access to credit from expanding the proposed performance criteria to allow more delinquencies and encompass more loans. Instead, inconsistent repayment reflected in more than two 30-day delinquencies could signal borrower distress or difficulties with ability to repay that do not necessarily culminate in foreclosure.

TABLE 6—DIFFERENCE IN PERCENTAGE POINTS OF LOANS UNDER BASELINE 1 THAT ENTERED FORECLOSURE BETWEEN POTENTIALLY SEASONABLE LOANS THAT MEET THIS FINAL RULE'S SEASONED QM PERFORMANCE CRITERIA AND LOANS THAT HAD SAFE HARBOR FROM CONSUMMATION AND WERE OPEN AND HAD NOT ENTERED FORECLOSURE AFTER THREE YEARS

Seasoning period (months)	Allowable 30-day delinquencies					
	0	1	2	3	4	5
12	1.00	1.13	1.31	1.38	1.41	1.41
24	0.56	0.61	0.74	0.78	0.82	0.90
36	0.32	0.46	0.47	0.49	0.51	0.53
48	0.10	0.20	0.23	0.25	0.25	0.27
60	−0.07	0.00	0.03	0.06	0.06	0.06

Varying the number of allowable 30-day delinquencies does have some impact on foreclosure risk. Table 6 reports the difference in the share of foreclosures among loans that would have qualified for Seasoned QM status under this final rule with the share of foreclosures among loans that would have been originated as safe harbor QM loans under Baseline 1. For example, under this final rule, among loans that were open for at least three years, the Bureau estimates that with a performance standard of no more than two 30-day delinquencies, 0.47 of a percentage point more Seasoned QMs would enter foreclosure proceedings than would loans that had safe harbor status from consummation.

Holding constant the seasoning period, decreasing the number of allowable 30-day delinquencies by one decreases the differences in foreclosure share between loans that would have seasoned and loans that were safe harbor QM loans from origination by approximately 4 percent. Similarly, increasing the number of allowed 30-day delinquencies by one increases the difference by approximately 4 percent. Changing the length of the seasoning period generally has a larger effect on the relative foreclosure start rate than does changing the number of allowable 30-day delinquencies.

TABLE 7—PERCENTAGE OF POTENTIALLY SEASONABLE LOANS UNDER BASELINE 2 THAT WOULD HAVE SATISFIED THIS FINAL RULE'S SEASONED QM PERFORMANCE CRITERIA UNDER ALTERNATIVE SEASONING PERIODS AND ALLOWABLE 30-DAY DELINQUENCIES

Seasoning period (months)	Allowable 30-day delinquencies—(percent)					
	0	1	2	3	4	5
12	96.3	96.5	96.7	96.7	96.7	96.7
24	91.1	91.6	91.8	92.2	92.2	92.2
36	83.3	84.6	84.6	84.6	84.8	84.8
48	76.1	77.6	77.6	77.6	77.8	77.8
60	71.0	72.6	72.6	72.8	73.0	73.0

Table 7 repeats the analysis of Table 5 using Baseline 2. A larger fraction of loans—about 13 percentage points—originated as either non-QM or rebuttable presumption QM loans under the General QM standards would have met the seasoning requirements under this final rule. This reflects the fact that not only are there significantly more non-QM loans under Baseline 2 than under Baseline 1 but also that the additional non-QM loans have relatively stronger credit characteristics at consummation. The amendments to the General QM loan definition will provide many of these loans with a pathway to QM status.

TABLE 8—DIFFERENCE IN PERCENTAGE POINTS OF LOANS UNDER BASELINE 2 THAT ENTERED FORECLOSURE BETWEEN POTENTIALLY SEASONABLE LOANS THAT MEET THIS FINAL RULE'S SEASONED QM PERFORMANCE CRITERIA AND LOANS THAT HAD SAFE HARBOR FROM CONSUMMATION AND WERE OPEN AND HAD NOT ENTERED FORECLOSURE AFTER THREE YEARS

Seasoning period (months)	Allowable 30-day delinquencies					
	0	1	2	3	4	5
12	0.06	0.06	0.26	0.26	0.26	0.26
24	0.08	0.08	0.08	0.08	0.08	0.08
36	0.13	0.13	0.13	0.13	0.13	0.13
48	−0.09	−0.09	−0.09	−0.09	−0.09	−0.09
60	−0.09	−0.09	−0.09	−0.09	−0.09	−0.09

Table 8 shows that under Baseline 2, non-QM and rebuttable presumption QM loans that would have achieved safe harbor status through this final rule or alternatives with a seasoning period of at least three years have a 0.13 percentage point higher foreclosure start rate than open loans that were safe harbor QM loans at consummation. The difference in the foreclosure start rates does not dramatically vary with different numbers of allowable 30-day delinquencies.

C. Potential Impact on Depository Institutions and Credit Unions With $10 Billion or Less in Total Assets, as Described in Section 1026

Depository institutions and credit unions that are also creditors making covered loans (depository creditors) with $10 billion or less in total assets are expected to benefit from this final rule. As stated above, under each baseline, smaller institutions can originate Small Creditor QM loans or QM loans under the requirements of the EGRRCPA. Thus, they will likely not benefit from this final rule's providing a pathway to safe harbor status for non-QM loans, but they will benefit from the pathway to safe harbor status for rebuttable presumption QM loans. As a result of this final rule, certain loans that have a safe harbor from origination from the EGRRCPA would not have to continue to be held in portfolio after the seasoning period to maintain that safe harbor status if they meet the requirements to be a Seasoned QM.

D. Potential Impact on Rural Areas

As with the analysis of this final rule's benefits and costs overall, the Bureau can generally not predict how much or how little this final rule will cause the market in rural areas to expand under either Baseline 1 or Baseline 2. The Bureau analyzed HMDA data mirroring the description of the baselines in part VIII.A.2, continuing to assume that loans continue to be originated under each baseline with the same characteristics. Under Baseline 1, relatively more loans in rural areas than in urban areas will achieve only a stronger presumption of compliance or relief from portfolio retention requirements by meeting the performance criteria of this final rule. This share of loans is 9 percent for rural markets relative to 5 percent of the market overall. The rural share includes relatively more loans that do not meet the portfolio requirements under the EGRRCPA that will be either rebuttable presumption QMs under the revised General QM loan definition's requirements or non-QM (7.9 percent vs. 4.0 percent) and loans that will meet the portfolio and other requirements under the EGRRCPA (1.5 percent vs. 0.7 percent).

However, under Baseline 2, the difference in the share of potentially seasonable loans between rural areas (27.5 percent) and the market as a whole (27.8 percent) is relatively modest. This reflects relatively fewer loans being originated without QM status or with a rebuttable presumption that would gain the stronger presumption of compliance of safe harbor if they met the performance requirements of this final rule than under Baseline 2 alone (22.8 percent vs. 24.2 percent) and relatively more that were originated under the EGRRCPA QM definition and could potentially gain relief from the portfolio requirements (4.7 percent vs. 3.7 percent).

IX. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (RFA),[190] as amended by the Small Business Regulatory Enforcement Fairness Act of 1996,[191] requires each agency to consider the potential impact of its regulations on small entities, including small businesses, small governmental units, and small not-for-profit organizations. The RFA defines a ''small business'' as a business that meets the size standard developed by the Small Business Administration pursuant to the Small Business Act.[192]

The RFA generally requires an agency to conduct an initial regulatory flexibility analysis (IRFA) and a final regulatory flexibility analysis (FRFA) of any rule subject to notice-and-comment rulemaking requirements, unless the agency certifies that the rule would not have a significant economic impact on a substantial number of small entities (SISNOSE).[193] The Bureau also is subject to certain additional procedures under the RFA involving the convening of a panel to consult with small business representatives before proposing a rule for which an IRFA is required.[194]

Neither an IRFA nor a small business review panel was required for the proposal, because the Director certified that the proposal, if adopted, would not have a SISNOSE.

Similarly, a FRFA is not required for this final rule, because this final rule will not have a SISNOSE. The Bureau

[190] 5 U.S.C. 601 *et seq.*

[191] Public Law 104–121, tit. II, 110 Stat. 857 (1996).

[192] 5 U.S.C. 601(3) (stating also that the Bureau may establish an alternative definition after consultation with the Small Business Administration and an opportunity for public comment).

[193] 5 U.S.C. 603 through 605.

[194] 5 U.S.C. 609.

does not expect that this final rule will impose costs on small entities relative to any of the baselines. This final rule defines a new category of QMs. All methods of compliance with the ATR requirements under a particular baseline will remain available to small entities under this final rule. Thus, a small entity that is in compliance with the rules under a given baseline will not need to take any different or additional action under this final rule.

Accordingly, the Director certifies that this final rule will not have a SISNOSE.

X. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA),[195] Federal agencies are generally required to seek, prior to implementation, approval from the Office of Management and Budget (OMB) for information collection requirements. Under the PRA, the Bureau may not conduct or sponsor, and, notwithstanding any other provision of law, a person is not required to respond to, an information collection unless the information collection displays a valid control number assigned by OMB.

The Bureau has determined that this final rule does not contain any new or substantively revised information collection requirements other than those previously approved by OMB under OMB control number 3170–0015. This final rule will amend 12 CFR part 1026 (Regulation Z), which implements TILA. OMB control number 3170–0015 is the Bureau's OMB control number for Regulation Z.

XI. Congressional Review Act

Pursuant to the Congressional Review Act,[196] the Bureau will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to the rule's published effective date. The Office of Information and Regulatory Affairs has designated this rule as not a ''major rule'' as defined by 5 U.S.C. 804(2).

XII. Signing Authority

The Director of the Bureau, Kathleen L. Kraninger, having reviewed and approved this document, is delegating the authority to electronically sign this document to Grace Feola, a Bureau Federal Register Liaison, for purposes of publication in the **Federal Register**.

[195] 44 U.S.C. 3501 *et seq.*

[196] 5 U.S.C. 801 *et seq.*

List of Subjects in 12 CFR Part 1026

Advertising, Banks, banking, Consumer protection, Credit, Credit unions, Mortgages, National banks, Reporting and recordkeeping requirements, Savings associations, Truth-in-lending.

Authority and Issuance

For the reasons set forth above, the Bureau amends Regulation Z, 12 CFR part 1026, as set forth below:

PART 1026—TRUTH IN LENDING (REGULATION Z)

■ 1. The authority citation for part 1026 continues to read as follows:

Authority: 12 U.S.C. 2601, 2603–2605, 2607, 2609, 2617, 3353, 5511, 5512, 5532, 5581; 15 U.S.C. 1601 *et seq.*

Subpart E—Special Rules for Certain Home Mortgage Transactions

■ 2. Amend § 1026.43 by revising paragraphs (e)(1) and (e)(2) introductory text and adding paragraph (e)(7) to read as follows:

§ 1026.43 Minimum standards for transactions secured by a dwelling.

* * * * *

(e) *Qualified mortgages*—(1) *Safe harbor and presumption of compliance*—(i) *Safe harbor for loans that are not higher-priced covered transactions and for seasoned loans.* A creditor or assignee of a qualified mortgage complies with the repayment ability requirements of paragraph (c) of this section if:

(A) The loan is a qualified mortgage as defined in paragraph (e)(2), (4), (5), (6), or (f) of this section that is not a higher-priced covered transaction, as defined in paragraph (b)(4) of this section; or

(B) The loan is a qualified mortgage as defined in paragraph (e)(7) of this section, regardless of whether the loan is a higher-priced covered transaction.

* * * * *

(2) *Qualified mortgage defined—general.* Except as provided in paragraph (e)(4), (5), (6), (7), or (f) of this section, a qualified mortgage is a covered transaction:

* * * * *

(7) *Qualified mortgage defined—seasoned loans*—(i) *General.* Notwithstanding paragraph (e)(2) of this section, and except as provided in paragraph (e)(7)(iv) of this section, a qualified mortgage is a first-lien covered transaction that:

(A) Is a fixed-rate mortgage as defined in § 1026.18(s)(7)(iii) with fully amortizing payments as defined in paragraph (b)(2) of this section;

(B) Satisfies the requirements in paragraphs (e)(2)(i) through (v) of this section;

(C) Has met the requirements in paragraph (e)(7)(ii) of this section at the end of the seasoning period as defined in paragraph (e)(7)(iv)(C) of this section;

(D) Satisfies the requirements in paragraph (e)(7)(iii) of this section; and

(E) Is not a high-cost mortgage as defined in § 1026.32(a).

(ii) *Performance requirements.* To be a qualified mortgage under this paragraph (e)(7) of this section, the covered transaction must have no more than two delinquencies of 30 or more days and no delinquencies of 60 or more days at the end of the seasoning period.

(iii) *Portfolio requirements.* To be a qualified mortgage under this paragraph (e)(7) of this section, the covered transaction must satisfy the following requirements:

(A) The covered transaction is not subject, at consummation, to a commitment to be acquired by another person, except for a sale, assignment, or transfer permitted by paragraph (e)(7)(iii)(B)(*3*) of this section; and

(B) Legal title to the covered transaction is not sold, assigned, or otherwise transferred to another person before the end of the seasoning period, except that:

(*1*) The covered transaction may be sold, assigned, or otherwise transferred to another person pursuant to a capital restoration plan or other action under 12 U.S.C. 1831o, actions or instructions of any person acting as conservator, receiver, or bankruptcy trustee, an order of a State or Federal government agency with jurisdiction to examine the creditor pursuant to State or Federal law, or an agreement between the creditor and such an agency;

(*2*) The covered transaction may be sold, assigned, or otherwise transferred pursuant to a merger of the creditor with another person or acquisition of the creditor by another person or of another person by the creditor; or

(*3*) The covered transaction may be sold, assigned, or otherwise transferred once before the end of the seasoning period, provided that the covered transaction is not securitized as part of the sale, assignment, or transfer or at any other time before the end of the seasoning period as defined in § 1026.43(e)(7)(iv)(C).

(iv) *Definitions.* For purposes of paragraph (e)(7) of this section:

(A) *Delinquency* means the failure to make a periodic payment (in one full payment or in two or more partial payments) sufficient to cover principal,

interest, and escrow (if applicable) for a given billing cycle by the date the periodic payment is due under the terms of the legal obligation. Other amounts, such as any late fees, are not considered for this purpose.

(*1*) A periodic payment is 30 days delinquent when it is not paid before the due date of the following scheduled periodic payment.

(*2*) A periodic payment is 60 days delinquent if the consumer is more than 30 days delinquent on the first of two sequential scheduled periodic payments and does not make both sequential scheduled periodic payments before the due date of the next scheduled periodic payment after the two sequential scheduled periodic payments.

(*3*) For any given billing cycle for which a consumer's payment is less than the periodic payment due, a consumer is not delinquent as defined in this paragraph (e)(7) if:

(*i*) The servicer chooses not to treat the payment as delinquent for purposes of any section of subpart C of Regulation X, 12 CFR part 1024, if applicable;

(*ii*) The payment is deficient by $50 or less; and

(*iii*) There are no more than three such deficient payments treated as not delinquent during the seasoning period.

(*4*) The principal and interest used in determining the date a periodic payment sufficient to cover principal, interest, and escrow (if applicable) for a given billing cycle becomes due and unpaid are the principal and interest payment amounts established by the terms and payment schedule of the loan obligation at consummation, except:

(*i*) If a qualifying change as defined in paragraph (e)(7)(iv)(B) of this section is made to the loan obligation, the principal and interest used in determining the date a periodic payment sufficient to cover principal, interest, and escrow (if applicable) for a given billing cycle becomes due and unpaid are the principal and interest payment amounts established by the terms and payment schedule of the loan obligation at consummation as modified by the qualifying change.

(*ii*) If, due to reasons related to the timing of delivery, set up, or availability for occupancy of the dwelling securing the obligation, the first payment due date is modified before the first payment due date in the legal obligation at consummation, the modified first payment due date shall be considered in lieu of the first payment due date in the legal obligation at consummation in determining the date a periodic payment sufficient to cover principal, interest, and escrow (if applicable) for a given billing cycle becomes due and unpaid.

(*5*) Except for purposes of making up the deficiency amount set forth in paragraph (e)(7)(iv)(A)(*3*)(*ii*) of this section, payments from the following sources are not considered in assessing delinquency under paragraph (e)(7)(iv)(A) of this section:

(*i*) Funds in escrow in connection with the covered transaction; or

(*ii*) Funds paid on behalf of the consumer by the creditor, servicer, or assignee of the covered transaction, or any other person acting on behalf of such creditor, servicer, or assignee.

(B) *Qualifying change* means an agreement that meets the following conditions:

(*1*) The agreement is entered into during or after a temporary payment accommodation in connection with a disaster or pandemic-related national emergency as defined in paragraph (e)(7)(iv)(D) of this section and ends any pre-existing delinquency on the loan obligation upon taking effect;

(*2*) The amount of interest charged over the full term of the loan does not increase as a result of the agreement;

(*3*) The servicer does not charge any fee in connection with the agreement; and

(*4*) Promptly upon the consumer's acceptance of the agreement, the servicer waives all late charges, penalties, stop payment fees, or similar charges incurred during a temporary payment accommodation in connection with a disaster or pandemic-related national emergency, as well as all late charges, penalties, stop payment fees, or similar charges incurred during the delinquency that led to a temporary payment accommodation in connection with a disaster or pandemic-related national emergency.

(C) *Seasoning period* means a period of 36 months beginning on the date on which the first periodic payment is due after consummation of the covered transaction, except that:

(*1*) Notwithstanding any other provision of this section, if there is a delinquency of 30 days or more at the end of the 36th month of the seasoning period, the seasoning period does not end until there is no delinquency; and

(*2*) The seasoning period does not include any period during which the consumer is in a temporary payment accommodation extended in connection with a disaster or pandemic-related national emergency, provided that during or at the end of the temporary payment accommodation there is a qualifying change as defined in paragraph (e)(7)(iv)(B) of this section or the consumer cures the loan's delinquency under its original terms. If during or at the end of the temporary payment accommodation in connection with a disaster or pandemic-related national emergency there is a qualifying change or the consumer cures the loan's delinquency under its original terms, the seasoning period consists of the period from the date on which the first periodic payment was due after consummation of the covered transaction to the beginning of the temporary payment accommodation and an additional period immediately after the temporary payment accommodation ends, which together must equal at least 36 months.

(D) *Temporary payment accommodation in connection with a disaster or pandemic-related national emergency* means temporary payment relief granted to a consumer due to financial hardship caused directly or indirectly by a presidentially declared emergency or major disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*) or a presidentially declared pandemic-related national emergency under the National Emergencies Act (50 U.S.C. 1601 *et seq.*).

* * * * *

■ 3. In supplement I to part 1026—Official Interpretations, under *Section 1026.43—Minimum Standards for Transactions Secured by a Dwelling:*

■ a. Revise *43(e)(1) Safe harbor and presumption of compliance;*

■ b. Remove *43(e)(1)(i) Safe harbor for transactions that are not higher-priced covered transactions;*

■ c. Add *43(e)(1)(i)(A) Safe harbor for transactions that are not higher-priced covered transactions;*

■ d. Add the heading *43(e)(7) Seasoned Loans* and add *paragraphs 43(e)(7)(i)(A), 43(e)(7)(iii), 43(e)(7)(iv)(A), 43(e)(7)(iv)(A)*(2), *43(e)(7)(iv)(B), 43(e)(7)(iv)(C)*(2), *and 43(e)(7)(iv)(D)* after paragraph 43(e)(5).

The revision and additions read as follows:

Supplement I to Part 1026—Official Interpretations

* * * * *

Section 1026.43—Minimum Standards for Transactions Secured by a Dwelling

* * * * *

43(e)(1) Safe harbor and presumption of compliance.

1. *General.* Section 1026.43(c) requires a creditor to make a reasonable and good faith determination at or before consummation that a consumer will be able to repay a covered transaction. Section 1026.43(e)(1)(i) and

(ii) provide a safe harbor or presumption of compliance, respectively, with the repayment ability requirements of § 1026.43(c) for creditors and assignees of covered transactions that satisfy the requirements of a qualified mortgage under § 1026.43(e)(2), (4), (5), (6), (7), or (f). *See* § 1026.43(e)(1)(i) and (ii) and associated commentary.

43(e)(1)(i)(A) Safe harbor for transactions that are not higher-priced covered transactions.

1. *Higher-priced covered transactions.* For guidance on determining whether a loan is a higher-priced covered transaction, see comments 43(b)(4)–1 through –3.

* * * * *

43(e)(7) Seasoned loans.

Paragraph 43(e)(7)(i)(A)

1. *Fixed-rate mortgage.* Section 1026.43(e)(7)(i)(A) provides that, for a covered transaction to become a qualified mortgage under § 1026.43(e)(7), the covered transaction must be a fixed-rate mortgage, as defined in § 1026.18(s)(7)(iii). Under § 1026.18(s)(7)(iii), the term ''fixed-rate mortgage'' means a transaction secured by real property or a dwelling that is not an adjustable-rate mortgage or a step-rate mortgage. Thus, a covered transaction that is an adjustable-rate mortgage or step-rate mortgage is not eligible to become a qualified mortgage under § 1026.43(e)(7).

2. *Fully amortizing payments.* Section 1026.43(e)(7)(i)(A) provides that for a covered transaction to become a qualified mortgage as a seasoned loan under § 1026.43(e)(7), a mortgage must meet certain product requirements and be a fixed-rate mortgage with fully amortizing payments. Only loans for which the scheduled periodic payments do not require a balloon payment, as defined in § 1026.18(s), to fully amortize the loan within the loan term can become seasoned loans for the purposes of § 1026.43(e)(7). However, § 1026.43(e)(7)(i)(A) does not prohibit a qualifying change as defined in § 1026.43(e)(7)(iv)(B) that is entered into during or after a temporary payment accommodation in connection with a disaster or pandemic-related national emergency, even if such a qualifying change involves a balloon payment or lengthened loan term.

Paragraph 43(e)(7)(iii)

1. *Requirement to hold in portfolio.* For a covered transaction to become a qualified mortgage under § 1026.43(e)(7), a creditor generally must hold the transaction in portfolio until the end of the seasoning period, subject to the exceptions set forth in § 1026.43(e)(7)(iii)(B)(*1*) through (*3*). Unless one of these exceptions applies, a covered transaction cannot become a qualified mortgage as a seasoned loan under § 1026.43(e)(7) if legal title to the debt obligation is sold, assigned, or otherwise transferred to another person before the end of the seasoning period.

2. *Application to subsequent transferees.* The exception contained in § 1026.43(e)(7)(iii)(B)(*3*) may be used only one time for a covered transaction. The exceptions contained in § 1026.43(e)(7)(iii)(B)(*1*) and (*2*) apply not only to an initial sale, assignment, or other transfer by the originating creditor but to subsequent sales, assignments, and other transfers as well. For example, assume Creditor A originates a covered transaction that is not a qualified mortgage at origination. Six months after consummation, the covered transaction is transferred to Creditor B pursuant to § 1026.43(e)(7)(iii)(B)(*3*). The transfer does not fail to comply with the requirements in § 1026.43(e)(7)(iii) because the loan is not securitized as part of the transfer or at any other time before the end of the seasoning period. If Creditor B sells the covered transaction before the end of the seasoning period, the covered transaction is not eligible to season into a qualified mortgage under § 1026.43(e)(7) unless the sale falls within an exception set forth in § 1026.43(e)(7)(iii)(B)(*1*) or (*2*) (*i.e.,* the transfer is required by supervisory action or pursuant to a merger or acquisition).

3. *Supervisory sales.* Section 1026.43(e)(7)(iii)(B)(*1*) facilitates sales that are deemed necessary by supervisory agencies to revive troubled creditors and resolve failed creditors. A covered transaction does not violate the requirements in § 1026.43(e)(7)(iii) if it is sold, assigned, or otherwise transferred to another person before the end of the seasoning period pursuant to: A capital restoration plan or other action under 12 U.S.C. 1831o; the actions or instructions of any person acting as conservator, receiver or bankruptcy trustee; an order of a State or Federal government agency with jurisdiction to examine the creditor pursuant to State or Federal law; or an agreement between the creditor and such an agency. Section 1026.43(e)(7)(iii)(B)(*1*) does not apply to transfers done to comply with a generally applicable regulation with future effect designed to implement, interpret, or prescribe law or policy in the absence of a specific order by or a specific agreement with a governmental agency described in § 1026.43(e)(7)(iii)(B)(*1*) directing the sale of one or more covered transactions held by the creditor or one of the other circumstances listed in § 1026.43(e)(7)(iii)(B)(*1*). For example, a covered transaction does not violate the requirements in § 1026.43(e)(7)(iii) if the covered transaction is sold pursuant to a capital restoration plan under 12 U.S.C. 1831o before the end of seasoning period. However, if the creditor simply chose to sell the same covered transaction as one way to comply with general regulatory capital requirements in the absence of supervisory action or agreement, then the covered transaction cannot become a qualified mortgage as a seasoned loan under § 1026.43(e)(7), unless the sale met the requirements of § 1026.43(e)(7)(iii)(B)(*3*) or the covered transaction qualifies under another definition of qualified mortgage.

Paragraph 43(e)(7)(iv)(A)

1. *Due date.* In determining whether a scheduled periodic payment is delinquent for purposes of § 1026.43(e)(7), the due date is the date the payment is due under the terms of the legal obligation, without regard to whether the consumer is afforded a period after the due date to pay before the servicer assesses a late fee.

Paragraph 43(e)(7)(iv)(A)(2)

1. *60 days delinquent.* The following example illustrates the meaning of 60 days delinquent for purposes of § 1026.43(e)(7). Assume a loan is consummated on October 15, 2022, that the consumer's periodic payment is due on the 1st of each month, and that the consumer timely made the first periodic payment due on December 1, 2022. For purposes of § 1026.43(e)(7), the consumer is 30 days delinquent if the consumer fails to make a payment (sufficient to cover the scheduled January 1, 2023 periodic payment of principal, interest, and escrow (if applicable)) before February 1, 2023. For purposes of § 1026.43(e)(7), the consumer is 60 days delinquent if the consumer then fails to make two payments (sufficient to cover the scheduled January 1, 2023 and February 1, 2023 periodic payments of principal, interest, and escrow (if applicable)) before March 1, 2023.

Paragraph 43(e)(7)(iv)(B)

1. *Qualifying change.* An agreement that meets the conditions specified in § 1026.43(e)(7)(iv)(B) is a qualifying change even if it is not in writing.

Paragraph 43(e)(7)(iv)(C)(2)

1. *Suspension of seasoning period during certain temporary payment accommodations.* Section 1026.43(e)(7)(iv)(C)(*2*) provides that the seasoning period does not include any period during which the consumer is in a temporary payment accommodation extended in connection with a disaster or pandemic-related national emergency, provided that during or at the end of the temporary payment accommodation there is a qualifying change as defined in § 1026.43(e)(7)(iv)(B) or the consumer cures the loan's delinquency under its original terms. Section 1026.43(e)(7)(iv)(C)(*2*) further explains that, under these circumstances, the seasoning period consists of the period from the date on which the first periodic payment was due after origination of the covered transaction to the beginning of the temporary payment accommodation and an additional period immediately after the temporary payment accommodation ends, which together must equal at least 36 months. For example, assume the consumer enters into a covered transaction for which the first periodic payment is due on March 1, 2022, and the consumer enters a three-month temporary payment accommodation in connection with a disaster or pandemic-related national emergency, effective March 1, 2023. Assume further that the consumer misses the March 1, April 1, and May 1, 2023 periodic payments during the temporary payment accommodation period, but enters into a qualifying change as defined in § 1026.43(e)(7)(iv)(B) on June 1, 2023, and is not delinquent on June 1, 2023. Under these circumstances, the seasoning period consists of the period from March 1, 2022 to February 28, 2023 and the period from June 1, 2023 to May 31, 2025, assuming the consumer is not 30 days or more delinquent on May 31, 2025.

Paragraph 43(e)(7)(iv)(D)

1. *Temporary payment accommodation in connection with a disaster or pandemic-related national emergency.* For purposes of § 1026.43(e)(7), examples of temporary payment accommodations in connection with a disaster or pandemic-related national emergency include, but are not limited to a trial loan modification plan, a temporary payment forbearance program, or a temporary repayment plan.

* * * * *

Dated: December 10, 2020.

Grace Feola,

Federal Register Liaison, Bureau of Consumer Financial Protection.

[FR Doc. 2020–27571 Filed 12–21–20; 4:15 pm]

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LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

In the **List of Public Laws** printed in the *Federal Register* on December 23, 2020, S. 3703, Public Law 116-252, had an incorrect approval date. It should read as follows:

S. 3703/P.L. 116–252

Promoting Alzheimer's Awareness to Prevent Elder Abuse Act (Dec. 22, 2020; 134 Stat. 1133)

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